Georgia Rules and Regulations
Administrative Bulletin for March 2022

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Final rules filed with the Georgia Secretary of State during the month of *March 2022:*

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Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH

Chapter 111-2. HEALTH PLANNING

Subject 111-2-1. ADMINISTRATION

111-2-1-.01 Definitions

(1) "Board" means the Board of Community Health, the body created under O.C.G.A. § 31-2-3, appointed by the Governor, that establishes the general policy to be followed by the Department of Community Health.

(2) "Certificate of Need Appeal Panel" or "appeal panel" means the panel of independent hearing officers created pursuant to O.C.G.A. § 31-6-44 to conduct appeal hearings.

(3) "Commissioner" means the commissioner of community health established under O.C.G.A. § 31-2-6.

(4) "Department" means the Department of Community Health established under O.C.G.A. § 31-2-4.

(5) "Health Strategies Council" or "Council" means the body created by this chapter to advise the Department of Community Health.

Cite as Ga. Comp. R. & Regs. R. 111-2-1-.01

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Definitions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-1-.02 Health Planning Functions of the Department

(1) The Department is authorized to administer the health planning and Certificate of Need programs established under O.C.G.A. § 31-6 *et seq.* and a state health plan approved by the Board. The Department shall provide by rule for procedures to administer its functions. As appropriate, the Commissioner may delegate the authority to administer any function or duty prescribed by law or these Rules to one or more authorized designees in the Office of Health Planning and the Office of General Counsel.

(2) The functions of the Department shall be:

(a) to conduct the health planning activities of the State and, within appropriations made available by the General Assembly and consistent with the laws of the State of Georgia, to implement such parts of the State Health Plan as may relate to State government;

(b) to prepare and revise a draft State Health Plan with recommendations from technical advisory committees;

(c) to seek advice, at its discretion, from technical advisory committees;

(d) to adopt, promulgate, and implement rules and procedures necessary to carry out the provisions of O.C.G.A. § 31-6 *et seq.* in accordance with O.C.G.A. § 50-13 *et seq.*, the Georgia Administrative Procedure Act.

(e) to define the form, content, schedules, fees, and procedures for submission of applications for Certificates of Need, other determinations and periodic reports;

(f) to establish time periods and procedures consistent with O.C.G.A. § 31-6 *et seq.* to hold hearings and to obtain the viewpoints of interested persons prior to issuance or denial of a Certificate of Need;

(g) to provide for such payment as may be necessary to share the costs of preparing the record for Certificate of Need appeals before the Certificate of Need Appeal Panel;

(h) to provide for a reasonable and equitable fee schedule for Certificate of Need applications; provided, however, that a Certificate of Need application filed by or on behalf of a hospital in a rural county shall be exempt from any such fee;

(i) to grant, deny, suspend, rescind, cancel, or revoke a Certificate of Need as applied for or as amended;

(j) to impose civil penalties as permitted or required by law for violation of these Rules and O.C.G.A. § 31-6 *et seq.*; and

(k) to study the amount of uncompensated indigent and charity care provided by each type of health care facility, recommend requirements for the levels of uncompensated indigent and charity care required to be performed by each health care facility type and develop standardized reporting requirements for the Department to accurately track the amount of uncompensated indigent and charity care provided by each health care facility.

(3) The Commissioner shall have the power to establish and abolish technical advisory committees as he or she deems necessary, in consultation with the board, to inform effective strategy development and execution.

Cite as Ga. Comp. R. & Regs. R. 111-2-1-.02

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Health Planning Functions of the Department" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH

Chapter 111-2. HEALTH PLANNING

Subject 111-2-2. CERTIFICATE OF NEED

111-2-2-.01 Definitions

As used in these Rules, the term:

(1) "Acquisition of an existing health care facility" means to come into possession or control of a health care facility by purchase, gift, merger of corporations, lease, purchase of stock, inheritance, or by any other legal means.

(2) "Acquisition of diagnostic or therapeutic equipment":

(a) as it relates to a diagnostic, treatment, or rehabilitation center, means to come into possession, or control of, or to otherwise use diagnostic or therapeutic equipment by purchase, gift, donation, lease, transfer, or by any other legal means by or on behalf of the diagnostic, treatment, or rehabilitation center; and

(b) as it relates to a health care facility, means to come into possession or control of diagnostic or therapeutic equipment by purchase or lease by or on behalf of the health care facility.

(3) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services ("CMS"), by the Georgia Division of Medical Assistance ("DMA"), by the State Health Benefit Plans, or by any successor entities as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed 24 hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(4) "Ambulatory surgical or obstetrical facility", as defined at O.C.G.A. § 31-6-2(1), means a public or private facility, not a part of a hospital, which provides surgical or obstetrical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization.

(5) "Applicant" means the owner or lessee of an existing health care facility or the person who would be the owner or lessee of a proposed facility, as named in the application. An applicant may also be multiple owners or lessees of existing health care facilities who share common ownership or corporate affiliation and wish to submit an application to the Department for a single Certificate of Need for certain non-clinical health services, for example, but not limited to, parking decks, infrastructure improvement or replacement, and capital renovation expenditures.

(6) "Application", as defined at O.C.G.A. § 31-6-2(2), means a written request for a Certificate of Need made to the Department, containing such documentation and information as the Department may require.

(7) "Approved date" means the date that the Department issues a Certificate of Need to an applicant.

(8) "Associated with and simultaneously developed or proposed" means that if the Department determines that a single project or the substantial equivalent of a single project is divided into separate components which are associated and which are developed or planned simultaneously, so that the project or the substantial equivalent of a project or any component thereof does not require a total capital expenditure in excess of the capital expenditure or diagnostic or therapeutic equipment threshold, the Department shall combine the components for purposes of computing the amount of the total capital expenditure or expense and shall treat the combined components as a single project or substantial equivalent of a project. The Department shall include items and expenditures which are

related and which occur simultaneously in computing an applicable threshold regardless of whether the items or expenditures individually may otherwise be below the threshold or may be otherwise unreviewable exclusive of the items exempted from review by 111-2-2-.03(1) - (3) and 111-2-2-.03(5) - (19);

(a) The Department may determine that activities, services, expenditures, and items are associated if they share a relationship or association based on law, regulation, definition, function, procedure, or process; and

(b) The Department shall determine that expenditures related to activities, services, and items are simultaneously developed or planned if such expenditures occur within a 6-month period. The 6-month period shall run from operation of the activity, service or item to initial capital expenditure on the second activity or item or from operation of the activity or item to operation of the second activity or item. For services, the date of operation shall be the date that the service is actually offered. If applicable, for facilities, the date of operation shall be the date a Certificate of Occupancy is issued.

(9) **Reserved.**

(10) "Basic perinatal services" means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(11) "Bed capacity", as defined at O.C.G.A. § 31-6-2(4), means space used exclusively for inpatient care, including space designed or remodeled for inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by Rules of the Department, except that single beds in single rooms shall be counted even if the room contains inadequate square footage.

(12) "By or on behalf of" means any expenditures made by a health care facility, a political subdivision of the State, a diagnostic, treatment, or rehabilitation center, or a hospital authority, itself as well as capital expenditures made by other persons or related entities to assist the facility, subdivision, center, or authority, directly or indirectly, to offer services to its patients or residents. Related entities include entities that are associated or affiliated with, have control over or are controlled by, or have any direct financial interest in, the health care facility, political subdivision of the State, diagnostic, treatment, or rehabilitation center, or hospital authority, including, without limitation, an underwriter, guarantor, parent organization, sister organization, subsidiary or sub-entity, foreign corporation, joint venturer, partner, general partner, or building lessor, as applicable.

(13) "Capital expenditure" in relation to a proposed modification, renovation, or addition to a health care facility or to a diagnostic, treatment, or rehabilitation center, or acquisition of equipment, means an expenditure by or on behalf of a health care facility or diagnostic, treatment, or rehabilitation center that, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. Any series of capital expenditures, each less than a threshold, but which when taken together are in excess of a threshold, directed toward the accomplishment of a single project, requires a Certificate of Need. Any series of capital expenditures, which are associated and simultaneously developed or proposed, will be presumed to be a single project. In calculating the capital expenditure for modifications, additions, or renovations "capital expenditure" is the amount per construction bid or total amount of invoices or purchase orders for the single project excluding diagnostic, therapeutic, or other imaging equipment.

(14) "Certificate of Need" or "CON", as defined at O.C.G.A. § 31-6-2(6), means an official finding by the Department, evidenced by certification issued pursuant to an application, that the action proposed in the application satisfies and complies with the criteria contained in the Statute and Rules promulgated thereto.

(15) **Reserved.**

(16) "Clinical health services", as defined at O.C.G.A. § 31-6-2(8), means diagnostic, treatment, or rehabilitative services provided in a health care facility and includes, but is not limited to, the following: radiology and diagnostic imaging, such as magnetic resonance imaging and positron emission tomography (PET); radiation therapy; biliary

lithotripsy; surgery; intensive care; coronary care; pediatrics; gynecology; obstetrics; general medical care; inpatient nursing care, whether intermediate, skilled or extended care; cardiac catheterization; open heart surgery; inpatient rehabilitation; and alcohol, drug abuse, and mental health services.

(17) "Consumer", as defined at O.C.G.A. § 31-6-2(10), means a person who is not employed by any health care facility or provider and who has no financial or fiduciary interest in any health care facility or provider.

(18) "Cost estimate" means an estimate of the total cost of a project's development and construction prepared by a licensed architect or engineer within sixty days prior to the date of submittal of an application.

(19) "Defined location," as it relates to the approved location of a project or substantial equivalent of a project, means the address of the project, or in the case of a health care facility or diagnostic, treatment, or rehabilitation center with multiple addresses, the campus of such health care facility or diagnostic, treatment, or rehabilitation center. However, in no case shall a campus be considered a single defined location if varying locations and facilities of such campus are more than 3 miles apart or within more than one county.

(20) "Destination cancer hospital" means an institution with a licensed bed capacity of fifty (50) or less which provides diagnostic, therapeutic, treatment, and rehabilitative care services to cancer inpatients and outpatients, by or under the supervision of physicians, and whose proposed annual patient base is composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia.

(21) "Develop", as defined at O.C.G.A. § 31-6-2(14), with reference to a project, means constructing, remodeling, installing, or proceeding with a project, or any part of a project, or a capital expenditure project, the cost estimate which exceeds $10 million. Notwithstanding the provisions of this paragraph, the expenditure or commitment or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications, or working drawings, or to acquire, develop, or prepare sites shall not be considered to be the developing of a project.

(22) "Diagnostic imaging" means magnetic resonance imaging, computed tomography (CT) scanning, positron emission tomography (PET) scanning, positron emission tomography/computed tomography, and other advanced imaging services as defined by the Department by rule, but such term shall not include X-rays, fluoroscopy, or ultrasound services.

(23) "Diagnostic, treatment, or rehabilitation center", as defined at O.C.G.A. § 31-6-2(16), means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting which is not part of a hospital; provided, however, that any such diagnostic, treatment, or rehabilitation center that offers or proposes to offer surgery in an operating room environment and to allow patients to remain more than twenty-three (23) hours shall be considered a hospital for purposes of O.C.G.A. § 31-6, et seq.

(24) "Effective date" means:

(a) for approved projects that have not been appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, the approved date;

(b) for projects, which are appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, the date of the final resolution of any such administrative appeal if the resolution results in the approval of the project; or

(c) for projects which undergo judicial review, the effective date shall be the date referenced in (b) above, unless the Department, pursuant to Ga. Comp. R & Regs. r. 111-2-2-.07(2)(h), or the reviewing court stays the effective date of the project pending the outcome of the judicial review. If the Department or the reviewing court stays the effective date, the effective date shall be the date of the final resolution of any such judicial review if the resolution results in approval of the project.

(25) "Expiration date" is the date upon which a Certificate of Need expires and becomes null and void.

(26) "Functionally related diagnostic or therapeutic equipment" means that pieces of diagnostic, therapeutic, or other imaging equipment are interdependent to the extent that one piece of equipment is unable to function in the absence of or without the functioning piece or equipment, or that pieces of equipment are normally used together in the provision of a single health care facility or diagnostic, treatment, or rehabilitation center service.

(27) "General cancer hospital" means an institution which was an existing and approved destination cancer hospital as of January 1, 2019; has obtained final Certificate of Need approval for conversion from a destination cancer hospital to a general cancer hospital in accordance with O.C.G.A. § 31-6-40.3; and offers inpatient and outpatient diagnostic, therapeutic, treatments, and rehabilitative cancer care service or other services to diagnose or treat co-morbid medical conditions or diseases of cancer patients so long as such services do not result in the offering of any new or expanded clinical health service that would require a Certificate of Need under this chapter unless a Certificate of Need or letter of determination has been obtained for such new or expanded services.

(28) "Health care facility", as defined at O.C.G.A. § 31-6-2(17), means hospitals; destination cancer hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes; ambulatory surgical or obstetrical facilities; freestanding emergency departments or facilities not located on a hospital's primary campus; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitation centers, but only to the extent that O.C.G.A. § 31-6-40(a)(3) or (7) or both are applicable thereto.

(29) "Health maintenance organization", as defined at O.C.G.A. § 31-6-2(18), means a public or private organization organized under the laws of this state which:

(a) provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physicians' services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage;

(b) is compensated, except for co-payments, for the provision of the basic health care services listed in subparagraph (a) of this paragraph to enrolled participants on a predetermined periodic rate basis; and

(c) provides physicians' services primarily:

1. directly through physicians who are either employees or partners of such organization; or

2. through arrangements with individual physicians organized on a group practice or individual practice basis.

(30) "Home health agency", as defined at O.C.G.A. § 31-6-2(20), means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the places of residence used as such individuals' homes, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services:

(a) physical therapy;

(b) occupational therapy;

(c) speech therapy;

(d) medical social services under the direction of a physician; or

(e) part-time or intermittent services of a home health aide.

(31) "Hospital", as defined at O.C.G.A. § 31-6-2(21), means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of

injured, disabled, or sick persons. Such term includes public, private, psychiatric, rehabilitative, geriatric, osteopathic, micro-hospitals, general cancer hospitals, and other specialty hospitals.

(32) "Incur a financial obligation", in relation to the offering of a new institutional health service, means that, within time periods described in Ga. Comp. R. & Regs. r. 111-2-2-.02(5) and (6) of these Rules, the applicant has fulfilled the following performance requirements.

(a) With regard to new construction or renovation:

1. has acquired title, an option to purchase or a leasehold to an appropriate site;

2. has filed with the Department the complete set of plans, drawings, and specifications for the project in the electronic format designated by the Department;

3. has obtained a firm commitment for adequate capital financing; and

4. has entered into a construction contract that provides for a specific date for commencement, and completion of construction within a reasonable time span.

With regard to equipment not associated with a construction project;

1. a purchase or lease agreement has been entered into or, if acquired by a comparable arrangement, the applicant has possession of the equipment.

(33) **Reserved.**

(34) "Intermediate care facility", as defined at O.C.G.A. § 31-6-2(22), means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(35) "Joined applications" means two or more applications which involve similar projects in the same service area or overlapping service areas all of which have been declared complete within thirty days of the date the first application was declared complete, and whose time limits are scheduled to run from the latest date that any one of the joined applications was declared complete for review.

(36) "Joint venture ambulatory surgical center" means a freestanding ambulatory surgical center that is jointly owned by a hospital in the same county as the center or a hospital in a contiguous county if there is no hospital in the same county as the center and a single group of physicians practicing in the center and that provides surgery in a single specialty as defined by the Department; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures performed in the center, and a group practice in orthopedics which includes hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty. The ownership interest of the hospital shall be no less than thirty percent (30%) and the collective ownership of the physicians or group of physicians shall be no less than thirty percent (30%).

(37) "Life plan community" means an organization, whether operated for profit or not, whose owner or operator undertakes to provide shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting, and other services, as designated by agreement, to an individual not related by consanguinity or affinity to such owner or operator providing such care pursuant to an agreement for a fixed or variable fee, or for any other remuneration of any type, whether fixed or variable, for the period of care, payable in a lump sum, lump sum and monthly maintenance charges or in installments. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(38) "Medical use rights" means rights or interests in real property in which the owner of the property has agreed not to sell or lease such real property for identified medical uses or purposes.

(a) It shall be unlawful for any health care facility to purchase, renew, extend, lease, maintain, or hold medical use rights.

(39) "Micro-hospital" means a hospital in a rural county which has at least two and not more than seven inpatient beds and which provides emergency services seven days per week and 24 hours per day.

(40) "Mobile unit" means an object with the ability by structure, function or design to move or be moved from one site to another, such that upon arriving at a site the object is not permanently fixed but is temporarily secured for the purpose of providing a service to individuals.

(41) "New and emerging health care service" means a health care service or utilization of medical equipment which has been developed and has become acceptable or available for implementation or use but which has not yet been addressed under the Rules and regulations promulgated, adopted and included within and hereto.

(42) "New institutional health service", as defined at O.C.G.A. § 31-6-40(a) means:

(a) the construction, development, or other establishment of a new, expanded, or relocated health care facility, except as otherwise provided in O.C.G.A. § 31-6-47;

(b) any expenditure by or on behalf of a health care facility in excess of $10 million, which amount shall be adjusted annually as provided by law, and which, under generally accepted accounting principles consistently applied, is a capital expenditure, except expenditures for acquisition of an existing health care facility. See the definition of "threshold" below for expenditures that shall be counted to calculate the threshold;

(c) any increase in the bed capacity of a health care facility, regardless of whether a capital expenditure is made, which increases the total bed capacity. An exception to this Rule will be made in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.03(14);

(d) clinical health services that are offered in or through a health care facility, which were not offered on a regular basis in or through such health care facility within the twelve (12) month period prior to the time such services would be offered;

(e) any conversion or upgrading of any general acute care hospital to a specialty hospital or of a facility such that it is converted from a type of facility not covered by these Rules to any of the types of health care facilities which are covered by these Rules;

(f) the purchase or lease by or on behalf of a health care facility of diagnostic or therapeutic equipment except as otherwise provided in O.C.G.A. § 31-6-47 and Ga. Comp. R. & Regs. r. 111-2-2-.03 and Ga. Comp. R. & Regs. r. 111-2-2-.10;

(g) clinical health services which are offered in or through a diagnostic, treatment, or rehabilitation center which were not offered on a regular basis in or through that center within the twelve (12) month period to the time such services would be offered, but only if the clinical health services are any of the following:

1. Radiation therapy;

2. Biliary lithotripsy;

3. Surgery in an operating room environment, including but not limited to ambulatory surgery; and

4. Cardiac catheterization.

(h) The conversion of a destination cancer hospital to a general cancer hospital.

(43) "Nonclinical health services", as defined at O.C.G.A. § 31-6-2(25), means services or functions provided or performed by a health care facility, and the parts of the physical plant where they are located in a health care facility that are not diagnostic, therapeutic, or rehabilitative services to patients and are not clinical health services as defined in this chapter.

(44) "Offer", as defined at O.C.G.A. § 31-6-2(26), means that the health care facility is open for the acceptance of patients or performance of services and has qualified personnel, equipment, and supplies necessary to provide specified clinical health services.

(45) "Operating room environment", as defined at O.C.G.A. § 31-6-2(27), means an environment which meets the minimum physical plant and operational standards specified in the applicable administrative rules of the state which shall consider and use the design and construction specifications as set forth in the Guidelines for Design and Construction of Health Care Facilities published by the American Institute of Architects.

(46) "Pediatric cardiac catheterization" means the performance of angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization on children fourteen (14) years of age or younger.

(47) "Person", as defined at O.C.G.A. § 31-6-2(29), means any individual, trust, or estate, partnership, limited liability company or partnership, corporation (including associations, joint-stock companies and insurance companies), state, political subdivision, hospital authority, or instrumentality (including a municipal corporation) of a state as defined in the laws of this State. This term shall include all related parties, including individuals, business corporations, general partnerships, limited partnerships, limited liability companies, limited liability partnerships, joint ventures, nonprofit corporations, or any other for profit or not for profit entity that owns or controls, is owned or controlled by, or operates under common ownership or control with a person.

(48) "Personal Care Home", as defined at O.C.G.A. § 31-6-2(30), means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes including those facilities which monitor daily residents' functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

(a) Old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

(b) Boarding facilities that do not provide personal care.

(49) "Primary campus" means the building at which the majority of a hospital's or a remote location of a hospital's licensed and operational inpatient hospital beds are located, and includes the health care facilities of such hospital within 1,000 yards of such building. Any health care facility operated under a hospital's license prior to July 1, 2019, but not on the hospital's primary campus shall remain part of such hospital but shall not constitute such hospital's primary campus unless otherwise meeting the requirements of this paragraph.

(50) Project", as defined at O.C.G.A. § 31-6-2(31), means a proposal to take an action for which Certificate of Need review is required under these Rules. A project or proposed project may refer to the proposal from its earliest planning stages up through the point at which the new institutional health service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed", the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single project.

(51) "Remote location of a hospital" means a hospital facility or organization that is either created by, or acquired by, a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider.

(52) "Rural county" means a county having a population of less than 50,000 according to the United States decennial census of 2010 or any future such census.

(53) "Service-specific Rule" means those rules that are part of Ga. Comp. R. & Regs. r. 111-2-2 that regard specific clinical health care services as outlined at Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

(54) "Single specialty ambulatory surgical center" means an ambulatory surgical center where surgery is performed in the offices of an individual private physician or single group practice of private physicians if such surgery is performed in a facility that is owned, operated, and utilized by such physicians who are also of a single specialty; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures performed in the center, and a group practice in orthopedics which includes plastic hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty.

(55) "Skilled nursing facility", as defined at O.C.G.A. § 31-6-2(34), means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(56) "Specialty hospital" means a hospital that is primarily or exclusively engaged in the care and treatment of one of the following: patients with a cardiac condition, patients with an orthopedic condition, patients receiving a surgical procedure, or patients receiving any other specialized category of services defined elsewhere in these Rules. A "specialty hospital" does not include a destination cancer hospital or a general cancer hospital.

(57) "State health plan", as defined at O.C.G.A. § 31-6-2(36), means a comprehensive program based on recommendations by the Health Strategies Council and the board, approved by the Governor, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the State. The State Health Plan is divided into a series of component plans modified from time to time as needed.

(58) "Substantial equivalent of a project" means a proposal to take an action for which a letter of determination is sought under these Rules. A substantial equivalent of a project may refer to the proposal from its earliest planning stages up through the point at which the service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed", the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single substantial equivalent of a project.

(59) "Threshold" means the dollar amount of capital expenditures for which, when exceeded, a Certificate of Need is required.

(a) In calculating the dollar amounts of a proposed project for purposes of 111-2-2 .01(42)(b) and (42)(f), and 111-2-2-.01(54) and (36) of these Rules, the capital costs of all items subject to review by these Rules and items not subject to review by these Rules associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(b) The following threshold amounts are effective as of July 1, 2019:

1. The capital expenditure threshold of Ga. Comp. R. & Regs. r. 111-2-2.01(42)(b), is $10 million;

2. The equipment threshold of Ga. Comp. R. & Regs. r. 111-2-2.03(30) is $3 million;

3. The physician-owned, single-specialty, office-based ambulatory surgery center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(54) is $2.5 million;

4. The joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(36) is $5 million;

With respect to (b)1., above, beginning on July 1, 2019, and with respect to (b)3., and 4. above, beginning on July 1, 2009, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate composite price index that, in the judgment of the Department, represents national construction prices for the preceding calendar year such as those published by the Department of Commerce of the United States government or other government agency;

With respect to (b)2. above, beginning on July 1, 2010, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate consumer price index, or its successor or appropriate replacement index, for the preceding calendar year, such as those published by the United States Department of Labor or other United States government agency. However, diagnostic or other imaging services that are not offered in a hospital or in the offices of an individual private physician or single group practice of physicians exclusively for use on patients of that physician or group practice shall be deemed to be a new institutional health service regardless of the cost of the equipment. Also, however, this amount or threshold figure shall not include build out costs, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(c), but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five (5) years.

(c) For purposes of computing the capital expenditure threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(b) and Ga. Comp. R. & Regs. r. 111-2-2-.01(21) and the physician-owned, single specialty ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(21) and the joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(22), the Department shall include, but not be limited to, the following guidelines:

1. Pursuant to the definition of "associated with and simultaneously developed or proposed", the total cost of all associated capital expenditures for items to be obligated for or purchased within a six (6) month period for a single program, service, plan, or project, regardless of whether or not the cost of any individual item is in excess of the capital expenditure threshold and regardless of whether or not the expenditure or item is otherwise reviewable under these Rules or the CON Statute, is included in the computation;

2. The cost of depreciable equipment that is not used for diagnosis or treatment, such as office equipment, usual business equipment, and office and waiting room furniture, is included in the computation, if such items are associated with and simultaneously developed or proposed with the project. If such furnishing and equipment are used, the cost that shall be used in calculating the threshold shall be the depreciated value or current market value of the furnishings or equipment, whichever is greater;

3. The cost of normal inventories of supplies, such as glassware, chemicals, drugs, linens, and paper, is exempt from the computation as an operating expense;

4. The value of the facilities to be acquired by lease, gift, donation or other means is based on a current (within six (6) months) appraisal of the facility, except that the value of newly constructed facilities shall be based on the actual square footage cost to construct the facility;

5. For facilities that are acquired by lease, the computation of value shall be based on the rentable square footage of the facility and not the useable square footage. Notwithstanding this Rule, lease payments shall be considered to be operating expenses for leases other than capital leases;

6. For facilities that are only partly occupied by a person, the computation shall include a pro-rata share of the value of the common space, unless the rentable square footage is provided as required by 5. above and that rentable square footage already includes an allocation for common space, as documented by the lease agreement; and

7. In the case of a gift or donation, the value of equipment, furnishings or facilities is the fair market value of the equipment, furnishings, or facilities;

(d) For purposes of computing the equipment threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(59)(b)(2) and Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(f), the Department shall include, but not be limited to, the following guidelines:

1. The cost of diagnostic, therapeutic, or other imaging equipment includes all capital costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended, including but not limited to the following expenses:

(i) Any expense incurred for the purchase of a warranty on the diagnostic, therapeutic, or other imaging equipment from the manufacturer or vendor for the first five years of operation;

(ii) Any expense incurred for operator training;

(iii) Any expense incurred for installation and assembly of the equipment;

(iv) Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

(v) Any expense incurred for functionally related diagnostic, therapeutic or other imaging equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.

(vi) Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

(vii) Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

(viii) Any dollar amount attributable to service contracts for the first five (5) years of operation;

(ix) Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of determination by the manufacturer or vendor of the equipment;

(x) For mobile units of equipment, expenditures and values associated with the motor coach, trailer, van, rig, or other form of modular or transitional housing shall be included in the computation of the threshold;

2. The acquisition by whatever means of one or more items of functionally related diagnostic, therapeutic, other imaging equipment shall be considered as one project. The acquisition of functionally related accessories shall also be counted. Pursuant to the definition of "functionally related diagnostic, therapeutic, or other imaging equipment", any individual components or pieces of diagnostic, therapeutic, or other imaging equipment, which depend on one another in order to function and that are purchased within a six (6) month period, shall be considered in the aggregate in calculating the threshold;

3. Diagnostic, therapeutic, or other imaging equipment shall include single and multiple units of equipment, if such units are associated with and simultaneously developed or proposed with one another. Pursuant to the definition of "associated with and simultaneously developed or proposed", the Department may determine that individual pieces or units of diagnostic, therapeutic, or other imaging equipment are associated with one another if such pieces or units of equipment are used for the same or similar health services and if such pieces or units of equipment are developed, proposed, or acquired simultaneously. Such associated and simultaneous units purchased within a six (6) month period shall be aggregated to calculate the threshold;

4. Purchase or lease shall include purchases, contracts, encumbrances of funds, lease arrangements, conditional sales or a comparable arrangements that purport to be a transfer of ownership in whole or in part;

5. In the case of a lease, loan, or gift, the value of the diagnostic, therapeutic, or other imaging equipment is the fair market value of the diagnostic, therapeutic, or other imaging equipment, as evidenced by documentation from a reputable vendor or manufacturer.

(60) "Uncompensated indigent or charity care" means the dollar amount of "net uncompensated indigent or charity care after direct and indirect (all) compensation" as defined by, and calculated in accordance with, the Department's Hospital Financial Survey and related instructions.

(61) "Urban county" means a county having a population equal to or greater than 50,000 according to the United States decennial census of 2010 or any future such census.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.01

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq*.

HISTORY: Original Rule entitled "Definitions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Oct. 19, 2018; eff. Nov. 8, 2018.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.02 Nature of Certificate of Need

(1) **Purpose**. The purpose of the Certificate of Need evaluation process is to ensure that adequate health care services and facilities are developed in an orderly and economical manner and are made available to all Georgians and that only those health care services that are found to be in the public interest shall be provided in the State. The goals are to:

(a) Review proposed health care services;

(b) Contain health costs;

(c) Promote economic value;

(d) Ensure compatibility of health care services with the needs of various areas and populations of Georgia; and

(e) Prevent unnecessary duplication or services.

(2) **Contents.** The certificate, or attachments, shall specify, but not be limited to:

(a) the scope of the project;

(b) the defined location of the project;

(c) the person to whom the certificate was issued;

(d) the maximum capital expenditure, if any, which may be obligated under the certificate;

(e) the service area of the project;

(f) the valid dates;

(g) the schedule of time periods to be followed in making the service or equipment available or in completing the project;

(h) the services or units of services, which have been approved; and

(i) when the progress reporting requirements under Ga.Comp. R. & Regs. r. 111-2-2-.04(2) and Ga. Comp. R. & Regs. r. 111-2-2-.02(5) are due.

(3) **Validity.** A Certificate of Need shall be valid only for the defined scope, physical location, cost, service area, and person named in the application as the applicant.

(4) **Non-transferability.** A Certificate of Need shall not be transferable or assignable, nor shall a project for which a Certificate of Need has been issued be transferred from or assigned by one person to another, except under the following circumstances:

(a) the death of the holder of the Certificate, provided the transfer is solely from the estate of the holder to his or her heirs; or

(b) an existing licensed health care facility to which a Certificate has been issued is acquired by another person, in which instance the Certificate shall be valid for the person who acquires the facility and for the scope, location, cost, and service area previously approved by the Department.

(5) **Effective Period.** Unless otherwise provided by a service-specific rule, or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the effective period, the effective period of a Certificate of Need shall be as follows:

(a) Certificates involving neither construction nor equipment acquisition shall be effective for twelve (12) months;

(b) Certificates solely involving acquisition of equipment shall be effective for twelve (12) months, by which date the applicant must be in possession of the equipment; and

(c) Certificates for projects involving construction shall be effective based on a reasonable, phased timetable presented in the application, which may be amended during the review cycle, as planned, developed, proposed, and submitted by the applicant. In determining the reasonableness of the proposed phases and time periods, the Department will be guided by the applicable horizon year for the project. However, in appropriate circumstance, the Department may approve an effective period in excess of the applicable horizon year. The approved and valid phases and effective period shall be included in the Certificate of Need. When the Department extends the effective period pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7) or when, due to an appeal of a project, a project's effective date is not the approved date, the Department will update the effective period, including the horizon year, of the project accordingly.

(6) **Initial 12-month Implementation Period for Projects Involving Construction.** Unless otherwise provided in a service-specific rule or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the initial 12-month implementation period, all projects involving construction regardless of the dollar amount must, within twelve (12) months of the effective date of the certificate, demonstrate, as evidenced by a progress report (as described at Ga. Comp. R. & Regs. r. 111-2-2-.04(2)) and supporting documentation, substantial performance in beginning the project. Substantial performance shall be demonstrated by the following:

(a) The construction plans have been approved by the Department's Architect;

(b) The construction contract has been signed and specifically indicates beginning and completion dates; and

(c) Construction materials and equipment are on site.

(7) Extension of Time Periods. The Department may, upon written request of the certificate holder, grant an extension of the effective period of a Certificate of Need or of the initial 12-month implementation period if the applicant's request is received by the Department 30 days prior to expiration of the Certificate of Need or of the initial 12-month implementation period, as applicable.

(a) A request for an extension of the initial 12-month implementation period, or any extension thereof, shall demonstrate:

1. that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the initial 12-month implementation period may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences. Ordinarily, lack of adequate or accurate planning, uncertainty as to reimbursement and/or financial difficulties will not justify an extension of the implementation period;

2. that the certificate holder has made substantial and timely progress in implementing the project. In order to show substantial and timely progress in implementing the project, the certificate holder must show that the project was on schedule and could reasonably have been implemented during the initial 12-month implementation period or extension thereof, but for the occurrence or circumstance beyond the certificate holder's control;

(b) A request for an extension of the effective period of a Certificate of Need, or any phase or extension thereof, shall:

1. demonstrate that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the effective period, or any phase or extension thereof, may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences.

2. demonstrate that but for the circumstance beyond the control of the certificate holder, the project, or phase thereof, would have been completed within the effective period;

3. demonstrate that the certificate holder has made substantial and timely progress in completing the project, or phase thereof;

4. indicate the expected completion date of the project, or phase thereof, as applicable; and

5. affirm that the project, or phase thereof, will be completed within the requested extension period.

(c) The length of an extension of the effective period or of the initial 12-month implementation period of a Certificate of Need shall be determined by the Department and shall be reasonable and consistent with the circumstances. In no case, shall the Department extend the initial 12-month implementation period of a Certificate of Need beyond an additional 12 months.

(d) In circumstances where the certificate holder is precluded from normal progression due to litigation involving the Certificate or where the method of financing is precluded by litigation, the Department may, at its discretion, suspend any or all of the time periods specified herein until the litigation has been resolved.

(8) **Expiration and Cancellation**. If, within the effective period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(5) and initial 12-month implementation period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(6), as applicable, the required performance standards are not met, the Certificate will be deemed to have expired unless an extension has been obtained from the Department pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7). Unless the certificate holder demonstrated good cause not to deem the Certificate to have expired, which shall be determined by the Department, the Certificate will be canceled and notifications of same issued to the applicant, local governing authorities, Regional Development Center, and a newspaper of general circulation in the area where the application originated. An applicant whose Certificate has expired may not resubmit an application for the same or a substantially similar project until at least 120 days after expiration of the Certificate.

(9) **Modification by Operation of Law of Certificate for Failure to Complete**. Upon expiration of the effective period, if a certificate holder has not completed all activities or has not implemented all services or units of services granted in the Certificate of Need issued on the approved date (or if appealed, the effective date), the Certificate shall be modified upon such expiration to include and be valid for only those activities, services, or units of services, which have been completed and implemented as of the date of expiration.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.02

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Nature of Certificate of Need" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.03 Exemptions from Review

The following shall not be subject to Certificate of Need review and shall be exempted from the provisions of these Rules regarding Certificate of Need Review except as otherwise provided:

(1) infirmaries operated by educational institutions for the sole and exclusive benefit of students, faculty members, officers, or employees thereof;

(2) infirmaries or facilities operated by businesses for the sole and exclusive benefit of officers or employees thereof, provided that such infirmaries or facilities make no provision for overnight stay by persons receiving their services;

(3) institutions operated exclusively by the federal government or by any of its agencies;

(4) offices of private physicians or dentists, as determined in the sole discretion of the Department, whether for individual or group practice except as otherwise provided in Ga. Comp. R. & Regs. r .111-2-2-.01(54) and Ga. Comp. R. & Regs. r .111-2-2-.01(42)(f). Simple ownership of a facility by a practitioner or a group of practitioners of the healing arts does not, in and of itself, exempt such facility from the scope of these Rules. Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied exclusively as the office of private physicians or dentists. Therefore, any person who seeks licensure as a health care facility must secure a Certificate of Need if a new institutional health service is being offered or developed;

(5) Religious, nonmedical health care institutions as defined in 42 U.S.C. Section 1395x(ss)(1), listed and certified by a national accrediting organization;

(6) site acquisitions for health care facilities or preparation or development costs for such sites prior to filing a Certificate of Need application**;**

(7) expenditures related to adequate preparation and development of an application for a Certificate of Need;

(8) the commitment of funds conditioned upon the obtaining of a Certificate of Need;

(9) transfers from one health care facility to another such facility of major medical equipment previously approved under or exempted from Certificate of Need review, except where such transfer results in the institution of a new clinical health service for which a Certificate of Need is required in the facility acquiring said equipment, provided that such transfers are recorded at net book value of the medical equipment as recorded on the books of the transferring facility;

(10) expenditures for the restructuring or acquisition of existing health care facilities by stock or asset purchase, merger, consolidation, or other lawful means;

(11) the purchase of a closing hospital or of a hospital that has been closed for no more than twelve (12) months by a hospital in a contiguous county to repurpose the facility as a micro-hospital;

(12) capital expenditures otherwise covered by this Chapter required solely to eliminate or prevent safety hazards as defined by federal, state or local fire, building, environmental occupational health, or life safety codes of regulations,

to comply with licensing requirements of the Healthcare Facility Regulation Division, or to comply with accreditation standards of the Joint Commission or another nationally recognized health care accreditation body;

(13) except as otherwise provided in this subsection, all cost overruns are excluded from prior Certificate of Need review and approval. For purposes of this subsection, a cost overrun that is subject to prior Certificate of Need review and approval (i.e., a reviewable cost overrun) is defined as meaning any cost overrun which is in excess of the current capital or diagnostic, therapeutic, or other imaging equipment threshold, or in excess of ten percent (10%) of the approved capital expenditure amount, whichever is less. However, in no event shall an additional expenditure of less than $300,000 be deemed a reviewable cost overrun. Reviewable cost overruns will be reviewed by the Department in accordance with the following provisions:

(a) A reviewable cost overrun associated with ongoing construction or renovation activity which has not been incurred prior to a Certificate of Need approval and is solely related to an unanticipated engineering, major fixed equipment or other construction problem, or federal, state or local fire requirements which were adopted or became effective after the issuance of the Certificate of Need but prior to the completion of construction or renovation, will receive favorable review consideration if the applicant demonstrates that the overrun will have no impact or a minimal impact on costs and/or charges per patient day or procedure; and

(b) A reviewable cost overrun which is the result of subsequent project bidding prior to any contractual obligation for construction and/or renovation work will not receive favorable review consideration by the Department but will require the entire project to be reviewed as an entirely new project subject to all the applicable criteria, standards and plans; and

(c) A reviewable cost overrun which is due to delays of project construction and/or renovation activity resulting from an appeal proceeding, when such delay has been in excess of one year, and where the Department has suspended the time periods until the issues are resolved, will be given favorable consideration as long as the project has not changed in scope, square footage, services or number of new beds proposed.

(d) For projects involving either construction or renovation, but not both, a reviewable cost overrun which increases the square footage beyond five percent (5%) of the originally approved project's total new square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(e) For projects involving construction and renovation, a reviewable cost overrun which increases the square footage beyond five percent (5%) of the sum of the new construction square footage and renovated square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(f) Regardless of cost, during implementation of the project, any increase in the scope of the original project or any change in the number of beds (i.e., the subtraction, addition, replacement or conversion of different number of beds than authorized in the original Certificate of Need) will invalidate the original project and the Department will deem the original project to have been withdrawn unless prior written approval is obtained from the Department;

(14) increases in the bed capacity of a hospital up to ten beds or ten percent (10%) of capacity, whichever is greater, in any consecutive two-year period, in a hospital that has maintained an overall occupancy rate greater than seventy-five percent (75%) (exclusive of any skilled nursing units or comprehensive inpatient rehabilitation units) for the previous twelve (12) month period;

(15) expenditures of less than $870,000.00 for any minor or major repair or replacement of equipment by a health care facility that is not owned by a group practice of physicians or a hospital and that provides diagnostic imaging services if such facility received a letter of non-reviewability from the Department prior to July 1, 2008. This paragraph shall not apply to such facilities in rural counties;

(16) except as provided in paragraph (15) of this subsection, expenditures for the minor or major repair of a health care facility or a facility that is exempt from the requirements of these Rules, parts thereof or services provided or equipment used therein; or the replacement of equipment, including but not limited to CT scanners, magnetic

resonance imaging, positron emission tomography (PET), and positron emission tomography/computed tomography previously approved for a Certificate of Need.

(a) To qualify for this exemption, the replaced equipment must have received prior CON review and approval, or have been grandfathered, and the replaced equipment must be removed entirely from the premises and not be used in tandem with the replacement equipment, unless authorized in writing by the Department. Replacement equipment must be placed in the same defined location as the replaced equipment.

1. The Department may authorize in writing the retention of certain functionality of the equipment to be replaced if such retained functionality is not used in tandem with the replacement equipment and if the retained functionality would not otherwise result in the provision of a new institutional health service. The fair market value of the retained functionality must not exceed the applicable equipment threshold at the time of replacement.

(b) Expenditures associated with activities essential to acquiring and making operational the replacement equipment shall also be exempted from review. "Activities essential to acquiring and making operational the replacement equipment" means those activities that are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

(c) Replacement equipment shall be comparable diagnostic or therapeutic equipment in relation to the replaced equipment. "Comparable diagnostic or therapeutic equipment" means equipment which is functionally similar and which is used for the same or similar diagnostic or treatment purposes. Replacement equipment is comparable to the equipment being replaced if it is functionally similar and is used for the same or similar diagnostic, therapeutic, or treatment purposes as the equipment currently in use and is not used to provide a new health service;

(17) new institutional health services offered by or on behalf of a Health Maintenance Organization, or a health facility controlled, directly or indirectly, by a Health Maintenance Organization or a combination of Health Maintenance Organizations, provided specific and detailed documentation is provided to the Department that one of the following conditions are met:

(a) that seventy-five percent (75%) of the patients who can reasonably be expected to use the service will be individuals enrolled in a Health Maintenance Organization certified by the State of Georgia;

(b) that the service is needed by the Health Maintenance Organization in order to operate efficiently and economically and that it is not otherwise readily accessible to the Health Maintenance Organization because:

1. existing similar services are not available under a contract of reasonable duration;

2. full and equal staff privileges are not available in existing facilities; or

3. arrangements with existing facilities are not administratively feasible;

(18) capital expenditures for a project otherwise requiring a Certificate of Need if those expenditures are for a project to remodel, renovate, replace, or any combination thereof, a medical-surgical hospital and all the following conditions are met:

(a) the hospital has a bed capacity of not more than fifty (50) beds;

(b) the hospital is located in a county in which no other medical-surgical hospital is located;

(c) the hospital has at any time been designated as a disproportionate share hospital by the Department;

(d) the hospital has at least forty-five percent (45%) of its patient revenues derived from Medicare, Medicaid, or any combination thereof, for the immediately preceding three years;

(e) the project has at least eighty percent (80%) of its capital expenditures financed by proceeds of a special purpose county sales and use tax imposed pursuant to Article 3 of Chapter 8 of Title 48;

(f) the proposed replacement hospital is located within a three (3) mile radius of and within the same county as the hospital's existing facility; and

(g) the project does not result in any of the following:

1. the offering of any new clinical health services;

2. any increase in bed capacity;

3. any redistribution of existing beds among existing clinical health services; and

4. any increase in the capacity of existing clinical health services;

(19) Expenditures for nonclinical projects, including parking lots, parking decks, and other parking facilities; computer systems, software, and other information technology; medical office buildings; administrative office space; conference rooms; education facilities; lobbies; common spaces; clinical staff lounges and sleep areas; waiting rooms; bathrooms; cafeterias; hallways; engineering facilities; mechanical systems; roofs; grounds; signage; family meeting or lounge areas; other nonclinical physical plant renovations or upgrades that do not result in new or expanded clinical health services; and state mental health facilities;

(20) Life plan communities, provided that the skilled nursing component of the facility is for the exclusive use of residents of the life plan community and that a written exemption is obtained from the Department; provided, however, that new sheltered nursing home beds may be used on a limited basis by persons who are not residents of the life plan community for a period up to five years after the date of issuance of the initial nursing home license, but such beds shall not be eligible for Medicaid reimbursement. For the first year, the life plan community sheltered nursing facility may utilize not more than fifty percent (50%) of its licensed beds for patients who are not residents of the life plan community. In the second year of operation, the life plan community shall allow not more than forty percent (40%) of its licensed beds for new patients who are not residents of the life plan community. In the third year of operation, the life plan community shall allow not more than thirty percent (30%) of its licensed beds for new patients who are not residents of the life plan community. In the fourth year of operation, the life plan community shall allow not more than twenty percent (20%) of its licensed beds for new patients who are not residents of the life plan community. In the fifth year of operation, the life plan community shall allow not more than ten percent (10%) of its licensed beds for new patients who are not residents of the life plan community. At no time during the first five (5) years shall the life plan community sheltered nursing facility occupy more than fifty percent (50%) of its licensed beds with patients who are not residents under contract with the life plan community. At the end of the five (5) year period, the life plan community sheltered nursing facility shall be utilized exclusively by residents of the life plan community and at no time shall a resident of a life plan community be denied access to the sheltered nursing facility. At no time shall any existing patient be forced to leave the life plan community to comply with this paragraph. The Department is authorized to promulgate rules and regulations regarding the use and definition of "sheltered nursing facility" in a manner consistent with this Code section. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party;

(21) Any single specialty ambulatory surgical center that:

(a) 1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health services which do not exceed $2.5 million; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two (2) or fewer operating rooms; provided, however, that a center exempt pursuant to this paragraph shall be required to obtain a certificated of need in order to add any additional operating rooms;

(b) Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer

a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. Hospitals shall not unreasonably deny a transfer agreement or affiliation agreement to the center;

(c) 1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

(d) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70.

Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed project for purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with an simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(22) Any joint venture ambulatory surgical center that:

(a) Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5 million;

(b) 1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

(c) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70. Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed project for purposes of this paragraph, the

costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(23) Expansion of services by an imaging center based on a population needs methodology taking into consideration whether the population residing in the area served by the imaging center has a need for expanded services, as determined by the Department in accordance with its rules and regulations, if such imaging center:

(a) Was in existence and operational in this state on January 1, 2008;

(b) Is owned by a hospital or by a physician or a group of physicians comprising at least eighty percent (80%) ownership who are currently board certified in radiology;

(c) Provides three (3) or more diagnostic and other imaging services;

(d) Accepts all patients regardless of ability to pay; and

(e) Provides uncompensated indigent and charity care in an amount equal to or greater than the amount of such care provided by the geographically closest general acute care hospital; provided, however, this paragraph shall not apply to an imaging center in a rural county;

(24) Diagnostic cardiac catheterization in a hospital setting on patients fifteen (15) years of age and older;

(25) Therapeutic cardiac catheterization in hospitals selected by the Department prior to July 1, 2008, to participate in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Study and therapeutic cardiac catheterization in hospitals that, as determined by the Department on an annual basis, meet the criteria to participate in the C-PORT Study but have not been selected for participation; provided, however, that if the criteria requires a transfer agreement to another hospital, no hospital shall unreasonably deny a transfer agreement to another hospital;

(a) The standards for therapeutic cardiac catheterization, pursuant to the exemption in subsection (24) for hospitals who have not been selected for participation in the C-PORT Study shall be as follows:

A hospital that wishes to receive authorization to perform therapeutic cardiac catheterization procedures must:

1. submit a request for a letter of determination on the required form with the proper filing fee between May 1 and May 15 of each year, beginning with calendar year 2009; the sufficiency of the information submitted in the request shall be determined within the administrative discretion of the Department;

2. provide documentation which demonstrates it can perform a minimum of two hundred (200) percutaneous cardiac interventions (PCI) per year by the beginning of the third year of operation of a program, including both elective and primary PCI, with a minimum of thirty-six (36) primary PCI per year beginning the third year of operation;

3. provide documentation to support the criteria referenced in subsection 2 above that includes substantive information on the number of diagnostic cardiac catheterization procedures performed at the hospital, or referred to existing PCI providers by the hospital, in or out of the state of Georgia, in the two (2) calendar years immediately preceding the request;

4. provide documentation that it will have, prior to beginning a PCI program, on active medical staff, at least one (1) interventional cardiologist who will meet the American College of Cardiology (ACC) and American Heart Association (AHA) competency standards, including the performance of at least seventy-five (75) PCI procedures per year;

5. provide documentation that the interventional cardiologist is board certified, or is in the process at the time of the request, of obtaining board certification in Interventional Cardiology from the American Board of Internal Medicine;

6. provide documentation of access to at least one (1) other interventional cardiologist who meets the criteria of subsections 4. and 5. above, to participate in its program on an as-needed basis as determined by the hospital;

7. agree to report annually the data on number of PCI procedures, type, and outcomes to the National Cardiovascular Data Registry Cath/PCI registry;

8. provide documentation to show that one (1) or more interventional cardiologist(s), as qualified in subsections 4., 5. and 6. above, are available to perform primary PCI procedures twenty-four (24) hours a day, seven (7) days a week, three hundred sixty-five (365) days a year;

9. provide documentation one (1) or more interventional cardiologist(s) are required to respond to a call, within the calendar availability specified in subsection 8. above, within sixty (60) minutes;

10. provide documentation that competent and trained nursing and technical cardiac catheterization staff are available at all times and are required to respond in a manner determined by the hospital in conjunction with the interventional cardiologists;

11. provide documentation of a transfer agreement with a tertiary medical facility that has an open heart surgery service to which a patient can be transferred when necessary within a period of sixty (60) minutes, by any means of transportation as chosen by the hospital, from the time the need for transfer is identified;

(i) if the provider of an open heart surgery service within the travel time parameters of this subsection refuses to enter into a transfer agreement with the requesting hospital, the hospital may submit documentation on the reasons given for the denial, and the Department may consider these reasons;

(ii) the Department may allow a requesting hospital to submit a transfer agreement with a provider of an open heart surgery service that is beyond the travel time parameters in this subsection if the reasons given for the denial of a transfer agreement by the tertiary provider are determined by the Department to be unreasonable;

(iii) if the Department determines the reasons for the denial of a transfer agreement by the tertiary provider within the time travel parameters in this subsection are reasonable, the Department may require the requesting hospital to address the reasons for the denial and enter into further negotiations for a transfer agreement prior to receiving a favorable determination from the Department;

12. provide documentation of an agreement with an ambulance service capable of advanced life support and intra aortic balloon pump services and that guarantees a thirty (30) minute or less response time;

13. agree to provide accurate and timely data, including outcomes analysis and formal periodic external and internal case review as required by the Department;

14. provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup consistent with C-PORT and ACC standards will be developed and maintained;

15. provide documentation to show the cardiac catheterization laboratory(s) at the requesting hospital is equipped in a manner consistent with C-PORT and ACC guidelines;

16. agree to participate in an elective and primary PCI Development Program at its expense, the successful completion of which will be verified by the Department through the use of an identified third-party; and

17. affirmatively agree authorization to begin a therapeutic cardiac catheterization program is expressly contingent upon successful completion of the development program as referenced in subsection 16. above.

(b) Any hospital approved to perform therapeutic cardiac catheterization procedures as a result of a request submitted between May 1 and May 15 of any calendar year after the adoption of this rule, must, between May 1 and May 15, of each subsequent year, submit a request which documents its compliance with the standards of this Rule,

and the Department must re-affirm the hospital's current compliance in writing in order for the hospital to continue its therapeutic cardiac catheterization program.

(c) Any administrative proceeding held pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.10(6), in opposition to a Department approval of a request from a hospital to perform therapeutic cardiac catheterization procedures in accordance with the standards established in this section, or in opposition to a Department decision to deny a hospital request to perform therapeutic cardiac catheterization procedures, shall not conduct a de novo review of the Department decision, and such decision shall only be reversed by an administrative hearing officer upon a showing the Department's action was without reason, arbitrary, or capricious;

(26) Infirmaries of facilities operated by, on behalf of, or under contract with the Department of Corrections or the Department of Juvenile Justice for the sole and exclusive purpose of providing health care services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution, including correctional institutions operated by private entities in this state which house inmates under the Department of Corrections or the Department of Juvenile Justice;

(27) The relocation of any skilled nursing facility, intermediate care facility, or micro-hospital within the same county, any other health care facility in a rural county within the same county, and any other health care facility in an urban county within a three-mile radius of the existing facility so long as the facility does not propose to offer any new or expanded clinical health services at the new location;

(28) Facilities which are devoted to the provision of treatment and rehabilitative care for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury, as defined in O.C.G.A. § 37-3-1;

(29) The renovation, remodeling, refurbishment, or upgrading of a health care facility, so long as the project does not result in any of the following:

(a) The offering of any new or expanded clinical health services;

(b) Any increase in inpatient bed capacity;

(c) Any redistribution of existing beds among existing clinical health services; or

(d) A capital expenditure exceeding the threshold contained in paragraph (2) of subsection (a) of O.C.G.A. § 31-6-40;

(30) Other than for equipment used to provide positron emission tomography (PET) services, the acquisition of diagnostic, therapeutic, or other imaging equipment with a value of $3,000,000.00 or less, by or on behalf of:

(a) A hospital; or

(b) An individual private physician or single group practice of physicians exclusively for use on patients of such private physician or single group practice of physicians and such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

The amount specified in this paragraph shall not include build-out costs, as defined by the Department, but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five years. The acquisition of one or more items of functionally related diagnostic or therapeutic equipment shall be considered as one project. The dollar amount specified in this paragraph and in paragraph (15) of this subsection shall be adjusted annually by an amount calculated by multiplying such dollar amounts (as adjusted for the preceding year) by the annual percentage of change in the consumer price index, or its successor or appropriate replacement index, if any, published by the United States Department of Labor for the preceding calendar year, commencing on July 1, 2010; and

(31) A capital expenditure of $10 million or less by a hospital at such hospital's primary campus for:

(a) The expansion or addition of the following clinical health services: operating rooms, other than dedicated outpatient operating rooms; medical-surgical services; gynecology; procedure rooms; intensive care; pharmaceutical services; pediatrics; cardiac care or other general hospital services; provided, however, that such expenditure does not include the expansion or addition of inpatient beds or the conversion of one type of inpatient bed to another type of inpatient bed; or

(b) The movement of clinical health services from one location on the hospital's primary campus to another location on such hospital's primary campus.

Pursuant to O.C.G.A. § 31-6-40(c)(1), any person who had a valid exemption granted or approved by the former Health Planning Agency or the Department of Community Health prior to July 1, 2008, shall not be required to obtain a Certificate of Need in order to continue to offer those previously offered services.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.03

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq*.

HISTORY: Original Rule entitled "Exemptions from Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. May 1, 2009; eff. May 21, 2009.

Amended: F. Oct. 19, 2018; eff. Nov. 8, 2018.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.04 Periodic Reports

The availability of accurate, current data is critical for adequate health planning and for the review process. Therefore, all inpatient and outpatient health care facilities and services subject to Certificate of Need review will be required to provide complete and accurate data, in a timely manner, as required by the Department. Pursuant to O.C.G.A. § 31-6-70(a), this reporting requirement shall also apply, beginning July 1, 2008, to all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a Certificate of Need under O.C.G.A. § 31-6 et seq. and these Rules.

(1) **Annual and Special Questionnaires.**

(a) All CON-regulated facilities and services, as well as all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a Certificate of Need under these Rules, shall complete and submit certain surveys annually and periodically to the Department, as deemed necessary by the Department.

(b) Any facility offering ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2; any diagnostic, treatment, or rehabilitation center offering diagnostic imaging or other imaging services in operation and exempt prior to July 1, 2008; or any facility operating pursuant to a letter of non-reviewability and offering diagnostic imaging services prior to July 1, 2008, shall:

1. Provide notice to the Department of the name, ownership, location, single specialty, and services provided in the exempt facility; and

2. Beginning on January 1, 2009, provide annual reports in the same manner and in accordance with the provisions of this Rule.

(c) The Department shall publish a notice giving a date when the information responsive to subsection (b)1. of this Rule by December 30, 2008, or the Department does not receive the annual report referenced in subsection (a), and

subsection (b)2., of this Rule from a health care facility requiring a Certificate of Need or an ambulatory surgical center or imaging center, whether or not exempt from obtaining a Certificate of Need under these Rules, on or before the date such report is due or receives a timely but incomplete report, the Department shall notify the health care facility or center regarding the deficiencies and shall be authorized to fine such health care facility or center an amount not to exceed $500.00 per day for every day up to thirty (30) days and $1,000.00 per day for every day over thirty (30) days for every day the Department has not received a report or an incomplete report has not been sufficiently corrected based on the Department's notice of deficiencies.

(d) Survey notices will be mailed or electronically transmitted by the Department to each such facility. The accurately and fully completed survey, covering the report period indicated, shall be filed with the Department within the time frame specific in the notice. The Survey shall be filed with the Department in the electronic format designated by the Department in the Survey Notice or on the Department's website. The survey shall include an electronic signature as authorized by law, of the chief executive officer or principal administrator of the facility, who shall attest to the accuracy and completeness of the information provided.

(e) Reporting requirements shall also apply to new health facilities and services approved through Certificate of Need review. Generally, new facilities and services will be required to report if approved for operation or occupancy for sixty (60) days or more of the report period.

(f) Surveys submitted to the Department pursuant to these Rules and any service-specific Rules shall not be available for public review until after the deadline for submission for all surveys of that type;

(g) Required surveys submitted for a given period of time may not be revised by the facility or service after the survey filing deadline unless the request for revision is approved by the Department at its sole discretion.

(h) If the Department does not receive an annual report from a health care facility within one hundred eighty (180) days following the date such report was due or receives a timely but incomplete report which is not sufficiently completed within such one hundred eighty (180) days, the Department shall be authorized to revoke the Certificate of Need of the health care facility in accordance with O.C.G.A. § 31-6-45 and Ga. Comp. R. & Regs. r. 111-2-2-.05.

(i) The Department shall make publicly available all annual reports submitted pursuant to O.C.G.A. § 31-6-70 on the Department website. The Department shall also provide a copy of such annual reports to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the chairpersons of the House Committee on Health and Human Services and the Senate Health and Human Services Committee.

(j) All health care facilities, ambulatory surgical centers, and imaging centers required to submit an annual report pursuant to O.C.G.A. § 31-6-70(a) shall make such annual reports publicly available on their websites.

(2) **Post-Approval Reporting.**

(a) All entities receiving a Certificate of Need shall maintain a valid and accurate mailing and electronic mail address with the Department. Any notification, notice, or letter required by these Rules is deemed to be received by the certificate holder when the Department sends such notification, notice, or letter to the mailing or electronic mail address on file with the Department.

(b) Persons holding Certificates for construction projects shall, within twelve (12) months of the effective date of the Certificate, i.e., at the end of the implementation period, provide a progress report to the Department including documentation of the following:

1. that the construction plans have been approved by the Department;

2. that a construction contract has been signed, specifically indicating beginning and completion dates;

3. that construction materials and equipment are on the site and construction of the project has actually begun.

(c) The Department shall monitor the Certificate of Need holder's progress in completing the project and phases thereof, as applicable, within the effective period as specified at Ga. Comp. R. & Regs. r. 111-2-2-.02(5). Each Certificate of Need issued requires a regular reporting of the different stages of development to completion. All projects approved as presented with phases shall submit a progress report within forty-five (45) days of the completion of each phase. All Certificate of Need projects must satisfy the pertinent reporting requirements or the Certificate shall be subject to revocation. These reports shall include information as to the total dollar amount of capital expenditures that have been obligated under the certificate, and any changes in amounts of proposed or previously obligated capital expenditures or changes to the timing of phases, if approved by the Department in advance. These reports will be made on a form provided by the Department on its website and will be due on the date or dates indicated by the Department on attachments to the Certificate of Need and in subsequent correspondence.

(d) The Department may also request additional reports as often as necessary in order to determine:

1. if the timetable specified in the certificate is being met;

2. if the scope of the project is being completed as described on the certificate and in the application for the Certificate of Need;

3. if the amount of the capital expenditure or expenditures obligated under the certificate has exceeded or can be expected to exceed the maximum under the certificate; and

4. if the condition(s) of approval, if any, have been satisfactorily met.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.04

AUTHORITY: O.C.G.A. Secs. 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Periodic Reports" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.05 Enforcement

(1) Revocation

(a) In the event that the Department has cause to consider revocation of a Certificate, in whole or in part, the Department shall provide notice to the holder of the Certificate and shall hold a hearing to determine whether the holder has:

1. Intentionally provided false information to the Department;

2. Failed to incur a financial obligation in accordance with the Certificate as granted;

3. Failed to implement the project in accordance with the specific purpose(s) for which the certificate was granted or failed to meet the initial twelve (12) month performance standards or failed to request an extension of such standards. For certificates issued on or after July 1, 2008, failed to implement the services or units of services for which the Certificate of Need was issued, and that were outlined in or on the certificate granted, in a timely manner as also outlined in or on the certificate granted, as provided by O.C.G.A. § 31-6-45(a.1);

4. Transferred controlling ownership in the facility before completion of the project without prior written approval of the Department, except as authorized by Ga. Comp. R. & Regs. r. 111-2-2-.02(4);

6. Changed the defined location of the project except as allowed by O.C.G.A. § 31-6-45(a) authorizing change in location under certain conditions;

7. Failed to comply with any and all requirements or conditions of the Certificate;

8. Failed to submit a timely or complete periodic report within 180 days following the date the report is due pursuant to O.C.G.A. § 31-6-70 and as otherwise required by Ga. Comp. R. & Regs. r. 111-2-2-.04;

9. Failed repeatedly to pay any fines or moneys due to the Department;

10. Failed to maintain minimum quality of care standards that are outlined within the Certificate as granted; or

11. Failed to participate as a provider of medical assistance for Medicaid purposes if made a condition of the Certificate as granted pursuant to O.C.G.A. § 31-6-45.2(a).

(b) In the event that there is sufficient evidence to justify revocation of a Certificate, the Department shall provide written notification to the holder, which shall be effective as of the postmark date on the notification letter. Notice shall also be provided to the public, to the county or municipal authority and to the appropriate Regional Development Center. Any person whose Certificate is revoked under this Rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(c) A person whose Certificate of Need has been revoked or denied may not reapply for a Certificate of Need for the same or substantially similar project for at least one hundred twenty (120) days from the date that the revocation or denial becomes final, at which time the person may submit a new application. For purposes of this subparagraph, a decision revoking or denying a Certificate of Need shall become final when the time for appealing that decision expires without an appeal of such decision having been timely filed. If an appeal is timely filed, the decision is not final until the resolution of the administrative appeal, if any.

(d) A person holding a Certificate of Need may voluntarily request revocation of the Certificate without prejudice by submitting such request to the Department in writing.

(e) A health care facility which has a Certificate of Need or is otherwise authorized to operate pursuant to this chapter shall have such Certificates of Need or authority to operate automatically revoked by operation of law without any action by the Department when that facility's permit to operate pursuant to O.C.G.A. § 31-7-4 is finally revoked by order of the Healthcare Facility Regulation Division. For purposes of this subsection, the date of such final revocation shall be as follows:

1. When there is no appeal of the order pursuant to O.C.G.A. § 31-5, the one hundred and eightieth (180th) day after the date upon which expires the time for appealing the revocation order without such an appeal being filed; or

2. When there is an appeal of the order pursuant to O.C.G.A. § 31-5, the date upon which expires the time to appeal the last administrative or judicial order affirming or approving the revocation or revocation order without such appeal being filed.

The Department may become a party to any judicial proceeding to review a decision by the Healthcare Facility Regulation Division to revoke such a permit.

(f) A certificate shall be subject to revocation for the following failures, without limitation:

1. Failure to incur a project-specific capital expenditure, within the initial twelve (12) month implementation period specified at Ga. Comp. R. & Regs. r. 111-2-2-.02(6) and in the Certificate itself or within an extension implementation period granted by the Department, through initiation of substantial project above-ground construction or lease or purchase of the proposed equipment;

2. Failure to file the required Progress Report(s);

3. Failure to meet the conditions on the face of the Certificate; or

4. Failure to pay any penalty assessed pursuant to O.C.G.A. § 31-6-40.1.

(2) **Sanctions.**

(a) Any health care facility offering a new institutional health service without having obtained a Certificate of Need and which has not been previously licensed as a health care facility shall be denied a license to operate by the Healthcare Facility Regulation Division.

(b) In the event that a new institutional health service is knowingly offered or developed without having obtained a Certificate of Need as required by O.C.G.A. § 31-6 et seq., or by these Rules, or the Certificate of Need for such service is revoked according to the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.05(1), a facility or person may be fined an amount not to exceed $5,000.00 per day up to thirty (30) days, $10,000.00 per day from thirty-one (31) days through sixty (60) days, and $25,000.00 per day after sixty (60) days for each day that the violation of these Rules and O.C.G.A. § 31-6 et seq. has existed and knowingly and willingly continues; provided however, that the expenditure or commitment of or incurring an obligation for the expenditure of funds to take or perform actions not subject to this chapter or to acquire, develop or prepare a health care facility site for which a Certificate of Need application is denied, shall not be a violation of this Chapter and shall not be subject to such a fine. The Commissioner or his designee shall determine, after notice and a hearing if requested, whether the fines provided in the Code section shall be levied.

(c) Any person who acquires a health care facility by stock or asset purchase, merger, consolidation, or other lawful means shall notify the Department of such acquisition, the date thereof, and the names and address of the acquiring person. Such notification shall be made in writing to the Commissioner or his designee within forty-five (45) days following the acquisition and the acquiring person may be fined by the Department in the amount of $500.00 for each day that such notification is late.

(d) The Department may require that any applicant for a Certificate of Need commit to provide a specified amount of clinical health services to indigent or charity, Medicare, Medicaid, PeachCare, and similar patients as a condition for the grant of a Certificate of Need. A grantee or successor in interest of a Certificate of Need or authorization to operate under O.C.G.A. § 31-6 et seq. which violates such an agreement, whether made before or after July 1, 1991, shall be liable to the Department for a monetary penalty in the amount of the difference between the amount of services so agreed to be provided and the amount actually provided. Penalties authorized under this Code section shall be subject to the same notices and hearing for the levy of fines under Ga. Comp. R. & Regs. r. 111-2-2-.05(2)(b).

(e) All hearings under this Section shall be in accordance with the Georgia Administrative Procedure Act. Any person so penalized under this Rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(f) If the person assessed fails to pay the amount of the assessment to the Department within thirty (30) days after notice of assessment is postmarked to him, or within such longer period, not to exceed ninety (90) days, as the Department may specify, the Department may institute a civil action to recover the amount of the assessment or may revoke the Certificate of Need. The Department may add reasonable interest to the assessment.

(g) For purposes of this Rule, the State of Georgia, acting by and through the Department or any other interested person, shall have standing in any court of competent jurisdiction to maintain an action for injunctive or other appropriate relief to enforce the provisions of this Rule.

(3) **Department's Right to Inspect and Audit**. The Department or an authorized representative or employee designated by the Department shall have the right to inspect and audit any facility, site, location, book, document, paper, files, or other record of the holder of the Certificate of Need or letter of non-reviewability or other determination that is related to any project authorized by the Certificate of Need or letter of non-reviewability or other determination, in order to monitor and evaluate the person's compliance with the terms of issuance of the Certificate of Need or the letter of non-reviewability or other determination. The Department shall have the authority to make public or private investigations or examinations inside or outside of the state of Georgia to determine

whether all provisions of O.C.G.A. § 31-6-2 et seq. or any other law, rule, regulation, or formal order relating to the provisions of O.C.G.A. § 31-6-40 in particular, has been violated. Such investigations may be initiated at any time in the discretion of the Department and may continue during the pendency of any action initiated by the Department pursuant to section (1)(a) of this Rule. For the purpose of conducting any investigation or inspection pursuant to this subsection, the Department shall have the authority, upon providing reasonable notice, to require the production of any books, records, or other information related to any Certificate of Need issue.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.05

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Enforcement" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.06 Application for Certificate of Need

(1) **Letter of Intent.** Beginning July 15, 2008, all persons who wish to submit an application for a Certificate of Need for a new institutional health service or health care facility, as provided in O.C.G.A. § 31-6-40(a) and (b), must submit a letter of intent notifying the Department of their intent to do so at least thirty (30) days prior to submission of the Certificate of Need application. The notice must be in writing, must be submitted via the Department's web portal, and must contain the following information:

(a) Name and address of the legal applicant;

(b) Person to whom inquiries must be addressed;

(c) Name, address of facility, if different from legal applicant;

(d) Proposed project site location with specificity;

(e) Brief summary description of proposal;

(f) Proposed service area; and

(g) Cost of the project.

The Department will not accept any notices of intent submitted by either telephone, facsimile, or electronic mail, pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.06(6). Beginning with the date referenced above, no Certificate of Need application will be accepted without a previously filed letter of intent. The Certificate of Need application must be submitted no later than thirty (30) calendar days after the letter of intent has been received by the Department. In the event that the thirtieth (30th) calendar day falls either on a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. If a Certificate of Need application is not submitted as provided herein, it will not be accepted and an applicant filing an application beyond the time period specified will be required to submit a new letter of intent in the manner specified above.

(2) **Contents of Application.** Applications shall contain all relevant data, information and assurances required by the Department. The Department will provide application forms on request, and all applications must be on the form supplied by the Department or a copy thereof, and comply with the content requirements specified thereon. Applications shall provide information including, but not necessarily limited to, the following categories as they relate to the proposed projects:

(a) identification of the applicant;

(b) ownership;

(c) site identification;

(d) compliance with State and local codes and ordinances, including flood hazards;

(e) a detailed and complete description of proposed project;

(f) project justification, including specific documentation of the need (utilizing the Department's data and methodology) that the population to be served has for the project;

(g) staffing and operation;

(h) financial information, which shall include positive evidence of ability to obtain financing, the source of financing, and maximum interest rates, which will be paid to the lender. Applications submitted for or on behalf of a health care institution shall include one copy of the latest audit report (or internal financial statement for investor-owned facilities). Also submitted shall be all pro forma financial data requested in the application;

(i) cost containment and quality of care considerations;

(j) project design and construction schedule including as applicable:

1. Schematic Design Documents meeting the standards defined by the American Institute of Architects in section 2.4.2 of the Standard AIA Contract Language. These Schematic Design Documents shall establish the conceptual design of the Project illustrating the scale and relationship of the Project components. The Schematic Design Documents shall also include a conceptual site plan, if appropriate, and preliminary building plans, sections and elevations. Preliminary selections of major building systems and construction materials shall be noted on the drawings or described in writing;

2. A written summary of the Architect's evaluation and planning findings and recommendations meeting the standards defined by the American Institute of Architects in section 2.3 of the Standard AIA Contract Language. This summary shall include, as applicable, an evaluation of the Applicant's program and schedule requirements and budget for the Cost of the Work, each in terms of the other, a preliminary evaluation of the Applicant's site for the Project based on the information provided by the Applicant of site conditions, and the Applicant's program, schedule and budget for the Cost of the Work, and an evaluation of the applicant's proposed method of contracting for construction services; and

3. A detailed description of the proposed timeline and phases for project completion.

(k) a cost estimate prepared by a licensed architect or engineer within the sixty (60) days immediately preceding submission of the application;

(l) documentation from the Healthcare Facility Regulation Division of no uncorrected licensure operational standards in the applicant's facility, if applicable.

(3) **Submittal of Applications.**

(a) Using the Department's web portal, Applicants should submit one (1) copy of the application signed by the applicant or the legal representative of the applicant. Failure to do so will result in non-acceptance of the application.

(b) Applications received after 3:00 p.m. on any business day will be considered to have been received on the next business day. Receipt of the application will be acknowledged in writing by the Department.

(4) **Filing Fee Required.**

(a) Each application for a Certificate of Need review shall be accompanied by a fee, except for the provisions covered in Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(d) and Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(e), the amount of which shall be determined by the following schedule:

1. for applications with a total project cost from zero to $1,000,000.00, the fee shall be $1,000.00; and

2. for applications with a total project cost greater than $1,000,000.00, the fee shall be one-tenth of one percent (.001) of the total cost but not to exceed $50,000.00; and

3. for the review of cost overruns the fee shall be computed as shown above for the amount of the overrun only.

(b) For any project, which is to be accomplished by lease, gift or other means of acquisition, the dollar value for purposes of computing the fee will be based on the value of the major medical equipment or facilities to be acquired. The value of the major medical equipment is the expenditure, which would be required for purchase. The value of the facilities to be acquired is based on a current (within six (6) months of the submittal of the Certificate of Need application) appraisal of the property.

(c) Payment of the fee shall be by credit/debit card via the Department's website, certified check, or money order made payable to the State of Georgia and must be received by the Department before an application will be accepted for review. Failure to provide payment of the appropriate fee will result in non-acceptance of the application. Fee payments are collected as general State revenue.

(d) State-owned institutions shall be exempt from payment of a filing fee.

(e) The Department may waive payment of a filing fee, or any portion thereof, for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. A party requesting a waiver must make such request at the time the application is submitted to the Department.

(f) Subject to the Rules in (a) through (e) above, applicants shall submit an additional filing fee for additional information or amendments provided during the review period that increase the cost of the project. For such supplementary information which increases the cost of the project, the amount that shall be submitted is an amount equal to the difference between the calculation of the filing fee based on the total amended project costs as outlined in (a) and the filing fee paid at the time of application, except that in no case shall the amount submitted be less than $500.00. Should such supplementary information decrease the costs associated with a project, the filing fee shall not be reduced or refunded. The Department shall not issue decisions on applications for which such supplementary information has been provided where an applicant has not submitted the additional filing fee, as applicable.

(5) **Review for Completeness**.

(a) Upon receipt of an application, the Department shall determine whether the application is complete. No application shall be reviewed until it has been determined by the Department to be complete in accordance with information requirements specified in this Section.

(b) An application will be determined to be incomplete if any of the following were not either provided with the application or as may be specified in this Section, submitted previously to the Department:

1. all the required data, information and assurances provided on the correct forms, including but not limited to the following:

(i) detailed description of the proposed project as required by Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(e);

(ii) financial program to meet the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(h);

(iii) documentation of necessary financing for the project, such as a letter of credit, etc.;

(iv) financial pro forma to meet the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(h); and

(v) most recent audited financial statements, or personal financial statements if audited statements are not available (tax returns would meet this requirement for unaudited entities and individuals);

(vi) for projects invoking service-specific Rules, as outlined in Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq., the appropriate service-specific review considerations;

(vii) for projects involving construction, renovation, and/or expansion, schematic plans and cost estimates certified by an architect, engineer, or general contractor, as appropriate and as required by Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(j) and (k);

(viii) for projects involving the acquisition of equipment, purchase orders or invoices, as appropriate;

2. signature of the applicant;

3. payment of the filing fee, as described in Ga. Comp. R. & Regs. r. 111-2-2-.06(4);

4. the most recent three (3) years of all required surveys, as may be previously submitted to the Department, including the Annual Hospital Questionnaire, Annual Nursing Home Questionnaire, survey of home health agencies, or other data-gathering instruments required by the Department for any health care facilities and services owned or operated by the applicant, to include data requested pursuant to O.C.G.A. § 31-6-70. In order for an application to be deemed complete, such surveys and data-gathering instruments shall be complete and accurate, as determined by the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have submitted completed questionnaires with the Department;

5. written verification certifying entitlement to any necessary real estate property or leasehold as described by the applicant in the application. Verification of entitlement shall include, but not be limited to, deeds, contracts, lease arrangements, conditional sales agreements or a comparable arrangement that purports to be a transfer of ownership in whole or in part. If an unsigned lease arrangement is submitted, the Applicant shall also submit an original letter documenting both the lessor's and lessee's commitment to participate in the lease once the CON is approved;

6. authorization to conduct business, including but not limited to, as appropriate:

(i) if the applicant is an entity requiring authorization by the Secretary of State to become a legal entity entitled to do business in the State of Georgia, such documentation;

(ii) by-laws, articles of incorporation, or articles of organization; and

(iii) if the applicant is an existing and licensed or permitted entity, a copy of such license or permit.

7. The applicant shall file one copy of the application with the office of the County Commissioner of the county in which the project exists or is proposed. The applicant shall submit with the application an exact copy of the letter addressed and submitted to the County Commission that accompanied the submittal of the application to the County Commission;

8. all post-approval reporting requirements as mandated at Ga. Comp. R. & Regs. r. 111-2-2-.04(2) for all previously approved projects, as may be previously submitted to the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have met the said post-approval reporting requirements for all previously approved projects with the Department;

9. the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2);

10. In order to be determined complete, an applicant must be current will all indigent and charity care commitments, if any, made to the Department as a condition or requirement for past approval of a project. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation are current with any and all indigent and charity care commitments made to the Department; and

11. In order to be determined complete, an applicant must be current with any and all fines, if any, levied by the Department for violation of these Rules.

12. No applicant for a new Certificate of Need, a modification to an existing Certificate of Need, or a conversion of a Certificate of Need that has any outstanding amounts owed to the state including fines, penalties, fees, or other payments for noncompliance with any requirements contained in O.C.G.A. §§ 31-6-40.1, 31-6-45.2, 31-6-70, 31-7-280, or 31-8-179.2 shall be eligible to receive a new Certificate of Need or a modification to an existing Certificate of Need unless such applicant pays such outstanding amounts to the state. Any such fines, penalties, fees, or other payments for noncompliance shall be subject to the same notices and hearing for the levy of fines under O.C.G.A. § 31-6-45.

(c) The Department shall notify the applicant within ten (10) business days following receipt of the application that the application is complete as submitted or that additional information is required to complete the application. If additional information is required, the notice shall include a statement of the specific additional information required. Notice shall be effective the date it is sent electronically by the Department.

(d) The Department shall notify the applicant no later than ten business days following receipt of the additional information whether such information is sufficient to complete the application. If it is not sufficient, the notice shall include a specific statement of the information which needs clarification or which does not adequately respond to the original request.

(e) The Department will deem an application to be withdrawn if the applicant fails to provide the Department with information requested on a notice of incompleteness within two (2) calendar months after the date of the original letter notifying the applicant of the information necessary for completeness.

(f) In addition to the provisions of a paragraph (b) above, additional requirements shall be in effect where the application involves the acquisition of a hospital owned or operated by or on behalf of a political subdivision, any combination of such subdivisions, or by or on behalf of a hospital authority. These requirements shall be as follows:

1. in the event that a health care facility, which has been assisted at any time during the past twenty years through a grant of State funds, is proposed to be acquired by a non-grant-eligible entity, the Department, in accordance with O.C.G.A. §§ 31-7-53(c) and 31-7-57(d), is required to recover the funds granted by the State. A commitment regarding return to the State of such monies consistent with the Code should be forwarded to the Department no later than the end of the review period.

2. there shall be submitted a written agreement between the parties containing the following commitments:

(i) that the purchaser or lessee will annually allocate funds for the purpose of providing indigent/charity care. The funds allocated will be no less than three percent (3%) of the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare contractual adjustments have been deducted. The funds allocated will be based on the previous year's financial records, except the first year of operation following an acquisition the three percent (3%) will be based on the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare adjustments have been deducted. For purposes of this Rule; gross revenues will include all income derived from all sources;

(ii) that the purchaser will agree that no resident of the county in which the hospital resides will be denied emergency care (including emergency obstetrical care) due to inability to pay;

(iii) that the purchaser will participate in the Medicaid and Medicare programs and the State Health Benefit Plan, if authorized by the Department.

(6) **Submission of Information and Documents.**

For the purposes of meeting any deadlines imposed by either these Rules or O.C.G.A. § 31-6, the Department will not accept any information or documents that are submitted either via telephone or facsimile. In order to meet any of the above referenced deadlines, it will be necessary to submit the information or documents via the Department's web portal or as otherwise directed by these Rules. Except as otherwise provided, information and documents received after 5:00 p.m. on any business day will be considered to have been received on the next business day. Except as otherwise provided by these Rules, all documents required and described in these Rules, except for the periodic reports described in Ga. Comp. R. & Regs. r. 111-2-2-.04, including, but not limited to, applications, opposition letters, supplementary information, requests for determinations, and opposition to determinations, shall be submitted via the Department's web portal.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.06

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Application for Certificate of Need" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.07 Review Procedures

(1) **Beginning of Review Process.**

(a) When an application is deemed by the Department to be complete, the Department shall provide written notice to the applicant of the completeness of the application and the schedule for review. The Department shall provide similar notice to a newspaper of general circulation in the county of the project, to the appropriate Regional Development Center, and to the chief elected official of the county and municipal government, if any, within whose boundaries the proposed project would be located. The date on the letter of notification shall be deemed to be the date of notification and the beginning date of the Certificate of Need review cycle.

(b) The Department will schedule reviews so that, unless joined with another application, no review shall, except as noted in (d) below, take longer than one hundred and twenty (120) days from the date of notification of the beginning of review until the date the decision to issue or not to issue a Certificate of Need is sent electronically to the applicant. Absent good cause, the Department generally will not issue a decision prior to the sixtieth (60th) day of the review cycle.

(c) In the event that, from the time an application is declared complete until thirty (30) days thereafter, one or more additional applications are declared complete which involve similar projects in the same or overlapping service areas, the Department may declare that such applications will be joined with the first application for review purposes. Following such joinder, none of the subsequent applications so joined may be considered as a first application for purposes of future joinder. The Department shall notify all applicants whose applications have been joined and shall set a new time parameter for Department actions. The one hundred and twenty (120) day final decision deadline shall run from the latest date that any one of the joined applications was declared complete for review. Except as otherwise provided in Ga. Comp. R. & Regs. r. 111-2-2-.08(1), such joinder shall be the sole method of comparative review for all applications filed after July 1, 2008.

(d) Where the Department determines that conditions exist which make it impractical to complete a review in one hundred and twenty (120) days, the Department may, on notification to the applicant, extend the time limit another

thirty (30) days to one hundred and fifty (150) days. Conditions, including but not limited to the following, may constitute cause for extending the time:

1. The Department anticipates issuance of new demographic or utilization, data affecting the application;

2. The Department has received conflicting or contradictory information necessitating further investigation;

3. Results of impending legal action may have an effect on the application.

(e) For good cause shown, as shall be determined by the Department, a public hearing will be held at a time and location specified by the Department.

1. A request for a public hearing shall be signed by at least fifty (50) residents of the area where the project is located and must be received by the Department within twenty (20) days after the beginning date of the review cycle. The request shall include justification for the public hearing based on circumstances described in this paragraph.

2. To the extent possible, notification will be provided in a newspaper of general circulation in the area where the project is located approximately two weeks in advance of the hearing.

3. Any person desiring to offer testimony at the hearing will be given the opportunity to do so, but the providing of such testimony or evidence shall not confer upon the person or persons so testifying the status of "party" as that term is used in the Administrative Procedure Act.

4. Where distance and the nature of the project warrant, and within the budget constraints of the Department, the public hearing may be held by the Department in the area where the project is proposed to be located. Circumstances, which may indicate good cause for a hearing in the area, include but are not limited to:

(i) Projects, which could have significant effect on access to frequently used services by a sizable population group;

(ii) Projects generating strong conflicting viewpoints by the residents of an area;

(iii) Projects with potential for unusually significant impact on existing services.

5. A summary report of the hearing will be prepared, a copy of which will be sent to the party requesting the hearing and to the applicant. Such report will be made a part of the master record regarding the project. The Department may charge a fee for the summary report.

(f) If during the first two (2) months of the review of the application the Department finds there are factors that create a potential for denial of the application, the Department shall, on or before the sixtieth (60th) day of the review period, provide the applicant an opportunity to meet with the Department. The problems with the application will be described and an opportunity offered to amend or to withdraw the application or to submit additional information. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting. Such addition information must be submitted prior to the seventy-fifth (75th) day of the review period.

1. "Additional information" is information and data submitted in response to a direct request from the Department at the meeting afforded an applicant after the first two (2) months of the review of the application or in response to issues and concerns raised by the Department in said meeting, or in the lack of such a meeting or request by the Department, information and data submitted consistent with the scope, physical location, cost, charges, service, and owners in the originally submitted application. Additional information must be submitted to the Department prior to the seventy-fifth (75th) day of the review period;

2. "Amendment" is a revision to the additional information or application as originally submitted that is submitted to the Department no later than the one hundred and tenth (110th) day of the review cycle and that constitutes a change

in scope, physical location, cost, charge, service, or owner. The following changes in an application will qualify as an amendment:

(i) A reduction or increase in the proposed physical space capacity; or

(ii) A reduction or increase in the number of proposed beds or service units (e.g., operating rooms); or

(iii) A change in the owners of the legal applicant entity, as long as the legal applicant entity remains the same; or

(iv) A reduction or increase in a proposal's capital or operating costs; or

(v) A change in site within three (3) miles of the site proposed in the original application or within the same service area as long as the population to be served and the service area to be served is not substantially different from that originally proposed as long as the proposed change does not require the application of a new need study or different rules; or

(vi) A reduction or subtraction in the scope of the original application; or

(vii) A change in the amount of commitment to indigent or charity care, projected utilization, financial information or patient charges that do not alter the basic financing or operations of the proposed project.

(g) The Department shall be notified with either a new application or written amendment to the current completed application when there are changes in the scope, physical location, cost, charges, service or owners of the applicant entity. Any revisions that constitute a total change in or addition to the scope of an application, in the location (except for the exemption in Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(f) 2.(v)) , or in the legal applicant that would require the submission of a new application. If the Department determines that the amendment constitutes a total change in either the scope, location, or legal applicant, the original application will be considered to be withdrawn and the applicant will be so notified. An application may be amended by the applicant at any time up to the one hundred and tenth (110th) day of the review cycle. (g.1) No party may oppose an application for a Certificate of Need for a proposed project unless:

1. Such party offers substantially similar services as proposed within a 35 mile radius of the proposed project or has a service area that overlaps the applicant's proposed service area; or

2. Such party has submitted a competing application in the same batching cycle and is proposing to establish the same type of facility proposed or offers substantially similar services as proposed and has a service area that overlaps the applicant's proposed service area.

(h) Any party, pursuant to O.C.G.A. § 31-6-43(d)(2), who is permitted to oppose an application, or an application(s) joined for review, must submit a notice of opposition, on the form provided by the Department, no later than the sixtieth (60th) day of the review cycle. The notice must contain the information specified by the form. The notice of opposition form submission shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2). The notice of opposition must not contain the substantive arguments against a particular application.

1. Those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices. The opposition meeting provided for by O.C.G.A. § 31-6-43(h), shall be held no earlier than the ninetieth (90th) day of the review cycle. The applicant(s) shall be entitled to attend the opposition meeting. Only one designated person on behalf of each party opposed to a particular application will be allowed to speak on behalf of the opposition to said application at the opposition meeting. The time period provided for the opposition spokesperson shall be determined in the sole discretion of the Department. The applicant(s) will not be allowed to speak in rebuttal of the opposition remarks at the opposition meeting. The Department shall make no formal substantive comments regarding the review of the application(s) at the opposition meeting. The opposition parties shall submit via the Department's web portal, substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must provide one copy of the substantive opposition comments to the applicant at the opposition

meeting. In order for an opposing party to have standing to appeal an adverse decision pursuant to O.C.G.A. § 31-6-44, such party must attend and participate in an opposition meeting. Substantive opposition comments must pertain to only one application and one applicant. In no case shall the Department accept substantive opposition comments that concern multiple applicants or applications.

2. Letters of support for a particular application must be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6) via the Department's web portal, and can be submitted no later than the one hundredth (100th) day of the review cycle.

3. Applicants shall be given the opportunity to respond to the substantive opposition comments made orally and submitted in writing at the opposition meeting. The last day for the applicant(s) to submit final amendments to the application and/or to respond to the opposition meeting comments shall be the one hundred and tenth (110th) day of the review cycle. The Department reserves the right, but is not required to, ask the applicant(s) for information in response to the substantive opposition comments. If the Department asks the applicant for information as a result of the comments provided at the opposition meeting, the applicant must submit the information requested no later than the one hundred and tenth (110th) day of the review cycle.

4. The Department shall provide written notification of its decision to issue or deny a Certificate of Need no later than the one hundred and twentieth (120th) day of the review cycle, or, if the project was extended, no later than the one hundred and fiftieth (150th) day of the review cycle.

(i) The Department, in accordance with the provisions of subsections (k)-(m) below, will give special expedited consideration to emergency expenditures required solely to cope with a situation posing an immediate threat to the health and safety of patients, visitors, or staff. The General Counsel, or his designee, upon a showing that a proposed replacement facility is critical to the welfare, health and stability of the immediate community as evidenced by written support from the local, county and state governing bodies may, authorize an expenditure based on a request by telephone, with written documentation to be provided later. In the event that the authorized emergency expenditure requires an application to replace an existing health care facility, the application will not be subject to joinder.

"Emergency expenditures" as set forth in this subparagraph (i) shall include but not be limited to expenditures necessitated by circumstances arising from an authorized hazardous condemnation as well as from acts of God including but not limited to earthquakes, hurricanes, tornados or floods.

(j) The Department will decline to review through Certificate of Need application capital expenditures that do not reach the dollar threshold as required under the Certificate of Need program, provided the person proposing such expenditure receives from the Department a prior written authorization for the expenditure. Where a proposal is considered to meet the language of this subsection, a letter describing the reasons for the expenditure, the cost and the anticipated date the expenditure is proposed to be made should be submitted to the Department, in accordance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.10, prior to the obligation of such funds. If, in the opinion of the Department, the expenditure is consistent with those expenditures not subject to review the Department will issue a confirmation to the requestor, which shall serve as authorization for the expenditure;

(k) Pursuant to the provisions of O.C.G.A. § 31-6-43(g), the Department shall conduct an expedited review with a review period of no longer than (30) thirty days for those projects deemed an emergency. When the Governor has declared a state of emergency in a region of the state, existing health care facilities in the affected region may seek emergency approval from the Department to make expenditures in excess of the capital expenditure threshold or to offer services that may otherwise require a Certificate of Need. The Department shall give special expedited consideration to such requests and may authorize such requests for good cause. Once the state of emergency has been lifted, any services offered by an affected health care facility under this subsection shall cease to be offered until such time as the health care facility that received the emergency authorization has requested and received a Certificate of Need. For purposes of this subsection, "good cause" means that authorization of the request shall directly resolve a situation posing an immediate threat to the health and safety of the public.

(l) The Department shall issue a decision on applications for a Certificate of Need for emergency projects as provided in subsection (k) above, no later than thirty (30) days after the application has been deemed complete for

review; failure to issue the decision on or before the thirtieth (30th) day after it has been deemed complete for review shall result in an automatic approval of the application, subject to subsection (n) below; the decision issued by the Department shall be a summary statement of the findings during the review of the project;

(m) If, during the course of the review period, the Department finds that there are factors that create the potential for denial of the application, the Department shall immediately discontinue its emergency review, notify the applicant in writing of that decision, and review the application in accordance with the applicable non- emergency review procedures set forth in Ga. Comp. R. & Regs. r. 111-2-2-.07.

(n) The review of such projects as outlined in subsections (k) - (m) above shall be governed by the emergency provisions of the referenced subsections and not the provisions of subsections (a) - (h) above.

(o) The filing fee for applications of the type specifically listed in subsections (k) - (n) above shall be $1,000.00, notwithstanding the filing fee provisions of Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(a).

(2) **Department Review.**

(a) In reviewing the application, the Department will take into consideration the review considerations and policies provided in Ga. Comp. R. & Regs. r. 111-2-2-.09. The latest applicable data from official data sources will be used in the Department analysis, unless otherwise provided by a service-specific Rule. Such data sources will include, but not be limited to, the State Office of Planning and Budget, Medicare/Medicaid Cost Reports, and questionnaires or surveys initiated by the Department.

(b) Upon completion of review, the Department shall provide written notification of its decision to issue or deny a Certificate of Need. In the event of a favorable decision, the letter shall serve as the Certificate.

1. Such decision will be issued no later than one hundred twenty (120) days from the beginning of the review period unless the total review period is extended in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(d).

2. The date of the decision shall be the date on the notification letter of the Department.

(c) The decision letter shall contain at least the following:

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

2. Information pertaining to the availability of an appeal hearing.

(d) The decision shall be to approve or deny the application as submitted or as amended by the applicant during the course of review.

(e) A copy of the notification will be sent to the applicant or, in the case of joined applications, to all applicants, to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. A copy may be made available to other interested persons on request.

(f) Should the Department fail to issue a decision letter on a Certificate of Need application within the time limits set forth in these Rules, the application shall be deemed approved as of the one hundred and twenty-first (121st) day, or the one hundred fifty-first (151st) day if the review period was extended pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(d), following the date of notice from the Department that an application, or the last of any applications joined pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(c) was declared complete for review.

(g) Appeals of the decision of the Department shall be processed in accordance with rules promulgated by the Certificate of Need Appeal Panel found in Ga. Comp. R. & Regs. Chapter 274.

(h) When a project undergoes judicial review, the Department may stay the effective date of the CON pending the outcome of the judicial review upon appropriate terms for good cause shown.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.07

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

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111-2-2-.08 Alternative Application and Review Procedures

(1) **Batching Review Process**

(a) Pursuant to O.C.G.A. § 31-6-43(e), the Department may limit the time periods during which it will accept applications for the following health care facilities and/or services: skilled nursing facilities; intermediate care facilities; home health agencies, open heart surgical services, pediatric cardiac catheterization and open heart services, perinatal services, freestanding birthing centers, psychiatric and substance abuse services, comprehensive inpatient physical rehabilitation services, ambulatory surgical services, positron emission tomography services, and megavoltage radiation therapy services. Limitation of the time periods shall be to only such times after the Department has determined there is an unmet need for such facilities and/or services, or will accept applications pursuant to any service-specific need standard exceptions. The Department shall make a determination as to whether or not there is an unmet need for each type of facility at least every six (6) months and shall notify those requesting such notification of that determination. No application for the services listed above will be accepted for review by the Department except as provided for pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1). For purposes of batching only, the applications entered into the one hundred twenty (120) day review period shall be evaluated according to the data used to publish the unmet need, or to accept applications pursuant to any service-specific need standard exceptions, for the particular service at issue, for those services listed above, and not the latest available data at the time of decision, as is the case with all non-batched applications.

(b) Upon the determination of an unmet need for a particular facility/service in a given service area, the Department shall provide notice indicating which applications will be considered in that particular batching cycle to all interested parties requesting notice of that determination. It shall be the sole and exclusive responsibility of the interested party to notify the Department in writing of that party's desire to be informed of the Department's unmet need determination(s) for batching purposes. The Department's notice shall contain the unmet need for the type of facility/service in the given service area(s) and shall also contain the pertinent time frames and deadlines for submission of notices of intent to apply, for submission of applications, and the review of such applications.

(c) All parties interested in applying for the particular unmet need in a given service area must notify the Department of that party's intent to apply.

1. The notice must be in writing, submitted via the Department's web portal, and must address specifically the type of unmet need and service area(s) for which the applicant intends to apply.

2. The notice of intent must be received by the Department no later than the close of business on the thirtieth (30th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the thirtieth (30th) calendar day falls on either a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday.

3. Notwithstanding any other relevant provisions within this Rule, the notice of intent to apply must be received by the Department either before or simultaneously with the submission of the actual application in accordance with the notice of intent deadline.

4. In the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party shall be disqualified automatically from applying during that batching cycle.

(d) Subject to the proper submission of a notice of intent to apply, any interested party shall use the Department's web portal to submit an application no later than 12:00 P.M. on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. For purposes of batching only, all properly submitted applications will be deemed received on the sixtieth (60th) day, regardless of the actual date of submission.

(e) For the purposes of batching only, an application which has been deemed received according to (d) above, will only be deemed properly submitted and complete if the following requirements, in addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(5), are met:

1. The appropriate Certification Statement (an applicable service-specific related checklist) is submitted simultaneously with the original application; and

2. All of the items addressed in the Certification Statement are provided, as certified, with the original application.

(f) In the event that an application is deemed in receipt by (d) above, but is not deemed to be properly submitted and complete by (e) above by 12:00 PM on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need (in the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday), the application will be disqualified from the batching review.

(g) The batching review cycle will be conducted in the following manner:

1. The batching review cycle shall be one hundred and twenty (120) days in duration. As a result, no party participating in the batching review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day.

2. The first day of the batching review cycle shall be the day upon which all properly submitted applications are deemed to be received. [See Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(d) above.]

3. On or before the sixtieth (60th) day of the batching review cycle, the Department shall provide the applicant(s) an opportunity to meet with the Department. The Department will describe any issues with the application and provide an opportunity to the applicant(s) to amend or withdraw the application or to submit additional information. Any and all additional information must be submitted on or before the seventy-fifth (75th) day of the batching review cycle. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting.

4. Any party who is opposed to one or more applications submitted during a batching cycle must submit a notice of opposition via the Department's web portal, on the form provided by the Department, no later than the sixtieth (60th) day of the batching review cycle. The notice must contain the information specified by the form. The notice of opposition form submission shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2). The notice of opposition must not contain the substantive arguments against a particular application.

Those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices. The opposition meeting, provided for by O.C.G.A. § 31-6-43(h), shall be held no earlier than the ninetieth (90th) day of the batching review cycle. The applicant(s) shall be entitled to attend the opposition meeting. Only one designated person on behalf of each party

opposed to a particular application will be allowed to speak on behalf of the opposition to said application at the opposition meeting. The time period provided for that opposition spokesperson shall be determined in the sole discretion of the Department. The applicant(s) will not be allowed to speak in rebuttal of the opposition remarks at the opposition meeting. The Department shall make no formal substantive comments regarding the review of the application(s) at the opposition meeting. The opposition parties shall submit via the Department's web portal, substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must provide one copy of the substantive opposition comments to the applicant at the opposition meeting. In order for an opposing party to have standing to appeal an adverse decision pursuant to O.C.G.A. § 31-6-44, such party must attend and participate in an opposition meeting. Substantive opposition comments must pertain to only one application and one applicant. In no case shall the Department accept substantive opposition comments that concerns multiple applicants or applications.

Letters of support for a particular application must be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6) via the Department's web portal and can be submitted no later than the one hundredth (100th) day of the batching review cycle.

5. Applicants shall be given the opportunity to respond to the substantive opposition comments made orally and submitted in writing at the opposition meeting. The last day for the applicant(s) to submit final amendments to the application and/or to respond to the opposition meeting comments, shall be the one hundred and tenth (110th) day of the batching review cycle. The Department reserves the right, but is not required to, ask the applicant(s) for information in response to the substantive opposition comments. If the Department asks the applicant for information as a result of the comments provided at the opposition meeting, the applicant must submit the information requested no later than the one hundred and tenth (110th) day of the batching review cycle.

6. No later than the one hundred and twentieth (120th) day of the batching review cycle, the Department shall provide written notification of its decision to issue or deny a Certificate of Need to the pertinent applicant(s).

(h) In evaluating batched applications, if any or all of the batched applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. The past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. Specific services to be offered;

3. Appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. Demonstrated readiness to implement the project, including commitment of financing;

5. Patterns of past performance, if any, of the applicants in implementing previously approved projects in a timely fashion;

6. Past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. Evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care; and

8. Past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments.

(i) In the event of a favorable decision, the Department's notification letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter of the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the batching review

cycle, whichever is applicable. The effective date of the Certificate shall be the decision or approval date if not appealed. If administratively appealed in a timely fashion, the effective date of the Certificate shall be the date of final resolution of any administrative hearing. The Department may stay the effective date of a project appealed through judicial process at the request of any party to such appeal or upon the Department's own initiative. Any determination by the Department to stay the effective date will be based upon sound health planning principles. If the Department stays the effective date of a project appealed through judicial process, the effective date shall be the date of final resolution of any judicial appeal.

(j) The decision letter shall contain at least the following:

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

2. Information pertaining to the availability of an appeal hearing.

(k) A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

(l) Appeals of the Decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel found in Ga. Comp. R. & Regs. Chapter 274.

(2) **Alternative Healthcare Models**

(a) **Applicability**.

1. For Certificate of Need purposes, Alternative Healthcare Models are defined as new and/or innovative models of providing new or existing institutional health services delivered in a proposed or existing healthcare facility.

2. For Certificate of Need purposes, the applicant for an Alternative Healthcare Model CON will be as follows:

(i) If the service(s) will be provided within a single healthcare facility, the owner of that facility will be the applicant;

(ii) If the service(s) will be provided within two or more healthcare facilities that are part of a healthcare services network, the owner(s) of the facility(ies) in which the service(s) will be provided will be the co-applicant(s).

3. The Department shall evaluate the performance of the Alternative Healthcare Model according to the scope as defined by the Department decision and the standards set forth in these Rules. If after a review the Department determines that the Alternative Healthcare Model does not meet the defined scope or expected standards, the Department may either immediately revoke the Certificate of Need or grant a specified time period during which the Alternative Healthcare Model must meet the defined scope and the expected standards or lose its Certificate of Need.

(b) **Definitions**

1. "Alternative healthcare model" means a new and/or innovative model of providing new or existing institutional health service(s) delivered in or through a healthcare facility(ies) and/or healthcare services networks.

2. "Authorized service" means a Department sanctioned Alternative Healthcare Model, which is either existing or approved. An existing service is an authorized service, which has become operational, and an approved service is an authorized service, which has not yet become operational.

3. "Board" means the Board of Community Health.

4. "Health care facility", as defined at O.C.G.A. § 31-6-2(17), means hospitals; destination cancer hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes of at least twenty-five (25) beds; ambulatory surgical or obstetrical facilities; freestanding emergency departments or facilities not located on a hospital's primary campus; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitative centers, but only to the extent that O.C.G.A. § 31-6-40(a)(3) or (7) or both are applicable thereto.

5. "Healthcare services network" means a collaborative arrangement that consists of at least one healthcare facility plus one or more physician groups and/or one or more third party payers, or a collaborative arrangement that includes at least two or more healthcare facilities.

6. "Most recent year" means the most recent calendar year prior to submission of an application.

7. "Official inventory" means the inventory of all authorized Alternative Healthcare Models maintained by the Department based on CON approval and official Department records.

8. "Official state component plan" means the most recent document(s) that is/are most closely related to those services being provided by the Alternative Healthcare Model. The most recent document(s) will have been developed by the Department and approved by the Board.

9. "State health policies" means the most recent policies developed by the Board, which provide a framework for the service-specific policies included within each component of the State Health Plan. These state health policies include health promotion, financial accessibility, least restrictive care, regionalization, cost containment, health planning and citizen participation, healthcare personnel, and healthcare data and information networks.

(c) **Requests for Proposals**

1. Within the period of April 1 through May 31 of each year, the Board may accept abstracts describing potential Alternative Healthcare Models, based on the recommendation of the Department. The Board will review these abstracts, if any are solicited for that year, by August 31 of that year and select a list of those categories for which Alternative Healthcare Model Certificate of Need applications may be submitted.

2. Within thirty (30) days of the determination by the Board of the particular categories under which Alternative Healthcare Model Certificate of Need applications may be submitted, the Department shall provide notice of these categories to all interested parties. The notice shall contain:

(i) the listing of category(ies) related goals and desired outcomes and the probable scope of services;

(ii) the pertinent time frames and deadlines for submission of notices of intent to apply for Alternative Healthcare Model Certificate of Need;

(iii) the pertinent time frames and deadlines for submission of CON applications; and

(iv) the pertinent time frames and deadlines for the review of such applications, and any related criteria for review.

(d) **Intent to Apply**

1. All parties wanting to apply for Alternative Healthcare Model Certificates of Need under the selected categories must notify the Department of that party's intent to apply.

2. This notice must be:

(i) in writing, submitted via the Department's web portal, and must address specifically the particular category under which the applicant intends to apply;

(ii) received by the Department no later than the close of business on the sixtieth (60th) calendar day following the date that the Department publishes the notice of the selected categories. In the event that the sixtieth (60th) calendar day falls on either a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday;

(iii) must be received by the Department either before or simultaneously with the submission of the actual application; and

(iv) in the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party automatically shall be disqualified from applying during that particular review cycle.

(e) **Application Process**

1. Certificate of Need applications pertaining to the selected categories will be submitted via the Department's web portal on or before 3:00 p.m. June 1 of the year following the year in which the categories were selected by the Board. (Although applications may be submitted prior to 3:00 p.m. June 1, all application will be deemed received on June 1.) In the event that June 1 falls either on a weekend or a legal holiday, the day of submission shall become automatically the next business day that is neither a weekend nor a legal holiday;

2. Alternative Healthcare Model Certificate of Need applications must comply with the requirements in Ga. Comp. R. & Regs. r. 111-2-2-.06(2) and (3).

3. For the purposes of Alternative Healthcare Model Certificate of Need applications, an application will be deemed properly submitted if the following requirements are met:

(i) a summary of the Certificate of Need application is included to be used as information for the Board and general public;

(ii) a Certification Statement of Completeness is included designating under which category the application is being submitted; and

(iii) all items addressed in the Certification Statement of Completeness are provided with the application.

(f) **The Review Cycle**

1. The review cycle shall be automatically one hundred and twenty (120) days in duration. As a result, no party participating in the review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day;

2. The first day of the review cycle shall be the day upon which all properly submitted applications are deemed to be received as specified in Ga. Comp. R. & Regs. r. 111-2-2-.08(2)(e)3.

3. No later than the thirtieth (30th) day of the review cycle, the Department shall, if deemed necessary, submit a written request to any and all pertinent applicants for clarifying and/or supplemental information. This written request may be distributed within a meeting of the applicant(s). The purpose of the request for clarifying and/or supplemental information shall be to obtain information from the applicant(s) that clarifies or supplements the initial information submitted with the original application.

4. No later than the forty-fifth (45th) day of the review cycle, the applicant(s) shall, if deemed necessary by the Department, submit their clarifying and/or supplemental information. Failure to submit the required clarifying and/or supplemental information by the forty-fifth (45th) day may be grounds for denial of the application.

5. If, by the forty-fifth (45th) day, the review indicates potential for denial of the application(s), the Department, on or before the sixtieth (60th) day of the review cycle, shall provide the applicant(s) an opportunity to meet with the Department. The problems with the application(s) will be described and an opportunity offered to amend or

withdraw the application or to submit additional information. Any and all additional information and amendments must be submitted on or before the seventy-fifth (75th) day of the review cycle.

6. The last day for interested parties (including, but not limited to, competing applicant(s) and/or existing competing health care facilities) to submit letters of support or opposition addressing the underlying merits, or lack thereof, of any pending application(s) shall be the eighty-fifth (85th) day of the review cycle and must be submitted via the Department's web portal. Any letters of support and/or opposition that are received after the eighty-fifth (85th) day of the review cycle shall not be considered by the Department in its review of the pertinent application(s) and the letter(s) shall not become part of the master file compiled for the pertinent application(s).

7. The last day for applicant(s) to submit final amendments and responses to letters of opposition shall be the one hundred and tenth (110th) day of the review cycle.

8. No later than the one hundred and twentieth (120th) day of the review cycle, the Department shall provide a written letter notifying the applicant of their decision to issue or deny a Certificate of Need to the pertinent applicant(s).

9. In the event of a favorable decision, this letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter from the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the review cycle, whichever is applicable.

10. The decision letter shall contain at least the following:

(i) a detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

(ii) information pertaining to the availability of an appeal hearing.

11. A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

12. Appeals of the decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel.

(g) **Standards**

1. An Alternative Healthcare Model must be consistent with the State Health Policies adopted by the Board.

2. An Alternative Healthcare Model must clearly define its target population/community.

3. An Alternative Healthcare Model must:

(i) include a hypothesis(es) to be tested within a time-limited period not to exceed five (5) years;

(ii) demonstrate, as applicable, how it will support research, new service development, health professional education and training, and/or affiliation with an academic center of higher learning; and

(iii) demonstrate that the community supports the Alternative Healthcare Model.

4. An applicant for an Alternative Healthcare Model CON shall demonstrate the feasibility of operating the Alternative Healthcare Model in Georgia, based on a review of the experience in other states including the impact on health professionals of other healthcare programs or facilities and how the project is impacted by payers and regulatory entities.

5. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to reduce healthcare costs to consumers, third party payors and the system as a whole.

6. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to maintain or improve the standards of healthcare quality in some measurable fashion.

7. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to provide increased choices or access for consumers to a continuum of services within the target community.

8. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to meet existing or emerging health status and/or health system needs.

9. For any applicant that meets the requirements of this Rule the Department may waive all or part of otherwise applicable service-specific Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.08

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

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111-2-2-.09 General Review Considerations

(1) **General Considerations**. The burden of proof for producing information and evidence that an application is consistent with the applicable considerations and review policies, which follow, shall be on the applicant. In conducting review and making findings for Certificates of Need, the Department will consider whether:

(a) the proposed new institutional health services is reasonably consistent with the relevant general goals and objectives of the State Health Plan. The goals and objectives related to issues and addressed in the State Health Plan, which are relevant to the Certificate of Need proposal, will be considered in the review. It should be recognized that the goals of the State Health Plan express the ideal and, in some respects, may be incompatible with the concept of cost containment. The statutes and Rules represent the final authority for review decisions and the content of the Plan, or any component thereof shall not supersede the Rules in such determination;

(b) the population residing in the area served, or to be served, by the new institutional health service has a need for such services;

1. Population projections used by the Department will be resident population figures prepared or approved by the Office of Planning and Budget or other official figures that may be applicable as determined by the Department.

2. Updated resident population projections will be utilized upon the official effective date as stated by the Department, pursuant to these Rules, replacing and superseding the older data.

3. The projection period or horizon year for need determinations will be five years for hospital services and three years for all other services, unless otherwise provided by the Rules for the specified service. The projection period or horizon year will be advanced to the next projection year or horizon year on or about April 1 of each year.

4. Inpatient facilities will be inventoried on the basis of bed capacity approved, grandfathered, or authorized through the Certificate of Need process regardless of the number of beds in operation at any given time or which may be licensed by the Healthcare Facility Regulation Division.

5. Data sources to be utilized by the Department to evaluate need, population characteristics, referral patterns, seasonal variations, utilization patterns, financial feasibility, and future trends will include, but not be limited to, the following:

(i) any surveys required by the Department, including but not limited to those for hospitals, nursing facilities, home health agencies, specialized services, and ambulatory surgery facilities;

(ii) Cost reports submitted to fiscal intermediaries and the Department;

(iii) periodic special studies or surveys, as produced or formally adopted or used by the Department;

(iv) the United States Census and other studies conducted by the Census and other Federal and State agencies and bureaus, including but not limited to, the Department of Labor; and

(v) such other data sources utilized by the Department for measurement of community health status. Such data may include information submitted by the applicant pursuant to Ga. Comp. R. & Regs. 111-2-2-.06(2)(f), which may be necessary for the Department to ensure that the project is consistent with applicable general consideration provisions.

6. All data used by the Department in a Certificate of Need review will be available to the applicant on request, in accordance with Department policies on requested information. The most recent data reported and validated will be used in the analysis of a proposal.

(c) existing alternatives for providing services in the service area the same as the new institutional health service proposed are neither currently available, implemented, similarly utilized, nor capable of providing a less costly alternative, or no Certificate of Need to provide such alternative services has been issued by the Department and is currently valid

1. The Department supports the concept of regionalization of those services for which a service-specific Rule exists.

2. The Department shall consider economies of scale where need exists for additional services or facilities.

3. Utilization of existing facilities and services similar to a proposal to initiate services shall be evaluated to assure that unnecessary duplication of services is avoided. Where there exists significant unused capacity, initiating a similar service in another health care facility would require strong justification under other criteria.

(d) the project can be financed adequately and is in the immediate and long term, financially feasible;

(e) the effects of the new institutional health service on payors for health services, including governmental payors, are reasonable;

(f) the costs and methods of a proposed construction project, including the costs and methods of energy provision and conservation, are reasonable and adequate for quality health care. Construction plans will be reviewed in detail to assure that space is designed economically. Space shelled-in for some future use will not be accepted unless the applicant demonstrates that the shelled-in space will not be directly related to the provision of any clinical health service;

(g) the new institutional health service proposed is reasonably financially and physically accessible to the residents of the proposed service area and will not discriminate by virtue of race, age, sex, handicap, color, creed or ethnic affiliation;

1. In accordance with the provision found in O.C.G.A. § 31-6-42(7), the Department will evaluate the extent to which each applicant applying for a Certificate of Need participates in a reasonable share of the total community burden of care for those unable to pay. This provision shall not apply to applicants for life plan communities, skilled

nursing facilities or units, and to projects that are reviewed by the Department on an emergency basis in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(k). In all other instances, the following indicators will be evaluated:

(i) administrative policies and directives related to acceptance of indigent, medically indigent, and Medicaid patients;

(ii) policies relating medical staff privileges, if applicable, to reasonable acceptance of emergency referrals of Medicaid and PeachCare patients and all other patients who are unable to pay all or a portion of the cost of care;

(iii) evidence of specific informational efforts targeted toward patients regarding arrangements for satisfying charges;

(iv) documented records of refunds, if any, received from the Federal, State, county, city, philanthropic agencies, donations, and any other source of funds other than from direct operations, such as indigent care trust fund distributions and disproportionate share payments, if applicable;

(v) the applicant's commitment to participate in the Medicare/Medicaid and PeachCare programs; to provide legitimate emergency care, if applicable, regardless of ability to pay; and to provide indigent and charity care; and

(vi) documented records of care provided to patients unable to pay, Medicare and Medicaid contractual adjustment, Hill-Burton payments (if applicable), other indigent care, and other itemized deductions from revenue including bad debt. Such records shall demonstrate that the levels of care provided correspond to a reasonable proportion of those persons who are medically or financially indigent and those who are eligible for Medicare or Medicaid within the service area.

2. The evaluation in 1. above is in addition to satisfaction of a minimum indigent and charity care commitment required by prior CON(s), if any.

(h) the proposed new institutional health service has a positive relationship to the existing health care delivery system in the service area;

(i) the proposed new institutional health service encourages more efficient utilization of the health care facility proposing such service;

(j) the proposed new institutional health service provides, or would provide a substantial portion of its services to individuals not residing in its defined service area or the adjacent service area;

(k) the proposed new institutional health service conducts biomedical or behavioral research projects or new service development that is designed to meet a national, regional, or statewide need;

(l) the proposed new institutional health service meets the clinical needs of health professional training programs;

(m) the proposed new institutional health service fosters improvements or innovations in the financing or delivery of health services; promotes health care quality assurance that can be documented with outcomes greater than those which are generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations; promotes cost effectiveness; or fosters improvements or innovations in the financing or delivery of health services; or fosters competition that is shown to result in lower patient costs without a significant deterioration in the quality of care;

(n) the proposed new institutional health service fosters the special needs and circumstances of Health Maintenance Organizations;

(o) the proposed new institutional health service meets the Department's minimum quality standards, including, but not limited to, standards relating to accreditation, minimum volumes, quality improvements, assurance practices, and utilization review procedures;

(p) the proposed new institutional health service can obtain the necessary resources, including health care management personnel; and

(q) the proposed new institutional health service is an underrepresented health service, as determined annually by the Department. The Department shall, by rule, provide for an advantage to equally qualified applicants that agree to provide an underrepresented service in addition to the services for which the application was originally submitted.

(2) **Destination Cancer Hospitals**. In the case of Certificate of Need applications for the construction, development, or establishment of a destination cancer hospital, the applicable general considerations as to the need for such service shall not include paragraphs (a), (b), (c), (g), (h), (j), (k), and (n) of Section (1) of Ga. Comp. R. & Regs. r. 111-2-2-.09, but shall include:

(a) Paragraphs (d), (e), (f), (i), (l), (m), (o), (p), and (q) of Section (1) of Ga. Comp. R. & Regs. r. 111-2-2-.09;

(b) That the proposed new destination cancer hospital can demonstrate, based on historical data from the applicant or its affiliated entities, that its annual patient base shall be composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia;

(c) The proposed new destination cancer hospital states its intent to provide uncompensated indigent and charity care which shall meet or exceed three percent (3%) of its adjusted gross revenues and provide care to Medicaid beneficiaries;

(d) That the proposed new destination cancer hospital shall conduct biomedical or behavioral research projects or service development which is designed to meet a national or regional need;

(e) That the proposed new destination cancer hospital shall be reasonable financially and physically accessible;

(f) That the proposed new destination cancer hospital shall have a positive relationship to the existing health care delivery system on a regional basis;

1. That the proposed new destination cancer hospital shall enter into a hospital transfer agreement with one or more hospitals within a reasonable distance from the destination cancer hospital or the medical staff at the destination cancer hospital has admitting privileges or other acceptable documented arrangements with such hospital or hospitals to ensure necessary backup for the destination cancer hospital for medical complications. The destination cancer hospital shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the destination cancer hospital with adequate emergency room services. Hospitals shall not unreasonable deny a transfer agreement with the destination cancer hospital. In the event that a destination cancer hospital and another hospital cannot agree to the terms of a transfer agreement as required by this paragraph, the Department shall mediate between such parties for a period of no more than forty-five (45) days. If an agreement is still not reached within such forty-five (45) day period, the parties shall enter into binding arbitration conducted by the Department.

(g) That an applicant for a new destination cancer hospital shall document in its application that the new facility is not predicted to be detrimental to existing hospitals within the planning area. Such demonstration shall be made by providing an analysis in such application that compares current and projected changes in market share and payor mix for such applicant and such existing hospitals within the planning area. Impact on an existing hospital shall be determined to be adverse if, based on the utilization projected by the applicant, such existing hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data; and

(h) That the destination cancer hospital shall express its intent to participate in medical staffing work force development activities.

(3) **General Cancer Hospital**

(a) On and after July 1, 2019, a destination cancer hospital may apply for a letter of determination in accordance with O.C.G.A. § 31-6-40(a)(8).

(b) Upon its receipt of a complete application for a destination cancer hospital to convert to a general cancer hospital, the Department shall issue such determination within 60 days.

(c) Upon the conversion of a destination cancer hospital to a general cancer hospital:

1. The general cancer hospital may continue to provide all institutional health care services and other services it provided as of the date of such conversion, including but not limited to inpatient beds, outpatient services, surgery, radiation therapy, imaging, and positron emission tomography (PET) scanning, without any further approval from the Department;

2. The destination cancer hospital shall be classified as a general cancer hospital under this chapter and shall be subject to all requirements and conditions applicable to hospitals under this article, including but not limited to, indigent and charity care and inventories and methodologies to determine need for additional providers or services; and

3. The hospital's inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment existing on the date of conversion shall not be counted in the inventory by the Department for purposes of determining need for additional providers or services, except that any inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment added after the date of conversion shall be counted in accordance with the Department's rules and regulations.

(d) In the event that a destination cancer hospital does not convert to a general cancer hospital, it shall remain subject to all requirements and conditions applicable to destination cancer hospitals under this article.

(4) In the case of applications for basic perinatal services in counties where:

(a) Only one civilian health care facility or health system is currently providing basic perinatal services; and

(b) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services, the Department shall not apply the consideration contained in paragraph (b) of section (1) of this Rule.

(5) **Osteopathic Considerations**. When an application is made for a Certificate of Need to develop or offer a new institutional health service or health care facility for osteopathic medicine, the need for such facility shall be determined on the basis of the need and availability in the community for osteopathic services and facilities. Nothing in this Chapter shall, however, be construed as recognizing any distinction between allopathic and osteopathic medicine.

(6) **Minority-Administered Hospital Considerations**. If the denial of an application for a Certificate of Need for a new institutional health service proposed to be offered or developed by a minority-administered hospital serving a socially and economically disadvantaged minority population in an urban setting, or by a minority-administered hospital utilized for the training of minority medical practitioners, would adversely impact upon the facility and population served by said facility, the special needs of such hospital facility and the population to be served by said facility for the new institutional health service shall be given extraordinary consideration by the Department in making its determination of need. The term "minority-administered" means a hospital controlled or operated by a governing body or administrative staff composed predominantly of members of a minority race. The Department shall have the authority to vary or modify strict adherence to the provisions of Code Chapter 31-6-42(c) and this Chapter in considering the special needs of said facility and its population served and to avoid an adverse impact on the facility and the population served thereby.

(7) **Considerations for Joined Applications**.

(a) In evaluating joined applications, if the services proposed are found to be needed, and if any or all applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. the past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. specific services to be offered;

3. appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. demonstrated readiness to implement the project, including commitment of financing;

5. patterns of past performance, if any, of the applicants in implementing previously approved projects in timely fashion;

6. past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care;

8. past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments;

9. hospital and physician collaborations that promote greater cost efficiency to patients, ensure greater quality assurance outcomes and foster positive relationships within the existing healthcare delivery network which benefits both providers and members within the impacted service area population; and

10. proposed services that include or involve a clinical healthcare service that is or has been underrepresented in the proposed service area for more than twelve (12) months as evidenced by geographical barriers to the service, insufficient staffing to provide the service and/or recent termination of the service in the proposed planning area.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.09

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

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111-2-2-.10 Determinations

(1) **General Provisions Relating to Determinations**

(a) Determinations are conclusions of the Department that are based on specific facts and are limited to the specific issues addressed in the request for determination, as applicable. Therefore, the conclusions of a specific determination shall have no binding precedent in relation to parties not subject to the request and to other facts or factual situations that are not presented in the request.

(b) This Rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need.

(c) A person requesting a determination shall make such a request in writing and shall specify in detail all relevant facts, which relate to the proposed action or course of conduct. The request shall be directed to the General Counsel or his designee. The General Counsel or his designee shall respond to the request in writing. The request shall include, at a minimum, the following components:

1. a statement citing by appropriate reference the statutory provision or other authority under which the request is to be granted by the Department.

2. the exact legal name of each person whose rights are affected and who is requesting a determination and the address or principal place of business of each such person. A request may be submitted by an attorney or other party on behalf of such person, but the request must include the information required by this subsection relating to the person whose rights are affected;

3. The name, title, address, telephone number, facsimile telephone number and electronic mail address of the attorney or other person, if any, to whom correspondence or communications in regard to the request shall be addressed; and

4. An explanation of any unusual circumstances involved in the request which the Department will be expected to direct its particular attention, including the existence of emergency conditions.

(d) Requests for determination shall address only one matter per request.

(e) Requests for determination shall be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6). Such requests shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2).

(f) Requests for determination shall include payment of a request fee. Payment of the fee shall be by credit/debit card via the Department's website, certified check, or money order made payable to the State of Georgia Department of Community Health and must be received by the Department before a determination request will be reviewed. Failure to provide payment of the appropriate fee will result in non-acceptance of the request.

1. The request fee for determination shall be $250.00;

2. State-owned institutions shall be exempt from payment of these fees; and

3. The Department may waive payment of these fees for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. Such requests for waiver must be received at the time of the initial request.

(2) **Letters of Determination**. Pursuant to O.C.G.A. § 31-6-47, if a person believes or has reason to believe that the application of a Department Rule or statutory provision may directly affect or impair the legal rights of that person as to some proposed action or course of conduct being considered by that person, including, but not limited to, determinations regarding reviewability, grandfathering decisions, and relocation or replacement determinations, such person may request a written determination from the Department regarding the application of such Department Rule or statutory provision upon that person's proposed action or course of conduct. A determination request is distinguished from a general question as a determination does not address general issues relating to policy and procedure.

Any person proposing an activity that would make it a health care facility unless exempted from prior CON review and approval pursuant to O.C.G.A. § 31-6-47, or any other part of the CON statute at O.C.G.A. § 31-6 et seq. shall be required to, pursuant to O.C.G.A. § 31-6-47.1, submit a request for a letter of determination from the Department. The Department's written response which confirms that the proposed activity is exempt from review shall act as the official confirmation of exemption provided in this Code section. A party is not authorized to commence or undertake the activity in question which it believes to fall within any one or more of the statutory exemptions in O.C.G.A. § 31-6-47 until written approval is issued by the Department in response to a request for a letter of determination as provided in this Rule.

In reviewing a determination request pursuant to this Rule to relocate all or a portion of an existing skilled nursing facility, intermediate care facility, or intermingled nursing facility, pursuant to O.C.G.A. § 31-6-47(a)(24) and Ga. Comp. R. & Regs. r. 111-2-2-.03(27), the Department may allow such facility to divide into two or more such facilities if the Department determines that the proposed division is financially feasible and would be consistent with quality patient care. Under no circumstances will the Department allow, via a favorable determination, a facility as listed above to relocate as one facility, or divide into more than one facility, with more than the total number of beds authorized in the facility's location prior to any relocation and/or division.

(a) No person shall be entitled to request a determination that relates to an actual or proposed action or course of conduct which has been taken or which would be taken by a third party; and

(b) In addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.10(1), a determination request shall include a concise and explicit iteration of the facts on which the Department is expected to rely in granting the determination.

(c) The Department shall establish timeframes, forms, and criteria to request a letter of determination that an activity is properly exempt or excluded under this chapter prior to its implementation.

1. If no objection to a request for determination is filed within 30 days of the Department's receipt of such request for Determination, the Department shall have 60 days from the date of the Department's receipt of such request to review the request and issue a letter of determination.

2. Where conditions exist which make it impractical to complete a review in 60 days, the Department may, on notification to the requester, extend the time limit another 30 days to 90 days.

(d) The Department shall publish notice of all requests for letters of determination regarding exempt activity and opposition to such request.

(e) In addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.10(1) and pursuant to the meaning of threshold as defined at Ga. Comp. R. & Regs. r. 111-2-2-.01(59), the Department applies the following Rules as they concern requests for determinations that the value of certain diagnostic, therapeutic, or other imaging equipment does not exceed the Department's equipment threshold, pursuant to O.C.G.A. § 31-6-47(a)(28) and therefore that such equipment is not subject to prior CON review and approval.

1. The party who requests the letter of determination must submit a manufacturer's or vendor's price quotation or purchase order for the diagnostic, therapeutic, or other imaging equipment. This requirement applies even if the equipment is to be leased.

2. The party who requests the letter of determination must submit a sworn affidavit affirmed by a person capable of making a binding commitment on behalf of the manufacturer or vendor of the diagnostic, therapeutic, or other imaging equipment for which a determination containing the following affirmations:

(i) that the affiant is capable of making a binding commitment on behalf of the manufacturer or vendor; and

(ii) that the price shown on the price quotation or purchase order is the total expense the requesting party is incurring for the equipment shown and the total dollar amount that the manufacturer or vendor is receiving for the exact unit shown on the quotation or purchase order; or

(iii) In the case of a lease or other means of acquisition, that the price shown is the total dollar amount that would have been expended had the equipment been purchased.

(3) **Requests for Letters of Determination for Below Threshold Diagnostic, Therapeutic, or Other Imaging Equipment**. A party requesting a letter of determination for the acquisition of diagnostic, therapeutic, or other imaging equipment with a value below the equipment threshold must submit with the request a sworn affidavit from a person capable of making a binding commitment on behalf of the party containing the following affirmations:

(a) that the affiant is:

1. a hospital; or

2. an individual private physician or single group practice of physicians and is

(i) acquiring the equipment exclusively for use on patients of such private physician or single group practice of physicians; and

(ii) such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

3. that the affiant is capable of making a binding commitment on behalf of the party;

4. that no acquisition of additional items not listed on a Line Item Valuation Sheets or the Aggregate Valuation Sheet, to be added to or used with the operational configuration of the particular diagnostic, therapeutic, or other imaging equipment at issue to include functionally related equipment, will be made or will take place for a period of six (6) months from the date of installation of the equipment that would put the total expenditure incurred on the diagnostic, therapeutic, other imaging equipment or its operational configuration over the Department's equipment threshold;

5. that no acquisition of additional equipment reasonably related to or associated with the general type of service provided by the equipment to be acquired not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet will occur within a period of six (6) months, that is that such expenditure for associated, but not functionally related equipment, regardless of modality, shall occur simultaneously;

6. that no construction not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet that can reasonably be determined to be associated with the equipment to be acquired will occur within a period of six (6) months;

7. that the Line-Item Valuation Sheets and the Aggregate Valuation Sheet included in the request are accurate, reflect all of the expenses required by Ga. Comp. R. & Regs. r. 111-2-2-.10(2)(e), and reflects the true cost of acquiring the exact same equipment and any and all associated and simultaneous items and activities; and

8. that the price shown on the price quotation(s) or purchase order(s) reflects the exact amount of the total expense that will be incurred and paid to the manufacturer or vendor for the exact same equipment listed on the price quotation or purchase order; or

9. in the case of a lease or other acquisition, that the price shown on the purchase order(s) or quote(s) is the total dollar amount that would have been expended had the equipment been purchased.

(b) The request for a letter of determination must include an Equipment Line-Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to each category listed below of items the Department will evaluate for purposes of determining if the value of the diagnostic, therapeutic, or other imaging equipment is below the equipment threshold dollar amount. If an item is not applicable, the requesting party should include the item on the Line-Item Valuation Sheet and indicate the dollar amount as $0. For each simultaneous and associated unit of equipment, as outlined at Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(e) below, a separate line-item valuation sheet must be submitted.

1. The dollar amount of the base price of the unit before adding any of the following items;

2. Any expense incurred for the purchase of a warranty on the diagnostic, therapeutic, or other imaging equipment from the manufacturer or vendor for the first five (5) years of operation;

3. Any expense incurred for operator training;

4. Any expense incurred for installation and assembly of the equipment;

5. Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

6. Any expense incurred for functionally related diagnostic, therapeutic or other imaging equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.;

7. Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

8. Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

9. Any dollar amount attributable to service contracts for the first five (5) years of operation;

10. Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of determination by the manufacturer or vendor of the equipment;

11. For mobile equipment, any expense incurred for a mobile coach, trailer, or van in which the equipment will be operated; and

12. The final line of the Line Item Valuation Sheet should reflect the total of the preceding eleven (11) items.

(c) The value of diagnostic, therapeutic, or other imaging equipment for which a letter of determination is requested shall not include build out costs. Build out costs are defined as expenditures made for items such as electrical, plumbing, masonry such as concrete pads, construction of modular buildings, and renovation of the space that will actually house the equipment, such as the room where an MRI unit would be used. Build out costs shall also include expenditures for new construction for a building to house the equipment or to renovate a building or structure to house the equipment, or expenditures for administrative office space unrelated to the actual functionality of the equipment, related equipment, or software necessary to operate the equipment.

(d) A party acquiring functionally related equipment or items, including those items and expenses listed in Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(b) within a six (6) month period, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of Need authorization;

(e) All simultaneously acquired and associated diagnostic, therapeutic, and other imaging equipment regardless of modality shall be aggregated. See the definition of "associated with and simultaneously developed or proposed." If additional diagnostic, therapeutic, and other imaging equipment is to be acquired, the party must submit price quotations for each piece of simultaneously acquired diagnostic, therapeutic, and other imaging equipment;

(f) A letter of determination for the acquisition of diagnostic, therapeutic, or other imaging equipment shall be valid only for the defined equipment, physical location, cost, and entity or person named in the request as the acquirer and operator of the equipment and only to the pertinent facts that were disclosed in the request, except that cost may exceed the amount approved by the Department as long as the actual final expenditures do not exceed the equipment threshold. Such letters are non-transferable and may not be acquired. If the facts pertinent to the letter of determination change in any way, the letter is no longer valid;

(g) Upon completion of the acquisition of the equipment, the party requesting a determination shall submit a final statement of the total costs of the equipment. In addition, if the if the equipment and associated activities are not completed within one hundred and eighty (180) days of the issuance of the determination, the party requesting a determination shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the expenses incurred to

date, and any good faith estimates of the percentage of completion and the amount of costs expected to be incurred to complete. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a determination. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

(4) **Requests for Letters of Determination for Exempt Single Specialty or Joint Venture Ambulatory Surgical Centers**.

(a) When the Department receives a request for a letter of determination for the establishment of a physician-owned, single specialty, office-based ambulatory surgery facility, or a joint venture ambulatory surgical center, pursuant to O.C.G.A. § 31-6-2(33), (23), and O.C.G.A. § 31-6-47(a)(18), (19), the party requesting such a letter must comply with the following:

1. Identify the name and address of the proposed ambulatory surgery facility, including the principal business address of the sole physician or group practice that will own the facility.

2. Identify the individual private physician, or all owners (e.g. stockholders, partners, members) of the single group practice of private physicians who are also on the same single specialty, that will own, operate, and utilize the proposed facility. All members of the single group practice must be of the same specified surgical specialty. Physicians who perform procedures within the single specialty ambulatory surgical center must own at least eighty-five percent (85%) of the group practice and the surgery center. The Department will issue a determination, if all other criteria are met, to a single group practice which utilized the services of employee physicians of the same specialty in the surgery center if these employee physicians are not a member or employee of any other medical practice. All employee physicians must be identified, and an affirmative statement with regard to their practice affiliation must be included. The Department will allow no more than fifteen percent (15%) non-physician ownership in the physician(s) practice requesting a determination, and/or the surgery center in a single specialty ambulatory surgical center. Evidence of non-physician ownership, including the percentage of such ownership, must be provided with the determination request. For a joint venture ambulatory surgical center, the ownership interest of the hospital shall be no less than thirty percent (30%) and the collective ownership of the physicians or group of physicians shall be no less than thirty percent (30%). Any evidence of non-hospital or non-physician or group of physician's ownership in a joint venture ambulatory surgical center must be provided with the determination request.

3. All physicians must be licensed to practice in the state of Georgia, and must submit a copy of such license; should any physician members of a single group practice perform procedures in the ambulatory surgery facility created by the issuance of a determination lose their license to practice medicine in Georgia, the determination shall be revoked, unless within sixty (60) days of such physician losing their license, the group practice submits new evidence documenting that the physician ownership of the facility by the group practice does not include the physician who lost their license.

4. Submit evidence of the sole physician professional corporation or the entity comprising the single group practice of private physicians, to include authorizing and governing documents such as articles of incorporation, by-laws, operating agreements, partnership agreements, etc. Submit a sworn affidavit, signed by the owners, which lists all owners of the sole or group practice and the proposed surgery facility.

5. The physician(s) must show evidence of ownership by warranty deed or lease of the space housing the ambulatory surgery facility including the clinical office space.

6. Provide a detailed description of the proximity of the physician's or the group practice's clinical offices to the ambulatory surgery facility. The Department will only grant a determination to those proposed ambulatory surgical facilities, which are deemed to be in reasonable proximity to the clinical offices of the sole physician or single group practice that will own the proposed facility. Reasonable proximity will be determined on a case-by-case basis. Example of reasonable proximity include those ambulatory surgical facilities on the same floor and physically attached to the clinical offices; surgical suites on a different floor of the same building as the clinical offices with one public entrance to the proposed facility.

7. State the number of operating rooms in the proposed ambulatory surgery facility.

8. State the total square footage in the proposed ambulatory surgery facility. This total includes the square footage associated with all operating suites, reception and waiting areas, business offices, pre and post-operation areas, all building common areas including a pro rata share of the common areas of buildings utilized by multiple tenants, which are new and/or renovated and involve expenditures to be incurred in the development, construction and establishment of the proposed surgery facility.

9. List costs attributable to new construction or renovation of the total area comprising the ambulatory surgery facility. Documentation of the total costs of constructing, developing, and establishing the proposed ambulatory surgical facility, and the costs of all items associated with or simultaneously developed with the project, including, but not limited to, fixed equipment not included in the construction contract, moveable equipment, architectural and engineering fees, legal and administrative fees, interim financing (interest during construction), and underwriting costs. The documentation of construction and renovation costs must be in the form of a letter from a licensed Georgia architect verifying the estimated construction costs of the proposed ambulatory surgery facility. With regard to the construction of a new building (or a new wing including space devoted to services other than the surgery center) to house an ambulatory surgery facility, a pro-rata portion of the building shell costs, including all building common areas, must be allocated to the costs of the proposed ambulatory surgery facility. Other costs to be included are:

(i) The cost of new space (even if the space will be leased) based on the construction cost of the new space. Appropriate documentation from an architect licensed in Georgia must be submitted. A copy of all leases must be submitted;

(ii) The cost of all equipment (medical and non-medical) purchases for the ambulatory surgery facility.

(iii) The present value of any equipment to be leased for the surgery facility.

(iv) The Department must have a line item breakdown of all amounts attributable to new construction, renovation, furnishings, leases, and items of equipment in accordance with the provisions outlined above, including new expenditures for furnishings for non-patient care areas such as waiting areas, reception areas, and business offices.

The Department will require a sworn affidavit that no party associated with the practice or physicians requesting a determination, by virtue of ownership or employment, has incurred any expenditure for equipment of any kind to be utilized in the surgery center that has been subsequently donated to the practice for use in the surgery center and the cost of that equipment, whether purchased or leased, was not included in the dollar threshold applicable to the surgery center.

10. A schematic floor plan must be provided to the Department. This documentation must be clear and readable. The floor plan must clearly show all areas of the proposed ambulatory surgery facility.

11. Pursuant to O.C.G.A. § 31-6-2(14), list the cost of all other items, regardless whether they are independently subject to Certificate of Need review, that are associated and to be simultaneously developed with the proposed ambulatory surgery facility, except for the expenditure or commitment of funds to develop studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites.

12. The Department will not issue a determination to any sole physician or single specialty group practice of physicians proposing to bill a professional fee through a larger multi-specialty group practice in which the single specialty group practice requesting the determination remains a part of. For purposes of these Rules, this provision does not preclude the issuance of a determination to a physician(s), which utilizes a larger group practice for the sole purpose of billing services under the provider number of the sole physician or single group practice.

13. The Department will not issue a determination to any physician(s) who is a member of more than one single group practice, pursuant to O.C.G.A. § 43-1B-3(5) of the Georgia Patient Self-Referral Law.

14. The Department will not issue a determination to any group practice of physicians if any members of that group practice are also members of a multi-specialty clinical practice. For purposes of these Rules a multi-specialty clinical

group practice does not mean any volume purchasing association or managed care network whose function is managed care contracting in which the physician or group practice participates.

15. The Department will not issue a determination to any party proposing to share operating rooms or common space in a proposed ambulatory surgical facility between more than one group practice of the same specialty or between more than one surgical group practice of different specialties, or between more than one sole physician of the same or different specialties who are not members of the same medical practice.

16. Provide a sworn affidavit, signed by the physician(s) owners, that the party requesting a determination will not incur any additional capital expenditures involving new construction or renovation of physical space or the addition or replacement of equipment within three (3) years after the issuance of the determination, which, when coupled with prior expenditures, would exceed the threshold amount applicable to the statutory exemption for this type of facility unless it first secures a Certificate of Need. A party holding a determination issued by the Department may request, in writing, a waiver from this provision for expenditures for equipment involving newly recognized and innovative medical technologies (FDA approved) present in the marketplace. Any such expenditure will be applied to the original threshold amount unless the written consent of the Department is obtained prior to the expenditure.

17. Upon completion of construction of the ambulatory surgery facility, the party requesting a determination shall submit a final statement of the total costs of the facility, including a separate line item completed project cost sheet with the same detail and documentation as required in subsection (4)(a)11. above. In addition, if the proposed ambulatory surgery facility is not completed within one hundred and eighty (180) days of the issuance of a determination, the party requesting a determination shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the cost of the facility incurred to date, and any good faith estimates of the percentage of completion of the facility and the amount of costs expected to be incurred to complete the facility. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a determination and from the general contractor. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

18. The determination is not transferable to a purchaser of the sole physician or single group practice, which originally received a determination. This provision is not intended to limit the transferability of a sole physician practice or a group practice but is intended to put the new physician owners on notice that they must request a new determination as new owners of that practice. Such a new request will be evaluated based on the determination criteria applicable at the time of the new request, and the acquisition costs of the practice will not be a part of the applicable capital expenditure threshold.

(b) A single specialty ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $2,500,000.00; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two or fewer operating rooms; provided, however, that a center exempt pursuant to this provision shall be required to obtain a Certificate of Need in order to add any additional operating rooms;

3. Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. A party requesting a letter of determination must provide documentation to support an assertion that a hospital, pursuant to this requirement, has unreasonable denied a transfer agreement or affiliation agreement to the center;

4. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

5. If the center is not a participant in Medicaid or the PeachCare for KidsT Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

6. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

Noncompliance with any condition of subsections 4. and 5. of Section (4)(b) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 6. of section (4)(b) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(c) Any joint venture ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5,000,000.00;

2. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

3. If the center is not a participant in Medicaid or the PeachCare for KidsT Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

Noncompliance with any condition of subsections 2. and 3. of section (4)(c) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 4. of section (4)(c) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(c) Any joint venture ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5,000,000.00;

2. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

3. If the center is not a participant in Medicaid or the PeachCare for KidsT Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

Noncompliance with any condition of subsections 2. and 3. of section (4)(c) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 4. of section (4)(c) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(5) **Requirements Applicable to Valid Holders of Ambulatory Surgery or Diagnostic or Therapeutic Equipment Exemptions Prior to July 1, 2008.**

(a) Any facility offering ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2; any diagnostic, treatment, or rehabilitation center offering diagnostic imaging or other imaging services in operation and exempt prior to July 1, 2008; or any facility operating pursuant to a letter of nonreviewability and offering diagnostic imaging services prior to July 1, 2008, shall:

1. Provide notice to the department of the name, ownership, location, single specialty, and services provided in the exempt facility in accordance with the provisions of Rule 111-2-2-.04(1)(b)1.;

2. Beginning on January 1, 2009, provide annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and in accordance with the provisions of Rule 111-2-2-.04(1)(b)2.

(b) If, on or after July 1, 2008, any facility referenced in subsection (5)(a) above that, makes a capital expenditure associated with the construction, development, expansion, or other establishment of a clinical health service of the acquisition or replacement of diagnostic or therapeutic equipment with a value in excess of $800,000.00 over a two-year period; builds a new operating room; or chooses to relocate in accordance with Rule 111-2-2-.03, it shall:

1. Provide care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and provide uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the facility is not a participant in Medicaid or the PeachCare for KidsT Program, provide uncompensated care for Medicaid beneficiaries and, if the facility provides medical care and treatment to children, for PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue.

Noncompliance with any condition of subsection (b)1. and 2. above shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and

may be subject to revocation of its exemption status by the department for repeated failure to pay any fees or monies due to the department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the consumer price index, or its successor or appropriate replacement index, if any, published by the United States Department of Labor for the preceding calendar year, commencing on July 1, 2009. In calculating the dollar amounts of a proposed project for the purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop certificate of need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites. Subsections (b)1. and 2. of section (5) of this rule, shall not apply to facilities offering ophthalmic ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2 that are owned by physicians in the practice of ophthalmology.

(6) **Administrative Remedies for Adverse Determinations**.

When the Department makes a determination or decision pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.10(1) through (5) of this Rule or any other determination or decision over which the Certificate of Need Appeal Panel lacks subject matter jurisdiction, the person who requests and receives the determination or decision may appeal to the Commissioner or his designee for an administrative hearing pursuant to the Administrative Procedures Act if such person is aggrieved by the Department's determination or decision. Such request for a hearing must be made in writing and must be received by the Department within thirty (30) days of the date of the Department's determination or decision. If such written request is not received by the Department within thirty (30) days, the Department's determination or decision shall become final upon the thirty-first (31st) day. The Department shall publish notice of all requests for letters of determination regarding exempt activity and opposition to such request, whether pursuant to O.C.G.A. § 31-6-47 or any other provision of Code Section 31-6 and these Rules. Persons opposing a request for approval of an exempt activity, whether pursuant to an express statutory exemption or any other provision of the health planning statute or these Rules, shall be entitled to file a written objection with the Department and the Department shall consider any filed objection when determining whether an activity is exempt. A person who wishes to file a written objection to an exemption determination request, including requests for letters of determination for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, must do so no later than thirty (30) days after the date of Department receipt of the initial request for the exemption determination. Such written opposition should be submitted via the Department's web portal. The opposition shall be submitted in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6).

If no objection to a request for determination is filed within 30 days of the Department's receipt of such request for Determination, the Department shall have 60 days from the date of the Department's receipt of such request to review the request and issue a letter of determination. The Department may adopt rules for deciding when it is not practicable to provide a determination in 60 days and may extend the review period upon written notice to the requestor but only for an extended period of no longer than an additional 30 days. After the issuance of an approval to a response to the request for an exemption determination, including requests for letters of determination for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, a person in opposition that has complied with the provisions outlined above, shall have the right to a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act, and judicial review of a final decision in the same manner and under the same provisions as in O.C.G.A. § 31-6-44.1 and Ga. Comp. R. & Regs. r. 274-1 et seq. A person who requested and received the exemption determination shall have automatic standing to participate in any such administrative proceeding to defend the approved exemption determination. The Department may also participate to defend its decision. A person who opposes an exemption determination request that is denied, and who has complied with the written opposition submission requirements provided above, shall have standing to participate in any administrative proceeding requested by the person denied an approved exemption determination. If the written opposition is not submitted in accordance with the provisions outlined above, the Department shall not consider the opposition, and the rights to an administrative hearing, and/or any participation in any proceeding as outlined above, will not adhere to the opposing person.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.10

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Determinations and Letters of Non-Reviewability" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Aug. 28, 2006; eff. Sept. 17, 2006.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Nov. 14, 2008; eff. Dec. 4, 2008.

Amended: New title, "Determinations." F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.11 Service-Specific Review Considerations Generally

(1) The Department has adopted the following service-specific requirements and review considerations:

(a) Acute Care and Acute Care-Related Rules:

1. Short-Stay General Hospital Services, Ga. Comp. R. & Regs. r .111-2-2-.20;

2. Adult Cardiac Catheterization Services, Ga. Comp. R. & Regs. r. 111-2-2-.21;

3. Open Heart Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.22;

4. Pediatric Cardiac Catheterization and Open Heart Services, Ga. Comp. R. & Regs. r. 111-2-2-.23;

5. Perinatal Services, Ga. Comp. R. & Regs. r. 111-2-2-.24;

6. Freestanding Birthing Center Services, Ga. Comp. R. & Regs. r. 111-2-2-.25; and

7. Psychiatric and Substance Abuse Inpatient Services, Ga. Comp. R. & Regs. r. 111-2-2-.26;

(b) Long-Term Care Rules:

1. Skilled Nursing and Intermediate Care Facility Services, Ga. Comp. R. & Regs. r. 111-2-2-.30;

2. Personal Care Home Services, Ga. Comp. R. & Regs. r. 111-2-2-.31;

3. Home Health Services, Ga. Comp. R. & Regs. r. 111-2-2-.32;

4. Life Plan Community ("LPC") Sheltered Nursing Facilities, Ga. Comp. R. & Regs. r. 111-2-2-.33;

5. Traumatic Brain Injury Services, Ga. Comp. R. & Regs. r. 111-2-2-.34; and

6. Comprehensive Inpatient Physical Rehabilitation Services, Ga. Comp. R. & Regs. r. 111-2-2-.35;

7. Long Term Care Hospitals, Ga. Comp. R. & Reg. R. 111-2-2-.36

(c) Special and Other Health Services:

1. Ambulatory Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.40;

2. Positron Emission Tomography, Ga. Comp. R. & Regs. r. 111-2-2-.41; and

3. Radiation Therapy Services, Ga. Comp. R. & Regs. r. 111-2-2-.42.

(2) The review considerations and standards that are promulgated in service-specific rules are considerations and standards that apply to specific services in addition to the general considerations in Ga. Comp. R. & Regs. r. 111-2-2-.09. Any conflict between the meaning or application of a service-specific requirement and the general considerations shall be interpreted in favor of the service-specific consideration, unless a general consideration specifically indicates that it supersedes any and all service-specific considerations.

(3) The meaning of words as they are defined in a particular service-specific rule only applies to that service-specific rule, unless a specific citation is made to another service-specific rule.

(4) Numerical Need Calculations.

(a) The numerical need calculations, which shall apply to an application for a clinical health service for which service-specific rules exist, shall be the calculated need in effect on the date the application is deemed complete for review less any subsequently approved units and services during the review period. This provision does not apply to batching reviews as the need applicable to batching decisions is the need stated in the batching notice.

(b) In the instance of joined projects where one project is reviewed as an exception based on utilization and the other is reviewed as need-based, the approval of the utilization exception shall not preclude an approval based on a numerical need projection should, prior to the approval of any of the joined projects, the numerical need projection indicates a need for the clinical health service.

(c) Approved projects that affect service-specific numerical need calculations shall be added to the Department's service-specific inventories and the numerical need projections shall be adjusted as of the approved date of the project.

(d) Approved projects that are reversed through administrative and/or judicial appeal final resolution shall be subtracted from the Department's service-specific inventories and the numerical need projections shall be adjusted as of the date of such final resolution.

(5) Service-specific component plans provide general background on specific considerations that were undertaken in developing service-specific rules. The service-specific rules shall supersede a component plan.

(6) If any provision of these service-specific rules, or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the particular service-specific rule in question or of the service-specific rules in general which can be given effect without the invalid provision or application, and to this end the provisions of these service-specific rules are severable.

(7) The commissioner shall be authorized, with the approval of the board, to place a temporary moratorium of up to six (6) months on the issuance of certificates of need for new and emerging health care services. Any such moratorium placed shall be for the purpose of promulgating service-specific rules and regulations regarding such new and emerging health care services. A moratorium may be extended one time for an additional three (3) months if circumstances warrant, as approved by the board. In the event that final service-specific rules and regulations are not promulgated within the time period allowed by the moratorium, any applications received by the Department for a new and emerging health care service shall be reviewed under existing general statutes and regulations relating to certificates of need. Upon the identification by the Department of a new and emerging health care service as defined by Ga. Comp. R. & Regs. r. 111-2-2-.01(41), and the request for and receipt of approval by the board of a moratorium as provided in this subsection, the Department shall publish notice of the moratorium and the identified service in a manner used in the normal course for other Certificate of Need information and announcements.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.11

AUTHORITY: O.C.G.A. Secs. 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Service-Specific Review Considerations Generally" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Dec. 14, 2007; eff. Jan. 3, 2008.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.20 Specific Review Considerations for Short-Stay General Hospital Beds

(1) **Applicability.**

(a) A Certificate of Need will be required prior to the establishment of a new hospital, replacement of an existing hospital, or expansion of an existing hospital.

(b) The provisions in these Rules do not apply to the following situations:

1. bed replacements in existing hospital facilities which do not require a capital or equipment expenditure over the applicable dollar threshold; or

2. changing the physical location of existing beds within an existing facility regardless of cost; provided, however, that any project in excess of the applicable capital expenditure or equipment dollar threshold must be reviewed in accordance with the review considerations set forth in Ga. Comp. R. & Regs. r. 111-2-2-.09; or

3. projects that are otherwise exempt from review pursuant to O.C.G.A. § 31-6-47(a)(15).

(c) An existing hospital seeking an expansion to be used for new institutional health services, including perinatal services, rehabilitation services, or psychiatric and substance abuse services, must meet the applicable service-specific Rules found in this Chapter and, as a threshold matter, meet the need standards set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b)(3) but shall not be required to meet the other requirements in Ga. Comp. R. & Regs. r. 111-2-2-.20.

(d) A hospital that has been approved through the Certificate of Need process to use a certain number of short-stay hospital beds for long-term acute care ("LTAC") beds shall have such LTAC beds removed from the official inventory of available short-stay beds once the LTAC is certified by Medicare; provided, however, that such beds will revert to the hospital's official inventory of available short-stay beds at any point that the LTAC ceases operation or is no longer certified by Medicare. An application to use existing short-stay hospital beds for LTAC beds shall not be subject to the guidelines in Ga. Comp. R. & Regs. r. 111-2-2-.20.

(2) **Definitions.**

(a) "Age cohorts" for purposes of these Rules refers to the following age groups: persons zero (0) to seventeen (17); persons eighteen (18) to sixty-four (64); and persons sixty-five (65) and older.

(b) "Available beds" or "CON approved beds" means the total number of beds authorized for use by a hospital or group of hospitals based on capacity approved or authorized through the Certificate of Need process.

(c) "Children's hospital" means a hospital in which ninety percent (90%) or more of the patients served by the hospital are seventeen (17) or less years of age.

(d) "Critical Access Hospital" means a hospital designated as a critical access hospital pursuant to the state's rural health plan and the guidelines of the Medicare Rural Hospital Flexibility Program authorized by section 4201 of the Balanced Budget Act of 1997.

(e) "Destination cancer hospital" means an institution with a licensed bed capacity of fifty (50) or less which provides diagnostic, therapeutic, treatment, and rehabilitative care services to cancer inpatients and outpatients, by or under the supervision of physicians, and whose proposed annual patient base is composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia.

(f) "Expansion" means the addition of available beds or CON approved beds for an existing hospital.

(g) "Health planning area" or "planning area" means the twelve (12) state service delivery regions as defined in O.C.G.A. § 50-4-7.

(h) "Horizon year" means the last year of a five (5) year projection period for need determinations.

(i) "Optimal Occupancy Rate" means a target or expected level of use of available beds as calculated based on the annual patient days divided by the available beds multiplied by three hundred sixty-five (365). The optimal occupancy rate is variable based on the following:

1. for hospitals located in a rural county, sixty-five percent (65%);

2. for hospitals located in a non-rural county, seventy-five percent (75%); and

3. for teaching or children's hospitals, seventy percent (70%).

(j) "Patient days" means the number of days of inpatient services based on the most recent full year of hospital discharge data or the annual hospital questionnaire.

(k) "Replacement" means new construction to substitute another facility for an existing facility. New construction may be considered a replacement only if the replacement site is located three (3) miles or less from the facility being replaced or, in the case of the facility proposing a replacement site beyond the three (3) mile limit, if the replacement site is located within the same county and would serve substantially the same patient population, based on patient origin by zip code and payer mix, as the existing facility.

(l) "Rural county" means a county with a population of 35,000 or less based on the most recent decennial census, as defined in O.C.G.A. § 31-7-94.1(c)(3).

(m) "Safety net hospital" is defined as a hospital that meets at least two (2) of following criteria:

1. the hospital is a children's hospital or a teaching hospital;

2. the hospital is designated by the Healthcare Facility Regulation Division as a trauma center;

3. Medicaid and Peach Care inpatient admissions constitute twenty percent (20%) or more of the total hospital inpatient admissions;

4. Uncompensated charges for indigent patients constitute six percent (6%) or more of hospital adjusted gross revenue; or

5. Uncompensated charges for indigent and charity patients constitute ten percent (10%) or more of hospital adjusted gross revenue.

(n) "Short stay hospital" or "hospital" is defined as a facility with an average length of stay of less than thirty (30) days.

(o) "Target service area population" means the total populations of all counties, which are in part or in whole, within a ten (10) mile radius of the planned location of a new, expanded, or replacement hospital.

(p) "Teaching hospital" means a hospital designated as a teaching hospital by the Georgia Board for Physician Workforce, which serves as a sponsoring or major participating hospital for a program of graduate medical education accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) and maintains a written affiliation agreement with an accredited medical school located in Georgia or is owned and operated by an accredited medical school in Georgia.

(3) **Standards.**

(a) A new hospital must be at least fifty (50) beds in size if located in a rural county and at least one hundred (100) beds in size if located in a county other than a rural county.

(b) The need for a new, replacement or expanded hospital shall be determined through application of an appropriate numerical need methodology designed to assess need for the specific purpose sought in the application.

1. The numerical need for a new hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the use rate for current hospital services in the target service area population by dividing the patients days for each age cohort by the population for each age cohort for same year as patient days were calculated.

(ii) Project the horizon year use rate for hospital services in the target service area population by multiplying the use rate for current hospital services by age cohort by the horizon year population by age cohort.

(iii) Divide the results of the calculations in Step (ii) by 365 and sum these numbers to determine a baseline bed need.

(iv) Adjust the baseline bed need by adding a factor to account for use of the hospital services located within the target service area population by persons from out of state. The factor shall be determined by calculating the patient days for the hospitals in the target service area that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that percentage into the baseline bed need. In addition, if the target service area population includes any county or counties outside the state of Georgia, the projected bed need of the out-of-state counties should be calculated by applying the projected rate of beds needed per 1,000 for in-state counties in the target service area population to the prorated portion of population in out-of-state counties.

(v) Divide the baseline bed need by the optimal occupancy rate, as determined by the size of the proposed new facility, to project the total number of beds needed for the target service area population.

(vi) Calculate the number of available beds for the target service area population by adding all of the short stay beds located in the counties, including those outside of Georgia if applicable, which are in part or in whole within a ten (10) mile radius of the planned location of the new hospital.

(vii) Subtract the number of available beds from the total number of beds needed for the target service area population to determine the net number of beds needed.

2. A new hospital shall be approved only if the total target service area population is at least 50,000 persons.

3. The numerical need for a replacement or expanded hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the county use rate for the current hospital's services by dividing the patients days for Georgia residents by county within each age cohort by the population by county for each age cohort for the same year as patient days were calculated.

(ii) Project the horizon year use rate for the hospital's services by multiplying each county use rate by age cohort by the horizon year population of each county by age cohort.

(iii) Sum the number of patients resulting from Step (ii) and divide by three hundred and sixty-five (365) to determine a baseline bed need rate.

(iv) Adjust the baseline bed need rate by adding a factor to account for use of the hospital's services by persons from out of state. The factor shall be determined by calculating the patient days for the hospital that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that number into the baseline bed need.

(v) Divide by optimal occupancy rate, as determined by the size of the proposed facility, to project the total number of beds needed for the replacement or expanded hospital.

(vi) Compare the results of Step (v) with the number of beds requested for the replacement or expanded hospital and, if appropriate, the number of available beds to determine whether the proposed replacement or expanded hospital meets the need standards.

(c) The Department may allow an exception to need and adverse impact standards outlined in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b) and (d) for a facility meeting any one of the following criteria:

1. The facility is an existing facility designated by the Department of Public Health as a trauma center;

2. The facility is an existing teaching hospital;

3. The facility is a sole community provider and more than twenty percent (20%) of the capital cost of any new, replacement or expanded facility is financed by the county governing authority, as defined in O.C.G.A. § 1-3-3(7), of the home county or the county governing authorities of a group of counties; or

4. The facility is a designated critical access hospital and is seeking replacement of its existing facility at a size not to exceed twenty-five (25) CON approved beds.

(d) 1. An applicant for a new, replacement or expanded hospital shall demonstrate the expected effects of the proposed services on other hospitals within the target service area population, including how any enhanced competition will have a positive impact upon the cost, quality, and access to the services proposed; and in the case of applications for a new, replacement or expanded hospital where competition between providers will not have a favorable impact on cost, quality and access, the applicant shall be required to document that its application will not have an adverse impact.

2. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to safety net hospitals within the planning area. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any safety net hospitals. Impact on an existing safety net hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing safety net hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

3. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to any teaching hospitals in the state. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any teaching hospitals. Impact on an existing teaching hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing teaching hospital would have a total decrease of five percent (5%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

(e) In considering applications joined for review, the Department may give favorable consideration to whichever of the applicants historically has provided the higher annual percentage of unreimbursed care to indigent and charity patients and the higher annual percentage of services to Medicare, Medicaid and Peach Care patients.

(f) An applicant for a new, replacement or expanded hospital shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard that meets or exceeds three percent (3%) of annual, adjusted gross revenues for the hospital;

3. providing a written commitment to participate in the Medicare, Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the hospital is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(g) 1. An applicant for a replacement or expanded hospital shall document that the hospital is fully accredited by the Joint Commission or another nationally recognized accrediting body, and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three (3) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies. In the event that the hospital is not accredited by the Joint Commission or another nationally recognized health care accreditation body and relies solely on state licensure, the applicant should provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past five (5) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

2. An applicant for a new, replacement or expanded hospital shall:

(i) provide a written commitment that the applicant presently participates, or in the case of a new hospital, will participate, in a statewide or national external reporting and peer review process related to patient safety and control of medical errors;

(ii) provide evidence of the availability of resources, including health care providers, management personnel and funds for capital and operating needs, for the provision of the hospital services; and

(iii) document a plan for obtaining and maintaining staff and service quality standards necessary to promote effective patient care and clinical outcomes.

(h) 1. An applicant for a new, replacement or expanded hospital shall document a plan to operate an emergency room licensed by the Healthcare Facility Regulation Division.

2. An applicant for a new, replacement or expanded hospital shall provide a description of the proposed service area for the hospital and document a community planning process that addresses primary care relationships and the range of transfer and referral activities across the range of care levels. The descriptions and community planning process should address:

(i) Estimated geographic boundaries of primary and secondary service areas and the primary and outpatient providers in these areas;

(ii) Demographic and income characteristics of the service area by age, gender and racial compositions;

(iii) Anticipated payer sources by population totals and percentages to include public payers and indigent and charity care services;

(iv) Patient access to the full continuum of care, including discharge planning and long-term care options;

(v) The projected financial and economic impact that the project will have on the community;

(vi) Strategies related to physician recruitment and medical staffing to include the hospital's plan to ensure that the care provided by physicians and other clinicians is made available to patients without regard for ability to pay;

(vii) The manner in which the facility coordinates or will coordinate with the existing health care system;

(viii) The manner(s) in which the hospital will make available the necessary ancillary and support services; and

(ix) The manner in which the hospital will support the operation of any affiliated critical access hospitals, if applicable.

3. An applicant for a new, replacement or expanded hospital shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the hospital.

4. An applicant for a new, replacement or expanded hospital shall demonstrate that proposed charges for services shall compare favorably with charges for other similar hospital services in the planning area when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for hospital services, the Department may compare the applicant's history of charges if applicable, with other hospitals in the planning area(s) previously served by the applicant or its parent company.

(i) 1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one rural county or in contiguous rural counties. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same rural county or in contiguous rural counties, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same rural county or one of the same rural counties. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

(i) The available beds for the proposed consolidated facility must not exceed the total number of available beds of the existing facilities proposed for consolidation;

(ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

(iii) The applicant(s) must explain the impact of consolidation on the service area's health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The applicant(s) must comply with all other provisions of this Rule with exception of the need and adverse impact standards set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b) and (d).

(j) 1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one non-rural county. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same non-rural county, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same non-rural county. The consolidating facilities must apply as co-applicants. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

(i) The available beds sought for the proposed consolidated facility must not exceed the sum of the total number of beds for which each of the consolidating facilities would be authorized, at the time the application is filed, pursuant to the demand-based forecasting model for determining need set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b)3.

(ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data by zip code, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

(iii) The applicant(s) must explain the impact of consolidation on the facilities to be consolidated existing service area(s) health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The consolidating facilities must not seek to offer in a consolidation application any new clinical health service at the proposed new site not offered in each or all of the facilities to be consolidated.

(k) 1. A Certificate of Need will be issued to an applicant for a destination cancer hospital if it meets the following standards and under the following conditions.

2. An applicant for a destination cancer hospital must document that it meets the criteria described in the definition in Section (2)(e).

3. An applicant for a destination cancer hospital must:

(i) Document that the destination cancer hospital itself and all affiliated facilities are within twenty-five (25) miles of a commercial airport in the State of Georgia with five (5) or more runways;

(ii) Document that the services to be offered by the facility are solely related to the treatment of cancer patients;

(iii) Document the services to be offered within and by the facility that would otherwise be considered a separate new institutional health service. Such services will not be required to obtain separate Certificate of Need authorization, or be reviewed under any service-specific need methodology or rules other than those for a destination cancer hospital if included in the initial Certificate of Need application reviewed under the Rules outlined in section (k) of these Rules;

(iv) Document that the destination cancer hospital will not offer services that are not reasonable related to the diagnosis and treatment of cancer such as, but not limited to, open heart surgery, perinatal services, and cardiac catheterization;

(v) Document that at least sixty-five percent (65%) of its projected annual patient base will be composed of persons who reside outside of the State of Georgia;

(vi) Agree to provide uncompensated indigent and charity care for residents of the State of Georgia which meets or exceeds three percent (3%) of the applicant's adjusted gross revenue;

(vii) Agree to provide care to Medicaid beneficiaries;

(viii) Document that the applicant for a destination cancer hospital will comply with the criteria found in the General Review Considerations of these Ga. Comp. R. & Regs. r. at Section 111-2-2-.09(2).

4. A destination cancer hospital that does not meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia in a calendar year shall be fined $2,000,000.00 for the first year of noncompliance, $4,000,000.00 for the second consecutive year of noncompliance, and $6,000,000.00 for the third consecutive year of noncompliance. Such fine amount shall reset to $2,000,000.00 after any year of compliance. In the event that a destination cancer hospital does not meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia for three (3) calendar years in a five (5) year period, such hospital shall be fined an additional amount of $8,000,000.00. All revenues collected from any such fine may be dedicated and deposited by the Department into the Indigent Care Trust Fund created pursuant to O.C.G.A. § 31-8-152. The Department, pursuant to O.C.G.A. § 31-6-45(a)(7), may revoke the Certificate of Need of a destination cancer hospital, in whole, or in part, after notice and an opportunity for a hearing, for failure to meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia for three calendar years in any five-year period.

5. After commencing operations upon receipt of a Certificate of Need pursuant to these Rules, a destination cancer hospital seeking to add an additional new institutional health service, shall apply for and obtain an additional Certificate of Need under the applicable statutory provisions and the Rules in this section. Any such application shall only be granted if the patient base of the destination cancer hospital is composed of at least sixty-five percent (65%) of patients who reside outside of the State of Georgia for two consecutive years.

6. The Department may apply the Rules in section (k) of these Rules to an application from a destination cancer hospital for a Certificate of Need for services and equipment required for it to meet federal or state laws applicable to a hospital.

7. If a destination cancer hospital cannot show a patient base of a minimum of sixty-five percent (65%) of persons who reside outside of the State of Georgia, the application for a Certificate of Need for any new institutional health service shall be evaluated under the specific statutes and Rules applicable to that particular service.

8. If a destination cancer hospital applies for a Certificate of Need to add an additional new institutional health service before commencing operations or completing two (2) consecutive years of operation, the applicant may rely on historical data from its affiliated entities.

9. The number of beds, services, and equipment used in and by a destination cancer hospital shall not be counted as part of the Department's inventory when determining the need for those beds, services, or equipment for other providers in other Certificate of Need applications not involving destination cancer hospitals.

10. No person shall be issued more than one Certificate of Need for a destination cancer hospital.

11. The Department will not accept an application for a Certificate of Need for a destination cancer hospital on or after January 1, 2010; however, an existing destination cancer hospital may avail itself of all applicable Certificate of Need provisions regarding the upgrade, purchase, or replacement of diagnostic or therapeutic equipment.

12. An applicant for a destination cancer hospital shall agree to provide information related to the operation of and services provided by the facility in the time frame and manner requested by the Department. In addition, a destination cancer hospital shall submit an annual statement, in accordance with the timeframes and format specified by the Department, affirming that the hospital has met an annual patient based composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia. The chief executive officer of the destination cancer hospital shall certify under penalty of perjury that the statement as prepared accurately reflects the composition of the annual patient base. The Department shall have the authority to inspect any books, records, papers, or other information of the destination cancer hospital to confirm the information provided on such statement or any other information required of the destination cancer hospital. The report required by this sub-section shall not be construed to require the release of any information that would violate the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.20

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

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111-2-2-.21 Specific Review Considerations for Adult Cardiac Catheterization Services

(1) **Applicability.**

(a) For Certificate of Need purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center ("DTRC"). A Certificate of Need will be required prior to the establishment of a new or expanded adult cardiac catheterization service, if not exempt as provided by O.C.G.A. § 31-6-47(a)(21) and Ga. Comp. R. & Regs. r. 111-2-2-.03(24).

(b) If the service will be provided within a licensed acute care hospital, the hospital shall be the applicant.

(c) If cardiac catheterization services will be provided in a DTRC, the organizational entity that develops the service shall be the applicant.

(d) Seeking and receiving approval from the Department under the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)3. shall neither be considered a new adult cardiac catheterization service nor an expanded service. Additionally, the issuance of such an approval shall not be construed to be anything other than a time-limited approval to participate in the particular medical research trial specified in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)(3).

(2) **Definitions.**

(a) "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.

(b) "Adult" means a person fifteen (15) years of age and over.

(c) "Authorized service" means an adult cardiac catheterization service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not yet become operational.

(d) "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents. If pediatric catheterizations are performed in a room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents.

(e) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(f) "Cardiac catheterization service" means an organized program which serves inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and rehabilitation center (DTRC) with a room or a suite of rooms, with equipment to perform angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization procedures. An authorized adult cardiac catheterization service is prohibited from performing coronary angioplasty procedures unless the acute care hospital where the service is located meets the requirements identified in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f).

(g) "Coronary angioplasty" means a cardiac catheterization procedure to treat coronary artery disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(h) "Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether congenital or acquired. Post-operative evaluation of the effectiveness of prostheses (e.g., heart valves or vein grafts) also can be accomplished through use of diagnostic cardiac catheterization.

(i) "Diagnostic, treatment, or rehabilitation center (DTRC)" means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting that is not part of a hospital.

(j) "Expanded Service" or "Expansion" means an adult cardiac catheterization service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the cardiac catheterization services are or will be offered, the cost of which exceeds the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of cardiac catheterization services; or that seeks the addition of a new catheterization laboratory or room regardless of cost. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such services is not an expansion for purposes of these Rules.

(k) "Horizon year" means the last year of a five-year projection period for need determinations for any adult cardiac catheterization services.

(l) "Official inventory" means the Department's inventory of all authorized hospital-based and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization laboratories or any other authorized laboratory approved for operation at the time of adoption of these Rules.

(m) "Official state component plan" means the document related to specialized cardiovascular services developed by the Department adopted by the Health Strategies Council and approved by the Board of Community Health.

(n) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization.

(o) "Planning area" means each of the planning areas designated in the official State Component Plan.

(p) "Therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of ameliorating certain conditions that have been determined to exist in the heart or great arteries or veins of the heart.

(3) **Standards.**

(a) The need for new or expanded adult cardiac catheterization services shall be determined through application of a numerical need method and an analysis of service demand based on an assessment of the aggregate utilization rate of existing services;

1. the numerical need for new or expanded adult cardiac catheterization services shall be determined by a population-based formula which includes current usage patterns and projected population as follows:

(i) calculate the current state adult cardiac catheterization rate for the most recent year of reported survey or hospital and outpatient discharge data by dividing the total number of adult cardiac catheterizations performed on Georgia residents by the total state adult Resident population;

(ii) determine the projected adult cardiac catheterization procedures for the horizon year by multiplying the state rate by the adult Resident population for the planning area for the horizon year;

(iii) adjust the projected adult cardiac catheterization procedures for the planning area by adding the out-of-state hospital-based catheterizations for the most recent year based on the percentage of total procedures performed on out-of-state patients by hospitals in each planning area;

(iv) convert projected adult cardiac catheterization procedures to procedure equivalents by multiplying the projected procedures by the statewide rate of equivalents per catheterization; and

(v) determine the projected net surplus or deficit for adult cardiac catheterization capacity, expressed in terms of rooms/laboratories, in the planning area by subtracting the rooms/laboratories needed for the total projected procedure equivalents calculated in steps (i) through (iv) from the total capacity (1300 procedure equivalents per room/laboratory) based on the official inventory.

2. before a new or expanded adult cardiac catheterization service will be approved in any planning area, the aggregate utilization rate of all adult cardiac catheterization services in that planning area shall be eighty-five percent (85%) or more during the most recent year;

(b) 1. The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(a) in the following circumstances:

(i) actual utilization in the applicant's existing service has exceeded ninety percent (90%) of capacity over the past two (2) years;

(ii) to remedy an atypical barrier to adult cardiac catheterization services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(I) An atypical barrier to services based on cost may include the failure of existing providers of adult cardiac catheterization services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state and/or planning area.

(II) An atypical barrier to services based on quality may include the failure of existing providers of adult cardiac catheterization services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.

(III) An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers of services within the community to provide services to indigent, charity, and Medicaid patients.

(IV) An atypical barrier to services based on geographic accessibility may include a planning area which has an adult cardiac catheterization rate significantly less than the state rate (two or more standard deviations from the mean), a cardiovascular disease rate as projected through death and hospital discharge data which is significantly

higher than the state rate (two or more standard deviations from the mean), and other demographic risk factors which can be documented through research and clinical studies.

(V) An applicant seeking approval for a new or expanded adult cardiac catheterization service solely for the purpose of providing cardiac electrophysiological studies may apply for consideration under the terms of an atypical barrier; provided, however, that any such applicant if approved shall be restricted to the provision of electrophysiological studies.

2. The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(a) and (3)(c) for any cardiac catheterization service seeking an expansion, other than the addition of another laboratory or room; provided the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(d), (e), (f), (g), (h), (j) ,(k) and (l).

(c) An applicant for a new or expanded adult cardiac catheterization service shall document that authorized cardiac catheterization services which could be adversely impacted by the establishment of the new or expanded service are not predicted to perform less than eighty percent (80%) of capacity as a result of the establishment of the new or expanded service. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application.

(d) An applicant for a new or expanded adult catheterization service shall demonstrate a plan whereby the service and its medical staff agree to provide a full array of cardiovascular services to the community, including, but not limited to, education and outreach, prevention and screening, diagnosis and treatment, and rehabilitation.

(e) An applicant for a new or expanded adult cardiac catheterization services shall:

1. demonstrate the ability to meet the optimal clinical and physical environment standards established in the most recent American College of Cardiology/American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. These standards include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services;

2. document the availability of, or shall present a plan for recruiting, at least two board-certified cardiologists with training and qualification in cardiac catheterization, and, if applicable with training and qualification in coronary intervention, who will reside within one hour drive of the service site; and

3. document a plan for obtaining a sufficient number of clinical, professional and technical staff to safely and effectively operate the service.

(f) An authorized adult cardiac catheterization service shall not perform catheterization procedures requiring open heart surgery backup as part of its service unless the acute care hospital where the service is located:

1. operates an existing adult open heart surgery service;

2. has a Department approved written agreement for open heart surgery backup with an adjacent acute care hospital as defined by these Rules; or

3. has been accepted as a participant in a randomized medical research trial comparing patient outcomes after non-primary Percutaneous Coronary Intervention (PCI) in hospitals with and without cardiac surgery on-site, which also requires the performance of Primary PCI and has a parallel Primary PCI Registry, and which is coordinated by the Atlantic Cardiovascular-Patient Outcomes Research Team (Atlantic C-PORT). The authorized adult cardiac catheterization service must receive such Atlantic C-PORT acceptance and also must obtain written approval from the Department to perform such procedures, except that the Department may approve no more than ten (10) existing and authorized hospital services for participation, regardless of the number of such services that are accepted by Atlantic C-PORT.

(i) Any request for such Departmental approval must be submitted to the Department no later than June 30, 2005 in writing on a form developed by the Department for such purposes. Prior to final approval to participate by the Department, the requesting authorized service must provide written proof it has been accepted by Atlantic C-PORT as a participant in said trial under all applicable protocols;

(ii) In reviewing and approving such requests, the Department shall take into consideration such factors including, but not limited to, rural, suburban or urban location of the service, mix of patients to be treated, whether the service has the capability of performing a minimum of 100 PCIs (elective and primary combined) during the first year of such approval, 200 PCIs (elective and primary combined) during the second year of such approval unless a lower number, but not below 150 PCIs, is approved for specific reasons by both the Department and the trial chairperson, and 200 PCIs (elective and primary combined) during the third year of such approval, and whether the service has on its staff physicians and support staff with training and experience in both therapeutic and diagnostic cardiac catheterizations;

(iii) The selection of an authorized service for participation pursuant to this Rule will be made at the sole discretion of the Department; however, the Department shall consult with medical experts in the fields of cardiology and percutaneous coronary intervention when making the decision to approve or not approve a particular service for participation in such trial;

(iv) Any approval obtained from the Department in this regard shall only be valid for as long as the health care facility receiving such approval is an active participant in the trial; however, in no case shall such approval continue to be valid upon Atlantic C-PORT declaring the trial concluded, or under no circumstance for a period in excess of three (3) years from the time the authorized service's first procedure is conducted under the authority of the Department's approval and Atlantic C-PORT's acceptance to begin active participation in the trial; whichever event occurs first; and

(v) As any such Departmental approval is conditioned on being an active participant in the trial, should an authorized service which has received approval under the provisions of this Rule be expelled or otherwise lose the approval of Atlantic C-PORT to continue participation, the Department's approval will be simultaneously withdrawn without said service's or facility's right to an appeal of the Department's withdrawal of its approval to participate in such trial.

(g) Catheterization procedures requiring open heart surgery backup include coronary angioplasty and the following:

1. catheter atherectomy;

2. catheter endomyocardial biopsy;

3. left ventricular puncture;

4. percutaneous transluminal coronary angioplasty;

5. percutaneous catheter balloon valvuloplasty; and

6. transeptal catheterization.

(h) An applicant for a new or expanded adult cardiac catheterization service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac catheterization services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) A clinical intervention program for all catheterization patients that shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program, if not operated by a facility with an existing Open Heart Surgical Service, shall submit a written affiliation agreement with at least one Open Heart Surgical Service that provides, at a minimum, for:

(I) a plan to transplant and handle acute cardiac emergencies;

(II) a plan to facilitate referral of patients for whom surgery or angioplasty may be indicated without unnecessarily repeating diagnostic studies; and

(III) a plan for ongoing communications between representatives of the Open-Heart Surgical Service and the proposed applicant, to allow for review of pre-operative and post-operative processes and specific cases.

(iii) The program shall provide for annual support and participation in at least three (3) professional education programs targeted to community-based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iv) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(i) An applicant for a new or expanded adult cardiac catheterization service must project and, if approved, shall document that the proposed service will be performing a minimum of 1,040 adult cardiac catheterization procedure equivalents within three (3) years of initiation of the service and annually thereafter within the authorized guidelines for such services. Such projections, at a minimum, shall include consideration of patient origin data for catheterization services, the use rate of existing services, referral data and market patterns for existing hospital and DTRC services in the community, and cardiovascular disease incidence rates and related health indicators. An applicant seeking approval solely for the purpose of providing electrophysiological (EP) studies shall not be required to document a projected performance minimum but shall be required to document compliance with guidelines for EP studies issued by the American College of Cardiology.

(j) An applicant for a new or expanded adult cardiac catheterization service shall provide documentation that the service is fully accredited by the Joint Commission or another nationally recognized health care accreditation body, in the case of an applicant proposing a new facility location, shall provide a written commitment to secure full

accreditation by the Joint Commission or another nationally recognized health care accreditation body within eighteen (18) months of initiating operation.

(k) An applicant for a new or expanded adult cardiac catheterization service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(h), that such services shall be provided regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the adult cardiac catheterization service, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(l) An applicant for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital or DTRC as well as a national, state or multi-program system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital or DTRC;

3. development of procedures to ensure that cardiologists and any other physicians providing care in the cardiac catheterization service or related services shall be required to accept Medicaid, PeachCare and Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(m) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.21

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.22 Specific Review Considerations for Adult Open Heart Surgery Services

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or, subject to certain stipulations, expanded adult open heart surgical service.

(2) **Definitions.**

(a) "Adult" means persons 15 years of age and over.

(b) "Authorized service" means an adult open heart surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(c) "Coronary Angioplasty" means a cardiac catheterization procedure to treat coronary heart disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(d) "Expanded Service" or "Expansion" means an adult open heart surgery service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the adult open heart surgery service is or will be offered, the costs of which exceed the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of open heart surgery services; or, for any service a full four (4) years or more following implementation of an approved Certificate of Need, that increases adult open heart surgery volume to a level resulting in a twenty-five percent (25%) or more increase in procedures being performed by the service over the higher annual number of procedures having been performed during the most recent prior two calendar years. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such service is not an expansion for purposes of these Rules.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung by-pass machine (extracorporeal pump) may be used to perform the work of the heart and lungs.

(g) "Open heart surgery service" means an organized surgical program that serves inpatients of a hospital that has a suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services

required to perform adult open-heart surgery. The adult open heart surgery service shall be located in an acute care hospital that has an authorized adult cardiac catheterization service.

(h) "Procedure" means an adult open heart surgery operation or combination of operations performed in a single session on a single patient who appears for open heart.

(3) **Standards.**

(a) 1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(i) An atypical barrier to services based on cost may include the failure of existing providers of open-heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.

(iii) An atypical barrier to services based on financial access may include the repeated failure as exhibited by a documented pattern over two or more years prior to the submission of the application, of an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b) 1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c), (d), (e), (g), (h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c), (d), (e), (g), (h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

(i) repair and replacement of heart valves;

(ii) cardiac revascularization;

(iii) treatment of cardiac trauma;

(iv) repair of congenital defects in adults; and

(v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(i) medicine: cardiology, hematology, nephrology;

(ii) radiology: diagnostic, nuclear medicine;

(iii) surgery: cardiovascular, thoracic;

(iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

(v) anesthesiology: inhalation therapy; echocardiology in the operating room;

(vi) neurology;

(vii) special laboratories: cardiac catheter/angiographic;

(viii) clinical dietary;

(ix) cardiac surgical intensive care unit;

(x) pacemaker therapy;

(xi) cardiac rehabilitation services;

(xii) renal dialysis; and

(xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives;

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

(iv) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.

(v) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

(3) **Standards.**

(a) 1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(i) An atypical barrier to services based on cost may include the failure of existing providers of open-heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.

(iii) An atypical barrier to services based on financial access may include the repeated failure as exhibited by a documented pattern over two or more years prior to the submission of the application, of an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b) 1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c), (d), (e), (g), (h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c), (d), (e), (g), (h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

(i) repair and replacement of heart valves;

(ii) cardiac revascularization;

(iii) treatment of cardiac trauma;

(iv) repair of congenital defects in adults; and

(v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(i) medicine: cardiology, hematology, nephrology;

(ii) radiology: diagnostic, nuclear medicine;

(iii) surgery: cardiovascular, thoracic;

(iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

(v) anesthesiology: inhalation therapy; echocardiology in the operating room;

(vi) neurology;

(vii) special laboratories: cardiac catheter/angiographic;

(viii) clinical dietary;

(ix) cardiac surgical intensive care unit;

(x) pacemaker therapy;

(xi) cardiac rehabilitation services;

(xii) renal dialysis; and

(xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives;

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

(iv) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.

(v) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(e) An applicant for a new or expanded adult open heart surgery service shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(d), that such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the adult open heart surgery service, or the applicant may request that the Department allow the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(f) In considering applications joined for review for new adult open heart surgery services, the Department may give favorable consideration to an applicant which historically has provided a higher annual percentage of unreimbursed services to indigent and charity patients and a higher annual percentage of services to Medicare and Medicaid patients.

(g) An applicant for a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the American College of Surgeons and the Advisory Council for Cardiothoracic Surgery of the American College for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, support services, physical plant, and equipment.

2. Document the availability of; or shall present a plan for recruiting, a qualified surgeon certified by the American Board of Thoracic Surgery with special qualifications in cardiac surgery.

3. Document a plan for obtaining a sufficient number of professional and technical staff; including cardiac intensive care nurses, for the size of the adult open heart surgery program proposed and document that the operating room team necessary for an adult open heart surgical procedure shall be available, including a cardiovascular surgeon who is board certified by the American Board of Thoracic Surgery; a second physician who is a cardiovascular or thoracic surgeon or surgical resident; a board-certified anesthesiologist trained in open heart surgery; a circulating nurse or scrub nurse (RN); an operating room technician or registered nurse trained in cardiac procedures; and one or two pump technicians, with one being certified and one qualified.

(h) An applicant for a new or expanded adult open heart surgery service shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation body, and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

(i) An applicant for a new adult open heart surgery service shall demonstrate that charges and/or reimbursement rates for the service shall compare favorably with charges and/or reimbursement rates in existing adult open heart surgery services in the state when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for adult open heart surgery procedures, the Department may compare the applicant's history of charges and/or reimbursement rates for cardiac catheterization procedures and other treatments and/or interventions for disorders of the circulatory system and for open heart procedures, if applicable, with such charges and/or reimbursement rates in other similar hospitals.

(j) An applicant for a new or expanded adult open heart surgery service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs; and

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;

3. development of procedures to ensure that any surgeon authorized to perform open heart surgery for the hospital shall be required to perform at least 100 procedures on annual basis across his or her various practice settings, and shall be required to accept Medicaid or Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(k) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.22

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

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111-2-2-.23 Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery

(1) **Definitions.**

(a) "Authorized service" means a pediatric cardiac catheterization service or pediatric cardiac surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(b) "Capacity" means:

1. for a pediatric catheterization service:

(i) in considering applications for a new pediatric cardiac catheterization service, 750 procedures per year per authorized service regardless of the number of rooms used; or

(ii) in considering applications for expansion of an existing service, 750 pediatric cardiac catheterization procedures per dedicated room per year in the existing service (3 per day per room, 5 days per week, 50 weeks per year) and for each multipurpose room in the existing service, 750 procedures (special procedures and pediatric cardiac catheterization procedures) per year. If adult and pediatric cardiac catheterization are performed in the same room in a service seeking to expand, the capacity of the room shall be equivalent to 750 pediatric procedures with adult procedures performed in the room weighted in proportion to pediatric procedures as being 0.50 for each adult cardiac catheterization or special procedure, except for each adult coronary angioplasty, which shall be 0.75, in order to determine the service's use rate; or

2. for a pediatric cardiac surgery service, the number of pediatric cardiac surgery procedures which could be performed annually as reported by each hospital with an authorized service and based on survey and other reported data. In determining capacity, a hospital must consider factors such as available operating rooms which can be used for pediatric cardiac surgery, cardiac surgical intensive care beds and other pediatric intensive care beds available for pediatric patients, general bed capacity, and any other factors which impact the determination.

(c) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image

intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(d) "Closed heart surgery" means an operation performed directly on the heart or its associated veins or arteries that does not require use of a heart and lung bypass machine (extracorporeal pump) to perform the work of the heart and lungs. Such operations often require the bypass machine to be available on standby for use if the surgery needs to be changed to open heart with the machine then performing the work of the heart and lungs.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department, established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung bypass machine (extracorporeal pump) is used to perform the work of the heart and lungs.

(g) "Pediatric" refers to children 14 years of age and under.

(h) "Pediatric cardiac catheterization service" means an organized program which serves pediatric patients of a hospital which has a room or suite of rooms with the equipment, staff, and all support services required to perform angiographic, physiologic, and, as appropriate, therapeutic cardiac catheterization procedures. The pediatric cardiac catheterization service shall be located in a pediatric tertiary hospital. Procedures may be performed in a room dedicated to cardiac catheterization and/or in a special procedures or multipurpose room not exclusively used for cardiac catheterization.

(i) "Pediatric cardiac surgery" means an operation performed directly on a pediatric patient's heart or its associated veins or arteries, including open heart and closed heart surgery procedures but excluding surgical procedures for the closure of neonatal patent ductus arteriosus.

(j) "Pediatric cardiac surgery service" means an organized surgical program which serves pediatric inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, and all support services required to perform closed heart and open-heart operations for pediatric patients. The pediatric cardiac surgery service shall be located in a pediatric tertiary hospital.

(k) "Pediatric tertiary hospital" means a teaching center, specialty medical or large community hospital characterized by serving pediatric patients from a large region or the entire state with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients.

(l) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization or a pediatric open or closed heart operation or combination of operations performed in a single session on a single patient who appears for pediatric cardiac surgery.

(m) "Service area", for pediatric cardiac catheterization and pediatric cardiac surgery means the State of Georgia.

(2) **Standards**.

(a) An applicant for new pediatric cardiac catheterization and pediatric cardiac surgery services must be a pediatric tertiary hospital. Due to the highly specialized nature of pediatric cardiac catheterization and pediatric cardiac surgery services, applicants for these services must propose to provide both pediatric cardiac catheterization and pediatric cardiac surgery. Only those projects that meet all applicable standards for both services will be approved.

(b) New pediatric cardiac catheterization services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate for all existing and approved pediatric cardiac catheterization services in the state has been at or above eighty percent (80%) of capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one-hundred fifty (150) procedures per year within three (3) years of initiation of the service in order to maintain and strengthen skills. Such projection at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac catheterization services that would be impacted by the establishment of the new service are not predicted to perform less than the minimum quality level of one-hundred fifty (150) procedures annually as a result of the establishment of the new service.

(c) An application for expansion of an existing pediatric cardiac catheterization service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two (2) years and the applicant can project a minimum of one-hundred fifty (150) additional pediatric procedures per year within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(d) New pediatric cardiac surgery services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate of all authorized pediatric cardiac surgery services in the state has been at or above eighty percent of (80%) capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one hundred (100) pediatric cardiac surgery procedures per year, of which at least fifty (50) are open heart operations, within three years of initiation of the service in order to maintain and strengthen skills. Such projections at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac surgery services which would be impacted by the establishment of the new services are not predicted to perform less than the minimum quality level of one hundred (100) procedures annually, of which at least fifty (50) are open heart operations, as a result of the establishment of the new service.

(e) An application for expansion of an existing pediatric cardiac surgery service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two years and the applicant can project a minimum of one hundred 100 additional pediatric cardiac surgery procedures, of which at least fifty (50) are open heart operations, within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(f) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult cardiac catheterization services, the hospital shall have support services and equipment necessary for the diagnosis and treatment of infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics.

(g) An applicant for a new or expanded pediatric cardiac surgery service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult open-heart surgery, the hospital shall have support services and equipment necessary for surgery on infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers. This includes a complete pediatric cardiology unit, a neonatal intensive care unit, a pediatric intensive care unit, and a general pediatric unit with pediatric sub-specialists in hematology, endocrinology, pulmonary neurology, and radiology.

(h) An applicant for a new or expanded pediatric cardiac catheterization service or for a new or expanded pediatric cardiac surgery service shall document that the service shall be available for the performance of procedures as needed at least eight hours per day, five days per week, and shall document the capability to rapidly mobilize the surgical and medical support teams for emergency procedures 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(i) An applicant for a new or expanded pediatric cardiac catheterization service and/or pediatric cardiac surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) A clinical intervention program for all patients that shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iii) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

3. propose a system of outcome monitoring and quality improvement and identify at least five (5) clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(j) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the pediatric cardiac catheterization and surgical services, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid and PeachCare programs and to accept any Medicaid- and/or PeachCare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(k) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. demonstrate the intent to achieve the optimal standards established by the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac catheterization services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment;

2. document the availability of, or shall present a plan for recruiting, a qualified service director who is a physician, board-certified in pediatrics, with subspecialty training and board eligibility in pediatric cardiology and who is competent to perform physiologic and angiographic procedures or both; and

3. document a plan for obtaining a sufficient number of professional and technical staff for the size of the pediatric cardiac catheterization service proposed, including a pediatric nurse, radiologic technologist, cardiopulmonary technician, and darkroom technician and document that the staff required for most procedures shall be available, including two physicians, one nurse, and two technicians, with the nurse and technicians cross trained to cover technical responsibility of the monitoring and recording technicians.

(l) An applicant for a new or expanded pediatric cardiac surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the Advisory Council for Cardiothoracic Surgery of the American College of Surgeons, and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment.

2. Document the availability of, or shall present a plan for recruiting, a qualified pediatric cardiac surgery director who is a pediatric cardiovascular surgeon, board-certified in thoracic surgery, with special emphasis and experience in surgery for congenital heart disease.

3. Document a plan for obtaining a sufficient number of professional and technical staff, including pediatric cardiac intensive care nurses, for the size of the pediatric cardiac surgery service proposed, including at least two board-qualified cardiac surgeons on the staff of the hospital and a cardiovascular surgical team which includes a neonatologist, a pediatric anesthesiologist, a pediatric radiologist, a pediatric cardiologist, a nurse clinician, and backup of medical social services.

(m) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation body and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and Medicaid certification deficiencies in the past three (3) years and has no outstanding licensure and Medicare and Medicaid certification deficiencies.

(n) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall demonstrate that the applicant's charges and/or reimbursement for pediatric cardiac catheterization and pediatric cardiac surgery services shall compare favorably with charges and/or reimbursement in existing pediatric cardiac catheterization and pediatric cardiac surgery services in the state, when adjusted for annual inflation.

(o) An applicant for new or expanded pediatric cardiac catheterization and/or pediatric cardiac surgery services must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;

3. development of procedures to ensure that any surgeon or cardiologists authorized to perform pediatric cardiac services for the hospital shall be required to accept Medicaid and PeachCare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(p) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.23

AUTHORITY: O.C.G.A. **§§** 31-2 *et seq.,* 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Pediatric Cardiac Catheterization and Open Heart Surgery" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: New title, "Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery." F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.24 Specific Review Considerations for Perinatal Services

(1) **Applicability.** For Certificate of Need purposes, Basic Perinatal Services, Neonatal Intermediate Care Services (Specialty/Level II), and Neonatal Intensive Care Services (Subspecialty/Level III) shall be defined as new institutional health services.

(2) **Definitions.**

(a) "Basic Perinatal Services (Level I)" means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(b) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has conducted a survey within six (6) months of the date of completion of the first application when applications are joined, the Department may consider the most recent year to be the report period covered by the prior survey.

(c) "Neonatal Intensive Care Service (Subspecialty/Level III)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service and meets the definition of a Subspecialty Perinatal Hospital Service as contained in the most recent edition of the Recommended Guidelines for Perinatal Care in Georgia, as published by the Council on Maternal & Infant Health.

(d) "Neonatal Intermediate Care Service (Specialty/Level II)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service and meets the definition of a Specialty Perinatal Hospital Service as contained in the most recent edition of the Recommended Guidelines for Perinatal Care in Georgia, as published by the Council on Maternal & Infant Health.

(e) "Neonatal Newborn Care Service (Basic/Level I)" means a hospital service which meets the minimum standards contained in Chapter 111-8-40 of the Rules of the Healthcare Facility Regulation Division, such chapter being entitled "Newborn Service. Amended."

(f) "Obstetric Service" means a hospital service that meets the minimum standards contained in Chapter 111-8-40 of the Rules of the Healthcare Facility Regulation Division, such chapter being entitled "Maternity and Obstetric Service. Amended."

(g) "Official Inventory" means the inventory for each hospital of Basic Perinatal Service and Neonatal Intermediate and Intensive Care Service beds maintained by the Department based upon responses to the Annual Hospital Questionnaire (AHQ) and/or its Perinatal Addendum and any Certificate of Need approved beds after the period covered by the AHQ and with the following provisions:

1. the official inventory for each facility will remain unchanged for the year following the last day of the report period on each hospital's completed AHQ and/or its Perinatal Addendum unless the Department approves a change of bed capacity through the Certificate of Need process; and

2. the capacity of existing freestanding birthing centers will not be counted as part of the official inventory of available services when computing unmet numerical need for Basic Perinatal Services in a planning area.

(h) "Perinatal physician training program" refers to obstetrics and gynecology, family practice and pediatrics disciplines.

(i) "Planning Areas" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Perinatal Services.

(j) "Regional Perinatal Center" (RPC) means those hospitals designated by the Department of Public Health to serve a defined geographic area to provide the highest level of comprehensive perinatal health care services for pregnant women, their fetuses and neonates of all risk categories. The RPC accepts patients in need of these services from its region regardless of race, creed, religion, ability to pay, or funding source. The RPC provides consultation and transport for patients requiring special services; coordination and assurance of follow-up medical care for maternal and neonatal patients requiring special care; educational support to ensure quality care in institutions involved in perinatal health care; compilation, analysis, and evaluation of perinatal data from the center and referring hospitals and coordination of perinatal health care within the region.

(k) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) **Standards.**

(a) The need for a new or expanded Obstetric Service, Neonatal Intermediate Care Service and Neonatal Intensive Care Service shall be determined through application of a Numerical Need method and an assessment of the aggregate occupancy rate of existing services.

1. The numerical need for a new or expanded Obstetric Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the average obstetric utilization rate (UR) by dividing the obstetric days (OBDays) reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the female population ages 15 to 44 (FP) for the corresponding years:

$$UR = \frac{OBDays_1 + OBDays_2}{FP_{YR}1 + FP_{YR}2}$$

(ii) Multiply the obstetric utilization rate by the projected female population ages 15 to 44 (PFP) for the horizon year to determine the number of projected obstetric days (POBDays):

$$POBDays = URxPFP$$

(iii) Calculate the number of projected obstetric beds (POBBeds) by dividing the number of projected obstetric days by 273.75 (the result of 365 days multiplied by the occupancy standard of seventy-five percent (75%)) with any fraction rounded up to a whole bed:

$$POBBeds = \frac{POBDays}{273.75}$$

(iv) Determine the net numerical unmet need (UN) for new or additional obstetric beds by subtracting the number of beds in the Official Inventory (OI) from the number of projected obstetric beds:

$$UN = POBBeds - OI$$

2. The numerical need for a new or expanded Level II Neonatal Intermediate Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Public Health or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intermediate care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intermediate care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live births divided by the actual number of resident live births (RB) available from the Department of Public Health or other official source for the most recent calendar year:

$$PN2Days = N2Daysx\frac{PRB}{RB}$$

(iv) Project neonatal intermediate care bed need (N2Beds) into the horizon year by dividing the projected patient days for neonatal intermediate care services by 292 (the result of 365 days multiplied by the occupancy rate of eighty percent (80%)) with any fraction rounded up to a whole bed:

$$N2Beds = PN2\frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intermediate care bed need:

$$UN = N2Beds - OI$$

3. The numerical need for a new or expanded Level III Neonatal Intensive Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Public Health or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intensive care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intensive care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live births divided by the actual number of resident live births (RB) available from the Department of Public Health or other official source for the most recent calendar year:

$$PN2Days = N2Days x \frac{PRB}{RB}$$

(iv) Project neonatal intensive care bed need (N2Beds) into the horizon year by dividing the projected patient days for neonatal intensive care services by 292 (the result of 365 days multiplied by the occupancy rate of eighty percent (80)) with any fraction rounded up to a whole bed:

$$N2Beds = PN2\frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intensive care bed need:

$$UN = N2Beds - OI$$

4. Prior to approval of a new or expanded Obstetric Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service in a planning area, the aggregate occupancy rate for all similar services in that planning area shall equal or exceed seventy-five percent (75%) for an Obstetric Service and eighty percent (80%) for a Neonatal Intermediate Care Service or Neonatal Intensive Care Service for each of the two (2) most recent years.

(b) Exceptions to need may be considered by the Department as follows:

1. To provide that an applicant for new basic perinatal services shall not be subject to the need standard of section (3)(a)1. or the aggregate occupancy standard of section (3)(a)4. of this Rule if:

(i) The proposed new service would be located in a county where only one civilian health care facility or health system is currently providing basic perinatal services; and

(ii) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services.

2. To allow expansion of an existing Level I or Level II or Level III service, if the actual utilization of that service has exceeded 80 percent occupancy over the most recent two years; or

3. To remedy an atypical barrier to perinatal services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care or Neonatal Intensive Care Service shall document the impact on existing and approved services in the planning area with the goal of minimizing adverse impact on the delivery system and as follows:

1. An existing perinatal physician training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient number and variety of

patients to maintain an appropriate number of providers and provider competencies and the training program's accreditation and funding status;

2. An existing nurse midwifery training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain an appropriate number of providers and provider competencies to sustain a sufficient number and variety of patients to maintain the training program's accreditation; and

3. An existing regional perinatal center shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient volume and case mix of patients including both low risk and high risk deliveries to maintain its regional center status.

(d) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the entire facility after Medicare and Medicaid contractual adjustments and bad debt have been deducted;

3. providing a written commitment to participate in the Medicaid program;

4. providing a written commitment to participate in any other public reimbursement programs available for perinatal services for which the hospital is eligible; and

5. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(e) The desired minimum bed size for a Basic Perinatal Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service is as follows:

1. At least four beds for a new Basic Perinatal, Neonatal Intermediate Care, or Neonatal Intensive Care Service.

2. The Department may grant an exception to these standards when the Department determines that unusual circumstances exist that justify such action.

(f) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of ability to meet the following continuity of care standards:

1. Document a plan whereby the hospital and its medical staff agree to provide a full array of perinatal services to the community, including but not limited to community education and outreach, prenatal, intrapartum, postpartum, newborn, and postnatal services; and

2. As appropriate, provide a formal transfer agreement with at least one hospital within reasonable proximity that provides services to high-risk mothers and babies.

(g) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of the ability to meet the following quality of care standards:

1. evidence that qualified personnel will be available to ensure a quality service to meet licensure, certification and/or accreditation requirements;

2. written policies and procedures for utilization review consistent with state, federal and other accreditation standards. This review shall include assessment of medical necessity for the service, quality of patient care, and rates of utilization;

3. written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division; and

4. evidence that there are no uncorrected operational standards in any existing Georgia hospitals owned and/or operated by the applicant or the applicant's parent organization. Plans of correction in the applying facility must be included in the application.

(h) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.24

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Perinatal Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.25 Specific Review Considerations for Freestanding Birthing Centers

(1) A Certificate of Need for a proposed new freestanding birthing center will be issued only if the services to be provided are consistent with the philosophy of family-centered care as defined in the State Health Plan and if there is evidence of safe and quality service at a charge lower than charges for deliveries provided on an inpatient basis.

(2) The applicant must agree to meet the rules and regulations for the development and operation of birthing centers required by the Healthcare Facility Regulation Division.

(3) The applicant must provide evidence that the birthing center will function as part of the established regionalized system of perinatal care. This includes arrangements for referral of those clients who develop complications that make them ineligible for delivery at the birthing center.

(4) A birthing center must have a written agreement for transfer and emergency services with a backup hospital(s) that provides at least Level II perinatal services. Each physician practicing at the center must have admitting privileges at the backup hospital.

(5) It must be demonstrated that agreements for ambulance service are available. In emergency situations, the center must have the capability of transporting the adult and/or newborn patients to the backup hospital within 30 minutes from initiation of transfer to the arrival at the hospital.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.25

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111-2-2-.26 Specific Review Considerations for Psychiatric and Substance Abuse Inpatient Programs

(1) **Applicability.**

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing acute care adult psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded acute care adult psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an acute care adult psychiatric and/or substance abuse inpatient program may offer both acute care psychiatric and acute care substance abuse inpatient care, acute care substance abuse inpatient care alone, or acute care psychiatric inpatient care alone. A facility approved to offer acute care adult psychiatric and/or substance abuse inpatient services may not offer an acute care pediatric psychiatric and/or substance abuse inpatient program, nor any type of extended care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing acute care pediatric psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded acute care pediatric psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an acute care pediatric psychiatric and/or substance abuse inpatient program may offer both acute care psychiatric and acute care substance abuse inpatient care, acute care substance abuse inpatient care alone, or acute care psychiatric inpatient care alone. A facility approved to offer acute care pediatric psychiatric and/or substance abuse inpatient services may not offer an acute care adult psychiatric and/or substance abuse inpatient program, nor any type of extended care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(c) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing extended care adult psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded extended care adult psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an extended care adult psychiatric and/or substance abuse inpatient program may offer both extended care psychiatric and extended care substance abuse inpatient care, extended care substance abuse inpatient care alone, or extended care psychiatric inpatient care alone. A facility approved to offer extended care adult psychiatric and/or substance abuse inpatient services may not offer an extended care pediatric psychiatric and/or substance abuse inpatient program, nor any type of acute care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(d) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing extended care pediatric psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded extended care pediatric psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an extended care pediatric psychiatric and/or substance abuse inpatient program may offer both extended care psychiatric and extended care substance abuse inpatient care, extended care substance abuse inpatient care alone, or extended care psychiatric inpatient care alone. A facility approved to offer extended care pediatric psychiatric and/or substance abuse inpatient services may not offer an extended care adult psychiatric and/or substance abuse inpatient program, nor any type of acute care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(2) **Definitions**.

(a) "Acute care psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means a psychiatric or substance abuse program, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a), that provides acute and/or emergency stabilization and other treatment for acute episodes. An acute care program provides medically oriented evaluation, diagnosis, stabilization, and short-term treatment using individual and/or group therapies as well as other treatment activities. Two acute care programs are defined: adult psychiatric and/or substance abuse and pediatric psychiatric and/or substance abuse.

(b) "Adult", for purposes of these Rules, means a person 18 years of age and over or an emancipated person.

(c) "Expansion" or "Expanded" means exceeding a health care facility's total approved inpatient bed capacity through the addition of beds to an existing CON-authorized or grandfathered psychiatric and/or substance abuse inpatient program. A CON-authorized or grandfathered freestanding psychiatric and/or substance abuse hospital may request a letter of determination to increase its bed capacity by the lesser of ten percent (10%) of existing capacity or ten (10) beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two (2) years and provided that the capital expenditures associated with the increase do not exceed the Capital Expenditure Threshold. If such an increase exceeds the Capital Expenditure Threshold, a Certificate of Need shall be required under these Rules.

(d) "Extended care psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means a psychiatric or substance abuse program, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a), that focuses on self-help and basic living skills to enhance the patient's abilities to perform successfully in society upon discharge by emphasizing psycho-social, vocational and/or prevocational, and educational components in its treatment plan. The program is designed to treat people who do not require acute care and who usually have already had at least one acute care admission. Due to this design, the staffing of extended care programs is different from that of acute care programs by having proportionately more therapeutic activities, educational, and social work staff and proportionately fewer nurses and physicians. Two extended care programs are defined: adult psychiatric and/or substance abuse and pediatric psychiatric and/or substance abuse.

(e) "Freestanding psychiatric and/or substance abuse hospital", for purposes of these Rules, means a self-contained hospital which provides only psychiatric and/or substance abuse treatment and is licensed as a separate hospital, either as a specialized hospital or specialized hospital/intensive residential treatment facility.

(f) "Inpatient" means services that are provided to patients admitted to a short-stay general hospital, specialized hospital, or specialized hospital/intensive residential treatment facility.

(g) "New" means a psychiatric and/or substance abuse inpatient program that has not offered a similar program in the prior twelve (12) months. Adult programs and pediatric programs and acute care programs and extended care programs shall each be considered independent programs such that a provider seeking to add a program not offered by that provider in the previous twelve (12) months shall be considered to be offering a new program for which a Certificate of Need must be obtained. For purposes of these Rules, an existing program which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(h) "Pediatric", for purposes of these Rules, means a person seventeen (17) years of age and under or persons age twenty-one (21) or under as clinically indicated.

(i) "Planning Region" means one of the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

(j) "Psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means an organized entity with a specific plan and intent to serve a special population via designated staff in designated beds in a licensed hospital. Such a program provides services on a 24-hour, seven days per week basis. The characteristics of a program shall include:

1. a clear, distinct plan which includes admission policies and criteria, treatment protocol, etc.; and

2. appropriately trained personnel for the age and disability group to be served by the program; and

3. all of the beds in a program are designated for patients in that specific program.

(k) "Psychiatric and/or substance abuse service", for purposes of these Rules, means any combination of organized psychiatric and substance abuse programs in a hospital.

(l) "Public sector bed", for purposes of these Rules, means a bed located in state owned and operated psychiatric and substance abuse regional hospitals which are maintained by the Department of Behavioral Health & Developmental Disability.

(m) "Similar existing and approved program", for purposes of these Rules, means an approved or existing organized program as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a) that provides services to the same age group (adults or pediatric), and for the same treatment model (acute or extended).

(3) **Standards.**

(a) An application for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide sufficient documentation of the need for such program(s) in the planning area. In the case of an application for an expanded psychiatric and/or substance abuse inpatient program, the applicant shall justify the need for the expansion by, at a minimum, documenting that the expansion program has achieved an occupancy rate of eighty percent (80%) for an adult program or an occupancy rate of seventy percent (70%) for a pediatric program for the most recent twelve (12) months prior to submitting an application, except that a pediatric program which has obtained an occupancy rate of sixty-five percent (65%) may be permitted to expand if such program demonstrates clinical reasons why seventy percent (70%) occupancy is not attainable.

(b) An application for a new or expanded psychiatric and/or substance abuse inpatient program(s) in an existing hospital shall not be approved unless the applicant provides sufficient documentation that it is not appropriate to convert existing hospital beds to beds designated for the proposed program(s) or to close existing hospital beds.

(c) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall document that the establishment or expansion of its program(s) will not have an adverse impact on similar existing and approved programs in its planning area. State-owned and -operated psychiatric and substance abuse regional hospitals shall not be required to document this standard.

1. Accounting for market share and future population growth, an applicant for a new or expanded adult psychiatric and/or substance abuse inpatient program(s) shall have an adverse impact on similar existing and approved programs if it will:

(i) decrease annual utilization of a similar existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twenty-four (24) months following the acceptance of the applicant's first patient; or

(ii) decrease annual utilization of a similar existing program, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twenty-four (24) months following the acceptance of the applicant's first patient.

2. Accounting for market share and future population growth, an applicant for a new or expanded pediatric psychiatric and/or substance abuse inpatient program(s) shall have an adverse impact on similar existing and approved programs if it will:

(i) decrease annual utilization of a similar existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than eighty percent (80%) within the first twenty-four (24) months following the acceptance of the applicant's first patient; or

(ii) decrease annual utilization of a similar existing program, whose current utilization is below eighty-five percent (85%), by five percent (5%) over the twenty-four (24) months following the acceptance of the applicant's first patient.

(d) A new psychiatric and/or substance abuse inpatient program(s) shall have the following minimum bed sizes based on type of program offered:

1. The minimum bed size of a new acute psychiatric and/or substance abuse program is eight beds.

2. The minimum bed size of a new extended care psychiatric and substance abuse inpatient program is eight beds.

3. The minimum bed size of a new freestanding psychiatric and/or substance abuse hospital primarily providing acute care and licensed as a specialized hospital is 50 beds.

4. The minimum bed size of a new freestanding psychiatric and/or substance abuse hospital primarily providing extended care and licensed as a specialized hospital or a specialized hospital/intensive residential treatment facility is 50 beds.

5. The minimum number of designated beds in the aggregate of any and all acute psychiatric and/or substance abuse programs in a general hospital is ten beds.

6. The minimum number of designated beds in the aggregate of any and all extended care psychiatric and substance abuse inpatient programs in a general hospital is ten beds.

(e) An applicant for a new psychiatric and/or substance abuse inpatient program(s) shall demonstrate the intent to meet the standards of the Joint Commission or another nationally recognized health care accreditation body applicable to the type of program to be offered within twelve (12) months of offering the new program. Extended care programs may demonstrate their intent to meet the standards of the Council on the Accreditation of Rehabilitation Facilities (CARF) or the Council on Accreditation (COA) in lieu of the Joint Commission or another nationally recognized health care accreditation body.

(f) An applicant for an expanded psychiatric and/or substance abuse inpatient program(s) shall be accredited by the Joint Commission for the type of program which the applicant seeks to expand prior to application. The applicant must provide proof of such accreditation. Extended care programs may be accredited by the Council on the Accreditation of Rehabilitation Facilities (CARF) or the Council on Accreditation (COA) in lieu of the Joint Commission or another nationally recognized health care accreditation body.

(g) An applicant for a new freestanding psychiatric hospital or intensive residential treatment facility shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such facilities.

(h) An applicant for an expanded freestanding psychiatric hospital or intensive residential treatment facility shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(i) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide documentation that the applicant has no uncorrected history of conditional level Medicare and Medicaid certification deficiencies in the past three years.

(j) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide sufficient documentation that the proposal is consistent with the following quality standards:

1. The program(s) shall maintain standards for the review and improvement of quality. To document such standards, the program(s) must submit quality improvement policies.

2. The program(s) shall maintain standards to ensure the continuity of patient care. To document such standards, the program(s) must submit policies governing admissions and availability of adequate discharge planning.

(k) An applicant for a new or expanded freestanding psychiatric and/or substance abuse inpatient program(s) shall document the existence of referral arrangements, including transfer agreements, with an acute-care hospital(s) within

the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(l) An applicant for a new or expanded acute or extended care psychiatric and/or substance abuse program(s) shall document that the program(s) will be financially accessible by:

1. providing sufficient documentation that unreimbursed services for indigent and charity patients in a new or expanded program(s) will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the program after provisions have been made for bad debt, and Medicaid and Medicare contractual adjustments have been deducted. If an applicant, or any facility in Georgia owned or operated by the applicant's parent organization, received a Certificate of Need for a hospital program(s) or service(s) or a total facility and the CON included an expectation that a certain level of unreimbursed indigent and/or charity care would be provided in the program(s), service(s), or hospital(s), the applicant shall provide sufficient documentation of the facility's(ies') provision of such care. An applicant's history, or the history of any facility in Georgia owned or operated by the applicant's parent organization, of not following through with a specific CON expectation of providing indigent and/or charity care at or above the expected level will constitute sufficient justification to deny an application; and

2. agreeing to participate in the Medicare and Medicaid programs, whenever these programs are available to the facility.

(m) Reserved.

(n) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall agree to provide the Department with requested information and statistical data related to the operation of such a program(s) on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.26

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Psychiatric and Substance Abuse Inpatient Programs" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.30 Specific Review Considerations for Skilled Nursing and Intermediate Care Facilities

(1) **Applicability**. A Certificate of Need will be required prior to the establishment of a new or expanded skilled nursing facility, intermediate care facility, or an intermingled facility.

(2) **Definitions.**

(a) "Horizon year" means the last year of the three-year projection period for need determinations for a nursing facility.

(b) "Hospital-based nursing facility" means a nursing facility which meets the current definition of "Hospital-Based Nursing Facilities" as defined in the current Policies and Procedures for Nursing Facility Services by the Georgia Department of Community Health, Division of Medical Assistance. A new hospital-based nursing facility can only result from conversion of existing inpatient space on the hospital's campus.

(c) "Intermediate care facility" ("ICF") means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(d) "Intermingled facility" means a nursing facility that provides both skilled intermediate levels of care.

(e) "Medicare distinct part skilled nursing unit" means a unit which meets the current definition of "Distinct Part of an Institution as SNF" as defined in the current Medicare Part A Intermediary Manual by the Centers for Medicare and Medicaid Services ("CMS") of the U.S Department of Health and Human Services.

(f) "Nursing facility" means a facility classified as either a skilled nursing facility, an intermediate care facility or an intermingled facility which admits patients by medical referral and provides for continuous medical supervision via 24-hour-a-day nursing care and related services in addition to food, shelter, and personal care.

(g) "Official State Health Component Plan" means the document related to the above-named services developed by the Department, established by the Georgia State Health Strategies Council, and adopted by the Board of Community Health.

(h) "Planning area" for all nursing facilities, with the exception of state nursing facilities, means the geographic regions in Georgia defined in the "Official State Health Component Plan". "Planning area for a state nursing facility" means the State of Georgia.

(i) "Retirement community-based nursing facility" means a nursing facility which operates as a lesser part of a retirement community which is a planned, age-restricted, congregate living development which offers housing, recreation, security, dietary services, and shared living areas accessible to all residents.

(j) "Skilled nursing facility" ("SNF") means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of the injured, disabled or sick persons.

(k) "State nursing facility" is a facility that meets the definition of a Nursing Facility as defined above and is owned and operated by a branch or branches of government of the State of Georgia.

(l) "Urban county" means a county with a projected population for the horizon year of 100,000 or more and population density for that year of 200 or more people per square mile. All other counties are "rural".

(3) **Standards**.

(a) The need for a new or expanded nursing facility in a planning area in the horizon year shall be determined through application of a numerical, supply-oriented need method and an assessment of current planning area utilization designed to measure demand for services.

1. The numerical need for a new or expanded nursing facility in any planning area in the horizon year shall be determined by a population-based formula which is a sum of the following:

(i) a ratio of 0.43 beds per 1,000 projected horizon year Resident population age 64 and younger;

(ii) a ratio of 9.77 beds per 1,000 projected horizon year Resident population age 65 through 74;

(iii) a ratio of 32.5 beds per 1,000 projected horizon year Resident population age 75 through 84; and

(iv) a ratio of 120.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The demand for services in each planning area will be measured by the cumulative facility bed utilization rate during the most recent survey year period. The utilization rate shall be determined by dividing the actual bed days of resident care by the bed days available for resident care.

3. In order to establish need for a new or expanded nursing facility in any planning area, the utilization rate in that planning area shall have equaled or exceeded ninety-five percent (95%) during the most recent survey year.

(b) The required bed size for a new nursing facility in a rural or urban county is as follows: (Rural/urban designation shall be based on the county within which the proposed facility is to be located.)

1. A freestanding nursing facility in a rural county: a minimum of 60 beds;

2. A freestanding nursing facility in an urban county: a minimum of 100 beds;

3. A hospital-based nursing facility in a rural county: a minimum of 10 beds and a maximum of 20 beds;

4. A hospital-based nursing facility in an urban county: a minimum of 20 beds and a maximum of 40 beds;

5. A retirement community-based nursing facility: 1 nursing home bed for each 4 residential units, with a minimum of 20 beds and a maximum of 30 beds.

(c) In competing applications, favorable consideration may be given for the inclusion of services for special needs populations, such as but not limited to, persons with Alzheimer's Disease and related disorders, medically fragile children, or persons with HIV/AIDS. An applicant must document a need for the service and that it is cost effective.

(d) The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a) under the following circumstances:

1. the establishment of a new Medicare distinct part skilled nursing unit if the proposed unit is to be in a county that does not have an existing Medicare unit; and if the applicant can document that there is limited access in the proposed planning area for skilled nursing services for Medicare patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years. The implementation of an approved Certificate of Need will be valid only if the proposed beds will be limited to Medicare recipients. This exception is available to existing nursing facilities and hospitals; or

2. the applicant for a new or expanded nursing facility can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to medically fragile children and HIV/AIDS patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years.

(e) An applicant for a new or expanded facility must document provision of continuity of care by meeting each of the following:

1. An applicant shall provide a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care; and

2. An applicant shall document the existence of proposed and/or existing referral agreements with a nearby hospital to provide emergency services and acute-care services to residents of the proposed or existing facility; and

3. An applicant shall provide existing or proposed rehabilitation plans for services to facility residents; and

4. An applicant shall provide existing or proposed discharge planning policies.

(f) An applicant for a new or expanded nursing facility must provide evidence of the intent to meet all appropriate requirements regarding quality of care as follows:

1. An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division;

2. An applicant shall provide evidence that there are no uncorrected operational standards in any existing Georgia nursing homes owned and/or operated by the applicant or by the applicant's parent organization. Plans to correct physical plant deficiencies in the applying facility must be included in the application;

3. An applicant and any facility owned and/or operated by the applicant or its parent organization shall have no previous conviction or Medicaid or Medicare fraud;

4. An applicant shall demonstrate the intent and ability to recruit, hire and retain qualified personnel to meet the current Medicaid certification requirements of the Department's Division of Medical Assistance for the services proposed to be provided and that such personnel are available in the proposed geographic service area;

5. An applicant shall provide a plan for a comprehensive quality improvement program that includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance; accordingly, and

6. In competing applications, favorable consideration will be given to an applicant that provides evidence of the ability to meet accreditation requirements of appropriate accreditation agencies within two years after the facility becomes operational.

(g) An applicant or a new or expanded facility must provide evidence of meeting the following standards pertaining to financial accessibility:

1. An applicant shall provide a written commitment of intent to participate in the Medicaid and Medicare programs if appropriate;

2. An applicant shall demonstrate a case-mix of Medicaid, Medicare and private pay patients; and

3. Document policies and practices of nondiscrimination by past performance of the applicant or its parent organization.

(h) A new or expanded state nursing facility may be exempted from the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a), (b), (c), (d), and (g) when the facility meets all of the following criteria:

1. documentation that the proposed facility will meet the definition of a state nursing facility as defined in Ga. Comp. R. & Regs. r. 111-2-2-.30(1)(k);

2. documentation that the applicant will admit patients from any of Georgia's counties with a primary focus on a pre-designated, multi-county service area or region;

3. the facility intends to become accessible to patients whose care, because of income and other limitations, would normally come under the jurisdiction of the state; and

4. such other considerations as may be considered necessary by the Department at the time of the application.

(i) An applicant for a new or expanded nursing facility shall document an agreement to provide Department requested information and statistical data related to the operation and provision of nursing facility services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.30

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Skilled Nursing and Intermediate Care Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.31 Specific Review Considerations for Personal Care Homes

(1) **Applicability.** A Certificate of Need for a personal care home will be required prior to the establishment of a new personal care home, of twenty-five beds or more, and the expansion of any personal care home which is or will be twenty-five beds or more.

(2) **Definitions.**

(a) "Health planning area" for all personal care homes, means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(b) "Horizon Year" means the last year of a three-year projection period for need determinations for a personal care home.

(c) "Official State Health Component Plan" means the document related to personal care homes developed by the Department adopted by the State Health Strategies Council and approved by the Board of Community Health.

(d) "Personal care home" means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes include those facilities which monitor daily residents' functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

1. old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

2. boarding facilities that do not provide personal care.

(3) **Standards.**

(a) 1. The numerical need for a new or expanded personal care home in a health planning area shall be determined by a population-based formula which is used to project the number of personal care home beds needed in the horizon year and which is a sum of the following:

(i) a ratio of 18.00 beds per 1,000 projected horizon year Resident population age 65 through 74;

(ii) a ratio of 40.00 beds per 1,000 projected horizon year Resident population age 75 through 84; and

(iii) a ratio of 60.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The net numerical unmet need for personal care home beds in each health planning area shall be determined by subtracting the number of existing and approved personal care home beds in the health planning area from the projected number of personal care home beds needed in the horizon year; provided, however, that if the net numerical unmet need exceeds fifty percent (50%) of the current existing and approved beds in the planning area, the net numerical unmet need shall be limited to fifty percent (50%) of the existing and approved beds at the time the calculation is made.

(b) The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.31(3)(a) as follows:

1. to allow expansion of an existing personal care home if actual utilization has exceeded ninety percent (90%) average annual occupancy based on number of licensed beds for the two-year period immediately preceding application;

2. to allow expansion of an existing personal care home if the applicant has substantial occupancy by out-of-state residents. "Substantial occupancy by out-of-state residents" shall be defined as having at least thirty-three percent (33%) of the available licensed beds in the personal care home utilized by individuals who resided outside of the State of Georgia immediately prior to moving into the personal care home; or

3. to remedy an atypical barrier to personal care home services based on cost, quality, financial access, or geographic accessibility.

(c) In competing applications, favorable consideration may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide a higher percentage of un-reimbursed services to indigent and charity residents than requirement by the indigent and charity standard of Ga. Comp. R. & Regs. r. 111-2-2-.31(3)(j). Favorable consideration also may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide personal care home residential services at monthly and/or annual rates that are affordable to the greatest number of individuals based on analysis of the national rate for services and the income ranges of individuals at or above age 65 and in the applicant's market area(s).

(d) A new or expanded personal care home shall be approved in a health planning area only if the applicant complies with the following physical standards:

1. the physical plant design and the program design shall support the concept of a non-institutional, home-like setting;

2. the proposed physical plant design is in compliance with the Rules and licensure standards of the Healthcare Facility Regulation Division and the applicant stipulates that the services required by such Rules and licensure standards will be provided and any services prohibited by such Rules and licensure standards will not be provided and will not be implied to be provided either through advertising or other means;

3. there shall be a designated area for staff on duty in each personal care home and on each floor in the case of a multistory facility;

4. the facility has the option of building kitchens or kitchenettes in the living units as long as the facility intends to provide three meals per day to residents. The kitchens or kitchenettes must comply with the Fire Marshal's and the Healthcare Facility Regulation Division's minimum licensure standards; and

5. the facility provides assurance that it will not lease or contract space within the personal care home to an outside entity to provide services that the personal care home would otherwise not be allowed to provide.

(e) An applicant for a new or expanded personal care home must document provision of continuity of care by providing a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care.

(f) An applicant for a new or expanded personal care home shall provide evidence of intent to comply with all appropriate licensure requirements, resident life safety standards and operational procedures required by the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded personal care home shall provide evidence of the intent and ability to recruit, hire, and retain qualified personnel and that such personnel are available in the proposed geographic service area.

(h) An applicant for a new or expanded personal care home shall provide evidence that no existing Georgia personal care home of any size owned and/or operated by the applicant, a related entity or by the applicant's parent organization has had a permit or license revoked, denied or otherwise sanctioned through formal licensure enforcement action by the Healthcare Facility Regulation Division within the two years immediately preceding application.

(i) An applicant for a new or expanded personal care home shall provide a plan for assuring quality of care which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators.

(j) An applicant for a new or expanded personal care home shall foster an environment which assures access to services to individuals by providing a written commitment that un-reimbursed services to residents who are indigent or meet the guidelines of a charity policy of the personal care home will be offered at a standard which meets or exceeds one percent (1%) of annual gross revenues for the personal care home after bad debt has been deducted.

(k) An applicant for a new or expanded personal care home shall agree to provide the Department with requested information and statistical data related to the operation and provision of personal care homes and to report that data to the Department in the time frame and format requested.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.31

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Personal Care Homes" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.32 Specific Review Considerations for Home Health Services

(1) **Applicability.** A Certificate of Need for a home health agency will be required prior to the establishment of a new home health agency or the expansion of the geographic service area of an existing home health agency unless such expansion is a result of a non-reviewable acquisition of another existing home health agency.

(2) **Definitions.**

(a) "Home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the place of residence used as such individual's home, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services: physical therapy, occupational therapy, speech therapy, medical-social services under the direction of a physician, or part-time or intermittent services of a home health aide.

(b) "Horizon year" means the last year of the three-year projection period for need determinations for a new or expanded home health agency.

(c) "Geographic service area" means a grouping of specific counties within a planning area for which the home health agency is authorized to provide services to individuals residing in the specific counties pursuant to an existing or future Certificate of Need. For purposes of establishing a service area for a new home health agency, the geographic service area shall consist of any individual county or combination of contiguous counties which have an unmet need as determined through the numerical need formula or the exception. For purposes of an expansion of an existing agency, the geographic service area shall consist of an individual county or any combination of counties which have an unmet need, and which are within any planning area in which the home health agency already

provides service; however, in no case may an existing home health agency apply to provide services outside the health planning areas in which its current geographic service area is located.

(d) "Nursing care" means such services provided by or under the supervision of a licensed registered professional nurse in accordance with a written plan of medical care by a physician. Such services shall be provided in accordance with the scope of nursing practice laws and associated rules.

(e) "Planning area" for all home agencies means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(3) **Standards.**

(a) The need for a new or expanded home health agency shall be determined through application of a numerical need method and an assessment of the projected number of patients to be served by existing agencies.

1. The numerical need for a new or expanded home health agency in any planning area in the horizon year shall be based on the estimated number of annual home health patients within each health planning area as determined by a population-based formula which is a sum of the following for each county within the health planning area:

(i) a ratio of 4 patients per 1,000 projected horizon year Resident population age 17 and younger;

(ii) a ratio of 5 patients per 1,000 projected horizon year Resident population age 18 through 64;

(iii) a ratio of 45 patients per 1,000 projected horizon year Resident population age 65 through 79; and

(iv) a ratio of 185 patients per 1,000 projected horizon year Resident population age 80 and older.

2. The net numerical unmet need for home health services shall be determined by subtracting the projected number of patients for the current calendar year from the projected need for services as calculated in (3)(a)1. The projected number of patients for the current calendar year is determined by multiplying the number of patients having received services in each county, as reported in the most recent survey year, by the county population change factor. The county population change factor is the percent change in total population between the most recent survey year and the current calendar year.

(b) 1. The Department shall accept applications for review as enumerated below:

(i) If the net numerical unmet need in a given planning area is 250 patients or more, the Department shall authorize the submission of applications for an expanded home health agency; or

(ii) If the net numerical unmet need in a given planning area is 500 patients or more, the Department shall authorize the submission of applications for a new home health agency as well as an expanded home health agency.

2. An applicant must propose to provide service only within a county or group of counties, each of which reflects a numerical unmet need, and contained within the given planning area for which the Department has authorized the submission of applications.

3. The Department shall only approve applications in which the applicant has applied to serve all of the unmet numerical need in any one county in which need is projected. The need within counties shall not be divided or shared between any two or more applicants.

(c) The Department may authorize an exception to Ga. Comp. R. & Regs. r. 111-2-2-.32(3)(a) if:

1. the applicant for a new or expanded home health agency can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. For purposes of this exception, an applicant shall be required to document, using population, service, special needs and/or disease incidence rates, a projected need for services in the planning area of

at least 200 patients within a defined geographic service area. A successful applicant applying under this section will be restricted to serving the special group or groups identified in the application within the county or counties stipulated in the application; or

2. a particular county is served by no more than two (2) home health agencies and either of the following conditions exists:

(1) less than one percent (1%) of the county's population has received home health services, or

(2) one of the two home health agencies has demonstrated a failure to adequately serve Medicaid patients as evidenced by a level of service to such individuals that is less than the statewide average within each of the past two years as reported on the Annual Home Health Services survey. For purposes of this exception, an applicant must already be approved to provide service in a contiguous county or be approved to provide service in a county that is no further than 15 miles from the county authorized through the exception. In all other aspects of the application process, the applicant shall be required to comply with provisions applicable to expanded home health agencies. For purposes of this exception, "served by" shall mean the agency(ies) are licensed to serve the county by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(d) An applicant for a new or expanded home health agency shall provide a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems which promote continuity rather than acute, episodic care. Working agreements with other related community services may include the ability to streamline referrals to other appropriate services and to participate in the development of cross-continuum care plans with other providers.

(e) An applicant for a new or expanded home health agency shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(f) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no history of uncorrected or repeated conditional level violations or uncorrected standard deficiencies as identified by licensure inspections or equivalent deficiencies as noted from Medicare or Medicaid audits.

(g) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no previous conviction of Medicaid or Medicare fraud.

(h) An applicant for a new or expanded home health agency shall provide a written plan which demonstrates the intent and ability to recruit, hire and retain the appropriate numbers of qualified personnel to meet the requirements of the services proposed to be provided and that such personnel are available in the proposed geographic service area.

(i) An applicant for a new home health agency shall provide evidence of the intent to meet the appropriate accreditation requirements of The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agencies.

(j) An applicant for an expanded home health agency shall provide documentation that they are fully accredited by The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agency.

(k) An applicant for a new or expanded home health agency shall provide its existing or proposed plan for a comprehensive quality improvement program.

(l) An applicant for a new or expanded home health agency shall assure access to services to individuals unable to pay and to all individuals regardless of payment source or circumstances by:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, disability, gender, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds one percent (1%) of annual, adjusted gross revenues for the home health agency or, in the case of an applicant providing other health services, the applicant may request that the Department allow the commitment for services to indigent and charity patients to be applied to the entire facility;

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients;

4. providing a written commitment to participate in the Medicare, Medicaid and PeachCare for KidsT programs; and

5. providing a written commitment to participate in any other state health benefits insurance programs for which the home health service is eligible.

(m) An applicant for a new or expanded home health agency shall demonstrate that their proposed charges compare favorably with the charges of existing home health agencies in the same geographic service area.

(n) An applicant for a new or expanded home health agency shall document an agreement to provide Department requested information and statistical data related to the operation and provision of home health services and to report that data to the Department in the time frame and format requested by the Department.

(o) The Department may authorize an existing home health agency to transfer one county or several counties to another existing home health agency without either agency being required to apply for a new or expanded Certificate of Need, provided the following conditions are met:

1. the two agencies agree to the transfer and submit such agreement and a joint request to transfer in writing to the Department at least thirty (30) days prior to the proposed effective date of the transfer;

2. the two agencies document within the written request that the transfer would result in increased and improved services for the residents of the county or counties including Medicare and Medicaid patients;

3. the agency to which the county or counties are being transferred currently offers services in at least one contiguous county or within the health planning area(s) in which county or counties are located; and

4. the two agencies are in compliance with all other requirements of these Rules; such compliance to be evaluated with the written transfer request.

No such transfer shall become effective without written approval from the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.32

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Home Health Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: New Rule entitled "Specific Rule Considerations for Home Health Services" adopted. F. Feb. 16, 2010; eff. Mar. 8, 2010.

Amended: New title, "Specific Review Considerations for Home Health Services." F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.33 Specific Review Considerations for Life Plan Community (LPC) Sheltered Nursing Facilities

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or expanded LPC Sheltered Nursing Facility, if not exempt as provided by O.C.G.A. § 31-6-47(a)(17) and Ga. Comp. R. & Regs. r. 111-2-2-.03(20). These Rules apply to sheltered nursing facilities located in LPC facilities defined herein as Type A and Type B Life Plan Communities. A LPC that has obtained nursing facility beds approved under the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.30 does not qualify for sheltered nursing facility beds, and to convert existing nursing facility beds to sheltered nursing facility beds, such a LPC must apply for a new Certificate of Need. Conversely, a LPC that obtains sheltered nursing facility beds under these Rules may not qualify for beds under Ga. Comp. R. & Regs. r. 111-2-2-.30, and is therefore only required to complete these specific review considerations for the sheltered nursing facility beds.

(2) **Duration.** Notwithstanding Ga. Comp. R. & Regs. r. 111-2-2-.02(6), the initial implementation period of a Certificate of Need granted for a new or expanded LPC Sheltered Nursing Facility pursuant to these Rules shall be twenty-four (24) months from the effective date.

(3) **Definitions.**

(a) "A Life Plan Community" (LPC) is an organization which offers a contract to provide an individual of retirement status, other than an individual related by consanguinity or affinity to the provider furnishing the care, with board and lodging, licensed nursing facility care and medical or other health related services, or both. These services are provided for a minimum period of more than one (1) year and may be for as long as the lifetime of the resident.

(b) "Type A Life Plan Community" (Type A LPC) provides LPC services at the same location for the life of an individual, including mutually terminable contracts, and in consideration of the payment of an entrance fee with or without other periodic charges. A Type A LPC offers nursing facility care for a little or no substantial increase in monthly payments, except normal operating costs and inflation adjustments.

(c) "Type B Life Plan Community" (Type B LPC) provides LPC services at the same location for a period in excess of one year, including mutually terminable contracts, and in consideration of the payment of an entrance fee with other periodic charges. A Type B LPC offers a specified amount of nursing facility care for little or no substantial increase in monthly payments except normal operating costs and inflation adjustments. After the specified amount of nursing care is received, residents pay either a discounted rate or the full per diem rate for nursing care required.

(d) "A Continuing Care Contract" means furnishing pursuant to an agreement shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting designated by the agreement for continuing care, to an individual not related by consanguinity or affinity to the provider furnishing such care upon payment of an entrance fee. Other personal services provided shall be designated in the continuing care agreement. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(e) "LPC Sheltered Nursing Facility", for purposes of these Rules, is a nursing facility that meets the definition of a nursing facility as defined by Ga. Comp. R. & Regs. r. 111-2-2-.30 of the Rules of the Department. A LPC Sheltered Nursing Facility shall be for the exclusive use of residents of a Type A or Type B LPC.

(f) "Official State Health Component Plan" means the document related to the above-named services developed by the Department, established by the Georgia Health Strategies Council, and signed by the Governor of Georgia.

(g) "Resident" is an individual entitled to receive continuing care in a Type A or Type B Life Plan Community.

(4) **Standards.**

(a) The numerical need for a new LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each five independent living units. The applicant for a LPC Sheltered Nursing Facility shall demonstrate to the Department that the potential market for LPC Independent Living Units in the proposed service area is based on a

valid feasibility study which takes into account factors such as, but not limited to, the age and annual household income of the target population and the geographic area to be served.

(b) The numerical need for an expanded LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each four independent living units provided that the LPC's existing nursing facility has experienced an occupancy rate of at least eighty percent (80%) during the most recent year.

(c) Sheltered nursing facility beds approved under these Rules shall be used exclusively for persons who are residents of the LPC, and who are a party to a continuing care contract with the facility or the parent organization and who have lived in a non-nursing unit of the LPC for a period of at least ninety (90) days. Exceptions shall be allowed when one spouse or sibling is admitted to the nursing unit at the time the other spouse or sibling moves into a non-nursing unit, or when the medical condition requiring nursing care was not known to exist or be imminent when the individual became a party to the continuing care contract.

(d) The applicant shall provide evidence of intent that at no time will the nursing facility be certified for participation in the Medicaid Program.

(e) A LPC which is the applicant for a new or expanded LPC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate authorization and disclosure requirements of the Georgia State Department of Insurance and of any appropriate accrediting agency(ies). The LPC shall furnish reports in such form and at such times as may be specified, which accurately and fully disclose it has met specified requirements.

(f) A new or expanded LPC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate requirements regarding licensure and accreditation of the nursing facility as follows:

1. Compliance with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division;

2. No uncorrected operational standards in any existing Georgia general or LPC sheltered nursing facilities owned and/or operated by the entity, its affiliates, or its principals. Plans to correct physical plant deficiencies must be provided;

3. No previous conviction of Medicaid and/or Medicare fraud by the entity, its affiliates, or its principals;

4. Provision of a plan for a comprehensive quality improvement program which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance and patient outcomes accordingly; and

5. Intent to meet accreditation requirements of the appropriate accrediting agency(ies).

(g) A LPC which is the applicant for a new or expanded LPC sheltered nursing facility shall demonstrate the existence of a Health Care Fund whose liability is documented by a relevant Actuarial Study and certified by a qualified actuary; or the existence of a Long Term Care Insurance Policy issued to individual residents; or a Group Long Term Care Insurance Policy issued to the LPC for the coverage of all residents. An Individual or Group Insurance Policy must conform to all the requirements of Chapter 120-20-16 of the Rules and Regulations of the State of Georgia Insurance Department entitled "Long Term Care Insurance Regulation". The period and scope of coverage must be identical to the period and scope of coverage in the continuing care contract.

(h) A LPC in which a new or expanded sheltered nursing facility is to be located shall provide the Department with requested information and statistical data related to the operation and programmatic elements of the LPC and the Sheltered Nursing Facility. Analyses are predicated upon accurate, consistent, and systematically obtained information.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.33

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Continuing Care Retirement Community ("CCRC") Sheltered Nursing Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Nov. 13, 2007; eff. Dec. 3, 2007.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: New title, "Specific Review Considerations for Life Plan Community (LPC) Sheltered Nursing Facilities." F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.34 Specific Review Considerations for Traumatic Brain Injury Facilities

(1) **Applicability.** The following Rules apply to Traumatic Brain Injury Facilities defined herein as providing transitional living programs and/or lifelong living programs.

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Transitional Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An application for Certificate of Need for a new or expanded Transitional Living Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Life Long Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An application for Certificate of Need for a new or expanded Life Long Living Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) "Expansion" or "Expanded Service" means increasing the number of beds in an existing Traumatic Brain Injury Facility or program; or an existing Traumatic Brain Injury Facility or program which makes expenditures which exceed the capital expenditure threshold; or an existing Traumatic Brain Injury Facility or program which seeks to add a program which it currently does not offer.

(b) "Life Long Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who have been discharged from a more intense level of rehabilitation, but who cannot live at home independently, and who require on-going lifetime support. Such clients are medically stable, may have special needs, but need less than 24 hour per day medical support.

(c) "New" means a facility that has not operated as a Traumatic Brain Injury Facility in the previous twelve (12) months. For purposes of these Rules, an existing Traumatic Brain Injury Facility or program which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(d) "Official State Health Component Plan" means the document related to Traumatic Brain Injury Facilities developed by the Department, established by the Georgia State Health Strategies Council and signed by the Governor of Georgia.

(e) "Planning Region" means one of the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

(f) "Transitional Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who require education and training for independent living with a focus on compensation for skills which cannot be restored. Such care prepares clients for maximum independence, teaches necessary skills for community interaction, works with clients on pre-vocational and vocational training and stresses cognitive, speech, and behavioral therapies structured to the individual needs of clients. Such clients are medically stable, may have special needs, but need less than twenty-four (24) hour per day medical support.

(g) "Traumatic Brain Injury" means a traumatic insult to the brain and its related parts resulting in organic damage thereto that may cause physical, intellectual, emotional, social, or vocational changes in a person. It shall also be recognized that a person having a traumatic brain injury may have organic damage or physical or social disorders but shall not be considered mentally ill.

(h) "Traumatic Brain Injury Facility" means a building or place which is devoted to the provision of residential treatment and rehabilitative care in a transitional living program or a life long living program for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury. Such a facility is not classified by the Healthcare Facility Regulation Division as a hospital, nursing home, intermediate care facility or personal care home.

(3) **Standards.**

(a) An application for a new or expanded Traumatic Brain Injury Facility or program shall provide sufficient documentation of the need for such a program in the Planning Region. In the case of an application for an expanded program, the applicant shall justify the need for the expansion by, at a minimum, documenting that the expansion program has achieved an occupancy rate of eighty percent (80%) or more for the most recent twelve (12) months prior to submitting application.

(b) An applicant for a new or expanded Traumatic Brain Injury Facility or program shall document that the establishment or expansion of its Facility or program will not have an adverse impact on existing and approved programs of the same type in its Planning Region. An applicant for a new or expanded Traumatic Brain Injury Facility or program shall have an adverse impact on existing and approved facilities or programs of the same type if it will:

1. decrease annual utilization of an existing facility or program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing facility or program, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twelve (12) months following the acceptance of the applicant's first patient.

The applicant shall provide evidence of projected impact by taking into account existing planning region market share of facilities or programs of the same type and future population growth or by providing sufficient evidence that the current population is underserved by the existing Traumatic Brain Injury facility or program of the same type within the planning region.

(c) The Department may grant an exception to the need methodologies of Ga. Comp. R. & Regs. r. 111-2-2-.34(3)(a) and (3)(b) to remedy an atypical barrier to the services of a Traumatic Brain Injury Facility or program based on cost, quality, financial access, or geographic accessibility.

(d) Minimum bed size for a Traumatic Brain Injury Facility or program is six beds; A Life Long Living Program may not exceed thirty beds, except that an applicant for a new or expanded Life Long Living Program may be approved for total beds to exceed thirty (30) beds only if the applicant provides documentation satisfactory to the Department that the program design, including staffing patterns and the physical plant, are such as to promote services which are of high quality, are cost-effective and are consistent with client needs.

(e) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities (CARF) which apply to post acute brain injury programs and residential services within twenty-four (24) months of accepting its first patient. An applicant for an expanded Traumatic Brain Injury Facility or program shall be CARF-certified as of the date of its application and shall furnish proof of the certification as a part of the Certificate of Need application process.

(f) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such facilities. An applicant for an expanded Traumatic Brain Injury Facility or program shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded Traumatic Brain Injury Facility shall have written policies and procedures for utilization review. Such review shall consider the rehabilitation necessity for the service, quality of client care, rates of utilization and other considerations generally accepted as appropriate for review.

(h) An applicant for a new or expanded Traumatic Brain Injury Facility shall document the existence of referral arrangements, including transfer agreements, with an acute care hospital within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(i) An applicant for a new or expanded Traumatic Brain Injury Facility shall document that the Facility will be financially accessible by:

1. providing sufficient documentation that un-reimbursed services for indigent and charity patients in a new or expanded Facility shall be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the Facility after provisions have been made for bad debt and Medicaid/Medicare contractual adjustments have been deducted. If an applicant, or any facility owned or operated by the applicant's parent organization, received a Certificate of Need for a Traumatic Brain Injury Facility and the Certificate of Need included an expectation that a certain level of un-reimbursed indigent and/or charity care would be provided in the Facility(ies), the applicant shall provide sufficient documentation of the Facility's provision of such care. An applicant's history, or the history of any facility owned or operated by the applicant's parent organization, of not following through with a Certificate of Need expectation of providing indigent and/or charity care at or above the level agreed to will constitute sufficient justification to deny an application; and

2. agreeing to participate in the Medicare and Medicaid programs, whenever these programs are available to the Facility.

(j) Reserved.

(k) An applicant for a new or expanded Traumatic Brain Injury Facility shall document an agreement to provide the Department requested information and statistical data related to the operation of such a Facility and to report that information and statistical data to the Department on a yearly basis, and as needed, in a format requested by the Department and in a timely manner.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.34

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Traumatic Brain Injury Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.

Amended: F. Nov. 13, 2007; eff. Dec. 3, 2007.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.35 Specific Review Considerations for Comprehensive Inpatient Physical Rehabilitation Services

(1) **Applicability.**

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Comprehensive Inpatient Physical Rehabilitation Adult Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Comprehensive Inpatient Physical Rehabilitation Pediatric Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) "Adults" means persons eighteen (18) years of age and over. However, a Certificate of Need authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Adult Program will not be in violation of the Certificate of Need laws and regulations if it provides service to a patient older than fifteen years if the provider has determined that such service is medically necessary, provided that the treatment days and patient census associated with patients sixteen and seventeen years of age do not exceed ten percent (10%) of annual treatment days and annual census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the adult age limitations; such programs may treat any patient aged twelve (12) and over.

(b) "Comprehensive Inpatient Physical Rehabilitation Programs" means rehabilitation services, which have been classified by Medicare as an inpatient rehabilitation facility pursuant to 42 C.F.R. § 412.23(b)(2), provided to a patient who requires hospitalization, which provides coordinated and integrated services that include evaluation and treatment, and emphasizes education and training of those served. The program is applicable to those individuals who require an intensity of services which includes, as a minimum, physician coverage twenty-four (24) hours per day, seven (7) days per week, with daily (at least five (5) days per week) medical supervision, complete medical support services including consultation, 24-hour-per-day nursing, and daily (at least five (5) days per week) multidisciplinary rehabilitation programming for a minimum of three hours per day. For regulatory purposes, the definition includes a program which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If a program, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked.

(c) "Expansion" and "Expanded" mean the addition of beds to an existing CON-authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Program. However, a CON-authorized or grandfathered provider of Comprehensive Inpatient Physical Rehabilitation in a freestanding rehabilitation hospital may increase the bed capacity of an existing program by the lesser of ten percent (10%) of existing capacity or ten (10) beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years and provided that the capital expenditures associated with the increase do not exceed the capital expenditure threshold. If such an increase exceeds the capital expenditure threshold, the increase will be considered an expansion for which a Certificate of Need shall be required under these Rules.

(d) "Freestanding Rehabilitation Hospital" means a specialized hospital organized and operated as a self-contained health care facility that provides one or more rehabilitation programs and which has been classified as an inpatient rehabilitation facility by the Medicare program pursuant to 42 C.F.R. § 412.23(b)(2). For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If an entity, which has been awarded a CON

pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to operate as a general acute care hospital.

(e) "New" means a Program that has not been classified by the Medicare program as a rehabilitation hospital or program in the previous twelve (12) months. Adult programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(a) and pediatric programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(b) shall be considered independent programs such that a provider seeking to add a program not offered by that provider in the previous twelve (12) months shall be considered to be offering a new program for which a Certificate of Need must be obtained. For purposes of these Rules, an existing program which proposes to be relocated to a location more than three (3) miles from its present location shall be considered "new".

(f) "Official State Health Component Plan" means the document related to Physical Rehabilitation Programs and Services developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(g) "Pediatric" means persons seventeen (17) years of age and under. However, a CON-authorized or grandfathered Comprehensive Inpatient Rehabilitation Pediatric Program will not be in violation of the CON laws and regulations if it provides service to a patient younger than twenty-two (22) years if the provider has determined that such service is medically necessary, provided that the treatment days and patient census associated with patients eighteen, nineteen, twenty, and twenty-one years of age do not exceed ten percent (10%) of annual treatment days and annual census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the pediatric age limitations; such programs may treat any patient aged twelve (12) and over.

(h) "Planning Region" means one of the four sub-state regions for Physical Rehabilitation Programs and Services as follows:

1. Rehabilitation Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe, Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson;

2. Rehabilitation Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford;

3. Rehabilitation Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole;

4. Rehabilitation Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(3) **Service-Specific Review Standards.**

(a) The need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program ("CIPR") shall be determined and applied as follows:

1. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program in a planning region shall be determined using the following demand-based need projection:

(i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by current year projected resident population (aged 18 and over) for the planning region and multiplying by 1,000. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire. The source for current and horizon year resident population shall be resident population projections from the Governor's Office of Planning and Budget. For the first Horizon Year projection using this Rule, and for the first horizon year projection only, the utilization rate per 1,000 for each planning region shall be reduced by sixteen percent (16%) to account for anticipated utilization reduction after full implementation of the Center for Medicare and Medicaid Services' ("CMS") seventy-five percent (75%) rule.

(ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 18 and over) for that planning region.

(iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by the current year inpatient rehabilitation discharges determined in Step (i).

(iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 18 and over) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

(v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for adults in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of adult CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

2. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program in a planning region shall be determined using the following demand-based need projection:

(i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by current year resident population (aged 17 and under) for the planning region. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

(ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 17 and under) for that planning region.

(iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by the current year inpatient rehabilitation discharges determined in Step (i).

(iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 17 and under) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

(v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for pediatric patients in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of pediatric CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall document that the establishment or expansion of its program will not have an adverse impact on existing and approved programs of the same type in its planning region. An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall have an adverse impact on existing and approved programs of the same type if it will:

1. decrease annual decrease annual utilization of an existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing program, whose current utilization is below eighty-five percent (85%), by ten percent over the twelve (12) months following the acceptance of the applicant's first patient.

(c) The Department may grant the following exceptions:

1. The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state.

2. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. or 111-2-2-.35(3)(a) 2. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-22-.35(3)(b) to remedy an atypical barrier to Comprehensive Inpatient Physical Rehabilitation Programs based on cost, quality, financial access or geographic accessibility or if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

3. The Department may grant an exception to the need methodologies of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. or Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 2. in a planning area which has no existing provider provided that the applicant demonstrates a need for the service based on patient origin data.

(d) A new Comprehensive Inpatient Physical Rehabilitation Program shall have the following minimum bed sizes based on type of program offered:

1. A new Comprehensive Inpatient Physical Rehabilitation Adult Program shall have a minimum bed size of twenty (20) beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, twenty (20) beds or in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

2. A new Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall have a minimum of 10 beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, 10 beds in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

(e) An applicant for a new Comprehensive Inpatient Physical Rehabilitation Program shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities ("CARF") applicable to the type of Program to be offered within eighteen (18) months of offering the new service.

(f) An applicant for an expanded Comprehensive Inpatient Physical Rehabilitation Program shall be accredited by the CARF for the type of Program which the applicant seeks to expand prior to application. The applicant must provide proof of such accreditation.

(g) An applicant for a new freestanding rehabilitation hospital shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such hospitals.

(h) An applicant for an expanded freestanding rehabilitation hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(i) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(j) An applicant for a new or expanded freestanding rehabilitation hospital shall document the existence of referral arrangements, including transfer agreements with an acute-care hospital(s) within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(k) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that un-reimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past

record of service to Medicare, Medicaid, and indigent and charity patients, including the level of un-reimbursed indigent and charity care.

(l) Reserved.

(m) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall agree to provide the State Health Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.35

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Comprehensive Inpatient Physical Rehabilitation Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.36 Specific Review Considerations for Long Term Care Hospitals

(1) **Applicability.** A Certificate of Need ("CON") shall be required prior to the establishment of a new or the expansion of an existing Long Term Care Hospital. An application for Certificate of Need for a new or expanded Long Term Care Hospital shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) "Expansion" or "Expanded" means the addition of beds to an existing CON-authorized or grandfathered Long Term Care Hospital. A CON-authorized or grandfathered Long Term Care Hospital may increase the bed capacity of an existing hospital by the lesser of ten percent (10%) of existing capacity or 10 beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years and provided that the capital expenditures associated with the increase do not exceed the Capital Expenditure Threshold. If such an increase exceeds the Capital Expenditure Threshold, the increase will be considered an expansion for which a Certificate of Need shall be required under these Rules.

(b) "Free-standing LTCH" or "Free-standing LTACH" means a Long Term Care Hospital organized and operated as a self-contained health care facility.

(c) "Hospital-within-a-Hospital LTCH" or "Hospital-within-a-Hospital LTACH" means a Long Term Care Hospital co-located within the same building or the same campus as another CON-Authorized hospital.

(d) "Long Term Care Hospital" or "LTCH" or "Long Term Acute Care Hospital" or "LTACH" means a hospital that is classified as a long term hospital by the Medicare program pursuant to 42 CFR 412.23(e). These hospitals typically provide extended medical and rehabilitative care for patients who are clinically complex and may suffer from multiple acute or chronic conditions. Services typically include comprehensive rehabilitation, respiratory therapy, head trauma treatment, and pain management. For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as a long term hospital within twenty-four (24) months of accepting its first patient. If an entity, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within this timeframe, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to operate as a general acute care hospital. However, an acute care hospital, which has been awarded a CON to convert acute care beds for use as a long term care hospital, may again use such beds for acute care if such beds have not been Medicare-classified as a long term care hospital within twenty-four (24) months of accepting its first patient. Furthermore, a hospital that has been approved through

the Certificate Of Need process to use all of its short-stay beds for a Freestanding LTCH shall have such beds removed from the official inventory of available short-stay beds when the LTCH is certified by Medicare; provided, however, that the hospital's beds will revert to the official inventory of available short-stay beds at any point that the facility ceases to be certified by Medicare as an LTCH.

(e) "New" means a hospital that has not been classified by the Medicare program as a long term hospital in the previous twelve (12) months. For purposes of these Rules, an existing hospital which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(f) "Occupancy Rate" means the ratio of beds occupied by inpatients as reported on the most recent Annual Hospital Questionnaire divided by the total licensed beds.

(g) "Official State Health Component Plan" means the document related to Long Term Care Hospitals developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(h) "Planning Region" means one of the four sub-state regions for Long Term Care Hospitals, as follows:

1. LTCH Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe, Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson;

2. LTCH Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford;

3. LTCH Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole;

4. LTCH Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(3) **Service-Specific Review Standards.**

(a) The need for new or expanded Long Term Care Hospital in a LTCH planning region shall be determined using the following need projection:

1. Determine the total discharges from general acute care hospitals less LTCH discharges, and less perinatal and neonatal discharges, and less psychiatric and substance abuse discharges, and less comprehensive inpatient physical rehabilitation discharges for the planning region in which the Long Term Care Hospital is or will be located. The source of discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

2. Calculate the discharge rate for each planning region by dividing the number of current acute care discharges obtained in Step 1 in each planning region by the corresponding year's resident population projection from the Governor's Office of Planning and Budget in each planning region.

3. Calculate the projected discharges for each planning region by multiplying the discharge rate obtained in Step 2 by the horizon year resident population projection for that planning region and then reduce that figure by six percent (6%) to account for overlap with rehabilitation facilities.

4. Calculate gross beds needed in the horizon year as follows:

(i) Multiply the projected discharges obtained in Step 3 by a utilization factor of 1.3% to determine the projected number of acute care discharge who may benefit from services at a LTCH.

(ii) Multiply the product obtained in Step 4(i) by the average LTCH length of stay for the most recent previous three-year period. Beginning with the first need calculation and continuing until the third complete year of survey data collected pursuant to this Rule, the Department shall use 28.1 as a proxy for the average LTCH length of stay for the previous three years.

(iii) Divide the product obtained in Step 4(ii) by 365 to determine the projected daily LTCH census.

(iv) Divide the result obtained in Step 4(iii) by .85 to determine the number of projected LTCH beds utilizing an eighty-five percent (85%) capacity standard.

5. Determine the current inventory of LTCH beds in the planning region from Departmental data. For all long term care hospital providers, which have been licensed as a Long Term Care Hospital by the Healthcare Facility Regulation Division, the current inventory of LTCH beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed rehabilitation hospitals even if such hospitals have a reported average length of stay of greater than twenty-five (25) days for Medicare patients; the beds of such facilities shall continue to be included in the applicable Comprehensive Inpatient Physical Rehabilitation inventory.

6. If the projected LTCH bed need in Step 4(iv) is greater than the current inventory of LTCH beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Long Term Care Hospital shall document that the establishment or expansion of its hospital will not have an adverse impact on an existing and approved long term care hospital in its planning region. An applicant for a new or expanded Long Term Care Hospital shall have an adverse impact on existing and approved hospitals of the same type if it will:

1. decrease annual utilization of an existing hospital, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing hospital, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twelve (12) months following the acceptance of the applicant's first patient.

The applicant shall provide evidence of projected impact by taking into account existing planning region market share of hospitals of the same type and future population growth or by providing sufficient evidence that the current population is underserved by the existing Long Term Care Hospitals within the planning region.

(c) The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state; or to remedy an atypical barrier to the services of a Long Term Care Hospital based on cost, quality, financial access or geographic accessibility. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-22-.36(3)(b) if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

(d) A new or expanded Long Term Care Hospital shall have the following minimum bed sizes:

1. A new freestanding LTCH shall have a minimum bed size of forty (40) beds.

2. A new Hospital-within-a-Hospital LTCH shall have a minimum bed size of twenty (20) beds.

3. The minimum number of beds for the expansion of an existing Long Term Care Hospital, including satellite locations, shall be ten (10) beds or ten percent (10%) of the total current licensed bed total of current Long Term Care Hospital, whichever is less.

(e) An applicant for a new Long Term Care Hospital shall demonstrate the intent to meet the standards of the Joint Commission or another nationally recognized health care accreditation body within twenty-four (24) months of accepting its first patient. An applicant for an expanded Long Term Care Hospital shall be Joint Commission-certified or certified by another nationally recognized health care accreditation body as of the date of its application and shall furnish proof of the certification as a part of the Certificate of Need application process.

(f) An applicant for a new Long Term Care Hospital shall demonstrate the intent to meet the Licensure Rules of the Healthcare Facility Regulation Division for such hospitals. An applicant for an expanded Long Term Care Hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded Long Term Care Hospital shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(h) An applicant for a new or expanded Long Term Care Hospital shall document the existence of referral arrangements, including transfer agreements, with an acute-care hospital(s) within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(i) An applicant for a new or expanded Long Term Care Hospital shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that un-reimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted;

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of un-reimbursed indigent and charity care;

4. providing documentation of current or proposed charges and policies, if any, regarding the amount or percentage of charges that charity patients, self pay patients, and the uninsured will be expected to pay; and

5. agreeing to participate in the Medicare and Medicaid programs if such programs reimburse for such services.

(j) Reserved.

(k) An applicant for a new or expanded Long Term Care Hospital shall agree to provide the Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.36

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Long Term Care Hospitals" adopted. F. Nov. 17, 2005; eff. Dec. 7, 2005.

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111-2-2-.40 Specific Review Considerations for Ambulatory Surgery Services

(1) **Applicability**. For Certificate of Need purposes, an Ambulatory Surgery Service is considered a new institutional health service if it is to be offered in an ambulatory surgery facility ("ASF") or in a diagnostic, treatment, or rehabilitation center ("DTRC").

(a) If the ambulatory surgery service is or will be provided as "part of a hospital", the hospital's provision of such service is not subject to Certificate of Need review under this Rule. For purposes of this Rule, the following are always considered to be "part of a hospital":

a) if the service is located within a hospital; or

b) if the service is located in a building on the hospital's primary campus and that building, or relevant portion thereof, is included within the hospital's permit issued by the State's licensing agency, subject to determination by the Department. The Department also will make a determination of reviewability on a case-by-case basis in other situations involving hospitals.

(b) The entity that develops any ambulatory surgery service shall be the applicant.

(c) A single specialty ambulatory surgery service will be issued a single specialty CON. A new CON will be required to become a multi-specialty service.

(d) These Rules do not apply to adult open-heart surgery, adult cardiac catheterization, pediatric cardiac catheterization, pediatric open-heart surgery, and obstetrical services because these services are covered under other CON Rules. If an ambulatory surgery service, which is part of a hospital, expands the number of ambulatory surgery operating rooms and the capital expenditure exceeds the CON threshold, the project will be reviewed under Ga. Comp. R. & Regs. r. 111-2-2-.40. If an ambulatory surgery service, which is part of a hospital, involves a capital expenditure, which exceeds the CON threshold and does not increase the number of ambulatory surgery operating rooms, the project will be reviewed under the General Review Considerations (Ga. Comp. R. & Regs. r. 111-2-2-.09).

(2) **Definitions.**

(a) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services ("CMS"), the Department's Division of Medical Assistance ("DMA"), the State Health Benefit Plans, or by any successor entities, as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed twenty-four (24) hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(b) "Ambulatory surgery facility" means a public or private facility, not part of a hospital, which provides surgical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization. In addition to operating rooms, an ambulatory surgery facility includes all components of pre and post-operative ambulatory surgery care.

(c) "Ambulatory surgery operating room" means an operating room located either in a hospital, in an ambulatory surgery facility, or in a DTRC facility that is equipped to perform surgery and is constructed to meet the specifications and standards of the Healthcare Facility Regulation Division.

(d) "Ambulatory surgery service" means the provision of ambulatory surgery including pre and post-operative care to patients not requiring hospitalization. An ambulatory surgery service may be provided within any of the following types of healthcare facilities: hospitals, ambulatory surgery facilities, or DTRCs.

(e) "Ambulatory surgery services patient" means a person who makes a single visit to an operating room during which one or more surgical procedures are performed.

(f) "Authorized ambulatory surgery service" means a Department sanctioned ambulatory surgery service, which is either existing or approved prior to the date on which the Department renders a decision on a proposed project. An existing ambulatory surgery service is an authorized service, which has become operational, and an approved ambulatory surgery service is an authorized service, which has not yet become operational, including any approvals under appeal.

(g) "Diagnostic, treatment, or rehabilitation center ("DTRC") facility" means, for purposes of this Rule, any professional or business undertaking, whether for profit or not-for-profit, which offers or proposes to offer an ambulatory surgery service in a setting that is not part of a hospital.

(h) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has received an annual or ad hoc survey within six (6) months of the date of completion of the application (or first application when applications are joined), the Department may consider the report period covered in such a survey as the most recent year.

(i) "Multi-specialty ambulatory surgery service" means an ambulatory surgery service offering surgery in more than one of, but not limited to, the following specialties; dentistry/oral surgery, gastroenterology, general surgery, obstetrics/gynecology, ophthalmology, orthopedics, otolaryngology, pain management/anesthesiology, plastic surgery, podiatry, pulmonary medicine, or urology.

(j) "Not requiring hospitalization" means patients who do not require an inpatient admission to an acute care general hospital prior to receiving ambulatory surgery services, who normally would not require a stay that is overnight or exceeds twenty-four (24) hours, and who are not expected to require an inpatient admission after receiving such services.

(k) "Official inventory" means the inventory of all facilities authorized to perform ambulatory surgery services maintained by the Department based on responses to the most recent Annual Hospital Questionnaire ("AHQ") Surgical Services Addendum and Freestanding Ambulatory Surgery Center Survey and/or the most recent appropriate surveys and questionnaires.

(l) "Official state component plan" means the document related to ambulatory surgery services adopted by the State Health Strategies Council, approved by the Board of Community Health, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the state.

(m) "Operating room environment" means an environment, which meets the minimum physical plant and operation standards specified by Chapter 111-8-4 of the Rules of the Healthcare Facility Regulation Division or such substantially equivalent standards as determined by the Department. Such acceptable standards shall be maintained on the Department's website.

(n) "Planning Area" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Ambulatory Surgery Services.

(o) "Single specialty ambulatory surgery service" means an ambulatory surgery service providing surgery in only one of the specialty areas as defined in Ga. Comp. R. & Regs. r. 111-2-2-.40(2)(i).

(3) **Standards.**

(a) The need for an ambulatory surgery service shall be determined through application of a numerical need method and an assessment of the aggregate utilization rate of existing services.

1. The numerical need for an ambulatory surgery service shall be determined by a demographic formula which includes the number of ambulatory surgery services cases in a planning area. The following need calculation applies to each planning area:

(i) determine the projected ambulatory surgery services patients for the horizon year by multiplying the planning area ambulatory surgery patients' rate by the total Resident population for the planning area for the horizon year;

(ii) determine the number of operating rooms needed by dividing the number of projected ambulatory surgery services patients (step i) by the capacity per operating room. Capacity per operating room per year is 1,000 patients. (This is based on 250 operating room days per year (50 weeks x 5 days/weeks) x 5 patients per room per day x 80% utilization.);

(iii) determine the existing and approved inventory of ambulatory surgery operating rooms by adding:

(I) The pro-rata portion of hospital shared inpatient/ambulatory surgery operating rooms devoted to ambulatory surgery services. This portion is determined as follows: (# ambulatory surgery patients x 90 min.) {(ambulatory surgery patients x 90 min)+(inpatient patients x 145 min.)} x # shared rooms

(II) # of hospital dedicated ambulatory surgery operating rooms; and

(III) # of freestanding ambulatory surgery operating rooms.

(iv) determine the projected net surplus or deficit for ambulatory surgery services by subtracting the total ambulatory surgery operating rooms needed (step iii) from the inventory of existing and approved ambulatory surgery services operating rooms in the planning area.

2. Prior to approval of a new or expanded ambulatory surgery service in any planning area, the aggregate utilization rate of all existing and approved ambulatory surgery service in that planning area shall equal or exceed eighty percent (80%) during the most recent year; and

3. A proposed multi-specialty ambulatory surgery service shall have a minimum of three operating rooms and a single specialty ambulatory surgery service shall have a minimum of two operating rooms.

(b) The Department may allow an exception to the need standard referenced in (3)(a), in order to remedy an atypical barrier to ambulatory surgery services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) Each applicant shall have a hospital affiliation agreement and/or the medical director must have admitting privileges and other acceptable documented arrangements to insure the necessary backup for medical complications. The applicant must document the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(d) An applicant shall submit written policies and procedures regarding discharge planning. These policies should include, where appropriate, designation of responsible personnel, participation by the patient, family, guardian or significant other, documentation of any follow-up services provided and evaluation of their effectiveness.

(e) An applicant shall provide evidence of a credentialing process that provides that surgical procedures will be performed only by licensed physicians who have been granted privileges to perform these procedures by the organization's governing body.

(f) An applicant shall assure that an anesthesiologist, a physician qualified to administer anesthesia, an oral surgeon, or a nurse anesthetist trained and currently certified in emergency resuscitation procedures is present on the premises at all times a surgical patient is present.

(g) An applicant shall submit evidence that qualified personnel will be available to insure a quality service to meet licensure, certification and/or accreditation requirements.

(h) An applicant shall submit a policy and plan for reviewing patient care, including a stated set of criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process.

(i) An applicant shall submit written policies and procedures for utilization review consistent with state federal and accreditation standards. This review shall include review of the medical necessity for the service, quality of patient care, and rates of utilization.

(j) An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division.

(k) An applicant for a new ambulatory surgery service shall provide a statement for the intent to meet, within twelve (12) months of obtaining state licensure, the appropriate accreditation requirements of the Joint Commission or another nationally recognized health care accreditation body, the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

(l) An applicant for an expanded ambulatory surgery service shall provide documentation that they fully meet the appropriate accreditation requirements of the Joint Commission or another nationally recognized health care accreditation body, the Accreditation Association for Ambulatory Health Care ("AAAHC"), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. ("ASF") and/or other appropriate accrediting agency.

(m) An applicant shall provide documentation that charges are reasonable compared to other similar surgery services serving the same planning area.

(n) An applicant shall foster an environment that assures access to services to individual's unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant or the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(o) An applicant for an ambulatory surgery service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of ambulatory surgery and to report that data to the Department in the time frame and format requested by the Department. This information shall include, but not be limited to, any changes in number of ambulatory surgery operating rooms that may occur as a result of service expansion.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.40

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Ambulatory Surgery Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Dec. 14, 2007; eff. Jan. 3, 2008.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.41 Specific Review Considerations for Positron Emission Tomography Units

(1) **Applicability.**

(a) A Certificate of Need shall be required for a new or expanded positron emission tomography ("PET") unit.

(b) On or after January 1, 2008, the Department shall only consider and approve applications for dual modality PET units; stand-alone PET units shall not be approved.

(c) On or after January 1, 2008, an applicant for a mobile unit site shall be the hospital or DTRC which has entered into an agreement to receive mobile services. The actual mobile service provider shall not be the applicant. The hospital or DTRC that is serviced by the mobile provider shall be responsible for the provision of annual surveys and the provision of information to the Department.

(d) On or after January 1, 2008, a mobile provider shall be required to obtain a CON only if the fair market value or purchase price of the unit and any and all functionally related equipment exceeds the equipment threshold. If the fair market value or purchase price exceeds the equipment threshold, the mobile provider shall apply for a Certificate of Need under the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1).

(e) A Certificate of Need obtained by a hospital or DTRC to offer mobile PET services shall be valid for the provision of mobile PET services only. A hospital or DTRC approved to offer mobile PET services must obtain a separate CON prior to offering fixed PET services.

(2) **Definitions.**

(a) "Health Planning Area" or "planning area" means the thirteen (13) geographic regions in Georgia as defined in the official State Health Component Plan for use in planning for PET Scan services.

(b) "Horizon Year" means the last year of a five-year projection period for need determinations.

(c) "Expansion" or "expanded service" means the addition of a fixed or mobile unit at a hospital or DTRC. The addition of a component or components, such as computer tomography (CT) imaging, to an existing fixed or mobile unit or the upgrade of an existing fixed or mobile unit shall not be considered an expansion and shall not be subject to the need standards; provided, however, that if any such addition or upgrade is subject to review due to the

equipment threshold at that time, the applicant shall demonstrate compliance with or document a plan and agreement to comply with Ga. Comp. R. & Regs. r. 111-2-2-.41(3)(d), (e), (f) and (g).

(d) "Fixed Unit" means a unit that is stationary within one approved facility.

(e) "Mobile Unit" means a unit that is operated by one or shared by two or more health care facilities and which has a data acquisition system and a computer. In order to meet the definition of mobile unit, the applicant must provide proof of the following:

1. The unit must not be on site at any Facility more than three (3) consecutive operating days per week or sixteen (16) total days per month.

2. The facilities involved with the mobile unit are fully informed and participating in the service as evidenced by written agreements or correspondence provided in the application.

3. For applications approved prior to January 1, 2008, a mobile provider is limited to providing service only to those facilities approved in the mobile provider's application for CON. On or after January 1, 2008, a mobile provider may serve any hospital or DTRC that receives a Certificate of Need for mobile PET services, provided that no hospital or DTRC may be serviced by more than one mobile provider at a time.

4. The applicant shall project scans per facility on a pro-rated basis for the first year of operation, and such projections shall be used in any need determinations during that first year of operation. Thereafter, in annual surveys, the applicant, if successful, must document scans by each service facility for use in need determinations.

(f) "Optimal Utilization" refers to scans per year and shall be defined as 2,750 PET scans per year. A PET Scan or Study means the gathering of data during a single patient visit from which one or more images may be constructed.

(g) "PET Scan Service" or "Service" means a facility that owns one or more units and provides diagnostic imaging through positron emission tomography exclusively or as a dedicated PET/CT or dual modality unit.

(h) "Positron Emission Tomography" or "PET" means a noninvasive diagnostic technology, which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals.

(i) "Unit" means a single piece of equipment that performs PET scans.

(3) **Standards.**

(a) The need for a new or expanded service shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing and approved units.

1. The numerical need for a new unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the projected number of patients diagnosed with cancer who might benefit from a scan.

(iii) Add the number of cancer cases that might benefit from a scan for each county within a Health Planning Area to determine the estimated need for services within a Health Planning Area for persons diagnosed with cancer.

(iv) Multiply the number of cancer cases for each Health Planning Area from subsection (iii) by 1.4 to accommodate for non-oncology patients and for follow-up scans for oncology patients in the projected need for services. On or

after January 1, 2010, in lieu of multiplying by 1.4 each year, the Department shall use actual data from the previous 2 survey years to determine the multiplication factor by adding 1 to the ratio of cardiology, neurology and follow up oncology scans to the number of initial oncology scans.

(v) Calculate the number of needed units by dividing the number of individuals who might receive scanning services as determined from subsection (iv) by 2,750, which represents the optimal utilization of a unit.

(vi) Determine the net numerical unmet need for PET scan unit(s) by subtracting the total number of PET/CT or dual modality units currently existing or approved for use from the number of needed units. Mobile units shall be subtracted based on the number of days providing service to sites within a planning area in the most recent survey year divided by 365. Stand-alone PET units shall not be included in the inventory and shall not be subtracted to determine the net numerical unmet need.

(vii) If the net numerical unmet need in any Health Planning Area is at or above seventy-five percent (75%) of a unit (approximately 2,062 individuals needing scans), the needed units shall be rounded up by one unit. If the balance net numerical need in any Health Planning Area is at or above 3.2875% of a unit (approximately (90) individuals needing scans), a mobile unit may be approved to serve the planning area. The maximum number of days a mobile unit may be approved to provide services in the planning area shall be determined using the following formula:

APPROVED DAYS PER YEAR

< NET NUMERICAL UNMET NEED

365

2. Prior to the approval of a new or expanded unit in a planning area, the aggregate utilization rate for all units in that planning area that existed during the most recent survey year and that provided data to the Department for the most recent survey year shall equal or exceed eighty percent (80%) of optimal utilization for the most recent survey year.

(b) Exceptions to the need standards and requirements in (3)(a) may be granted by the Department:

1. to an applicant seeking to remedy an atypical barrier to services based on cost, quality, financial access, or geographic accessibility when the applicant has documented such a barrier;

2. to an applicant seeking the addition of a fixed unit who has been served solely by a mobile PET when the applicant demonstrates that 850 studies have been performed on the mobile unit at the applicant's facility in the most recent survey year; and

3. to an applicant hospital that treats as inpatients persons who have been diagnosed with cancer and are undergoing treatment for the disease and who will offer the PET service to its patients through a contract with a mobile PET provider.

(c) In considering applications joined for review, the Department may give favorable consideration to an applicant that has historically provided a higher annual percentage of un-reimbursed services to indigent and charity patients.

(d) An applicant for a new or expanded service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant that stipulates that any such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds five percent (5%) of annual, adjusted gross revenues of the PET scan service; or

3. providing a written commitment to participate in Medicaid, Peach Care and Medicare programs, to the extent such programs reimburse for PET scan services, and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services;

4. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(e) An applicant for a new or expanded service shall provide evidence of the ability to meet the following quality of care standards:

1. Document certification or a plan for securing certification for operation of a unit from the Georgia Department of Natural Resources.

2. Document that the unit proposed for purchase is approved for use by the U.S. Food and Drug Administration and for reimbursement by the Center for Medicare and Medicaid Services.

3. Document that the service will function as a component of a comprehensive diagnostic service and that appropriate referral to treatment and follow-up will be provided. The applicant must have accessible the following modalities and capabilities on site or through agreements, as evidenced by documentation provided at the time of application: computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography.

4. Document that the PET service shall be under the direction of a physician who is board certified in nuclear medicine or diagnostic radiology; and is licensed as an authorized user of radioactive materials in accordance with the Rules of the Georgia Department of Natural Resources.

5. Document that the PET services has arrangements with board-certified interpreting physician(s) that are licensed in the State of Georgia.

6. Document the training and experience in PET scan services of the physician, nuclear medicine technologist, and radiology technologist. Such personnel shall be certified by appropriate national accreditation bodies.

7. Document fully the safe and timely access to radiopharmaceuticals.

(f) An applicant for a new or expanded service shall provide evidence of the ability to meet the following continuity of care standards:

1. Document that the applicant provides or has signed emergency transfer agreements and arrangements with one or more acute care hospital(s) located within the applicant's health planning area or in the case where the nearest acute care hospital is located in an adjacent health planning area, the nearest acute care hospital.

2. Document a referral system that includes a feedback mechanism for communicating scan results and any other pertinent patient information to the referring physician.

3. Document that the applicant will maintain current listings of appropriate clinical indications for PET procedures and will provide such listings to referring physicians and patients.

4. Document how medical emergencies will be managed in conformity with accepted medical practice.

(g) An applicant for a new or expanded service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.41

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Positron Emission Tomography Units" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: New Rule of same title adopted. F. May 13, 2008; eff. June 2, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

111-2-2-.42 Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units

(1) **Applicability.**

(a) A Certificate of Need will be required for the establishment of any new or expanded MegaVoltage Radiation Therapy Service.

(b) MegaVoltage Radiation Therapy, including Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) may be conducted on non-special units or on special purpose units.

(c) A Certificate of Need will be required for the addition of a non-special MRT unit. An application for the addition of a non-special MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(3) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a non-special unit may not provide service on a special purpose unit without obtaining a special purpose MRT Certificate of Need.

(d) A Certificate of Need will be required for the addition of a special purpose MRT unit. An application for the addition of a special purpose MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(4) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a special purpose unit may not provide service on a non-special unit without obtaining a non-special MRT Certificate of Need.

(e) An application for the establishment of a new or expanded MegaVoltage Radiation Therapy Service with the addition of both non-special and special purpose MRT units shall address the standards of Ga. Comp. R. & Regs. r. 111-2-2-.42(3), 111-2-2-.42(4) and the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1).

(2) **Definitions.**

(a) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, Palladium-103 and Iridium-192.

(b) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(c) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(d) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(e) "Health Planning Area" or "Planning Area" means the geographic regions in Georgia for use in planning for MRT services.

1. The Health Planning Areas or Planning Areas for non-special MRT services are the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

2. The Health Planning Areas or Planning Areas for special purpose MRT services are five sub-state regions comprised as follows:

(i) Special Purpose MRT Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Douglas, DeKalb, Rockdale, Newton, Henry, Clayton, and Fayette;

(ii) Special Purpose MRT Region 2, including the following counties: Elbert, Madison, Jackson, Barrow, Oconee, Clarke, Oglethorpe, Greene, Morgan, Walton, Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Glascock, Jefferson, Richmond, Burke, Screven, Jenkins, and Emmanuel;

(iii) Special Purpose MRT Region 3, including the following counties: Carroll, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, Upson, Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Brooks, Thomas, Grady, Decatur, and Seminole;

(iv) Special Purpose MRT Region 4, including the following counties: Hancock, Putnam, Jasper, Butts, Monroe, Jones, Baldwin, Washington, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, Crawford, Dooly, Crisp, Ben Hill, Irwin, Turner, Cook, Tift, Berrien, Lanier, Echols, and Lowndes; and

(v) Special Purpose MRT Region 5, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, McIntosh, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(f) "Heavy particle accelerator" means a machine such as a cyclotron, which produces beams of high-energy particles such as protons, neutrons, pions, or heavy ions with rest masses greater than that of an electron (mc2 = 0.511 MeV).

(g) "Horizon Year" means the last year of a five-year projection period for need determinations for MRT services.

(h) "Intensity modulated radiation therapy" or "IMRT" means a treatment delivery utilizing a radiotherapy treatment plan optimized using an inverse or forward planning technique to modulate the particle or energy fluence to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multi-leaf collimator or high resolution milled or cast compensators.

(i) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(j) "MegaVoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by an MRT unit.

(k) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(l) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MeV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(m) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit.

(n) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(o) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(p) "Simulation" is the process of defining relevant normal and abnormal anatomy, acquiring the images and data necessary to develop the patient's approved radiation treatment plan. Simulation always occurs prior to treatment and may be repeated multiple times during the course of treatment depending on the type of cancer, the radiation therapy technique utilized and the patient's clinical response to treatment. Simulation is used to direct the treatment beams to the specific volume.

(q) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units:

(i) heavy particle accelerator;

(ii) gamma knife;

(iii) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC), including CyberKnife; or

(iv) an OR-based IORT unit.

(r) "Stereotactic body radiation therapy (SBRT)" is a term used to describe extracranial stereotactic radiosurgery (SRS) or radiotherapy (SRT). SBRT is a radiotherapy treatment method to deliver a high dose of radiation to the target, utilizing either a single dose or a small number of fractions with a high degree of precision within the body.

(s) "Stereotactic treatment visit" or "SRS treatment visit" means a visit involving SRS or SBRT treatment techniques.

(t) "Stereotactic Radiosurgery (SRS)" is performed in a limited number of treatment visits (up to a maximum of five), using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system to treat lesions in the body (extracranial) or brain (intracranial). Technologies that are used to perform SRS include linear accelerators, particle beam accelerators and multi source Cobalt-60 units.

(u) "SRS LINAC" is a dedicated linear accelerator stereotactic radiosurgery unit that consists of three key components:

(i) an advanced linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation),

(ii) a device which can point the linear accelerator from a wide variety of angles, and

(iii) image-guidance patient positioning system using kilovoltage x-rays for either in-room diagnostic x-rays or tomographic images. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and use this information to target the radiation beam emitted by the linear accelerator, SRS LINAC includes units such as CyberKnives.

(v) "Treatment site" means the anatomical location of the MRT treatment.

(w) "Treatment visit" means one patient encounter during which MRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(x) "Unit" means a single machine used for MRT services.

(y) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) **Standards for Non-Special MRT.**

(a) The need for the addition of a non-special MRT unit shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing services not including units added through the exception in section (3)(b)(2) of this Rule.

1. The numerical need for the addition of a non-special MRT unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the number of projected cancer cases in each county that could be treated with a non-special MRT unit;

(iii) Add the number of treatable cases for each county within a Health Planning Area to determine the projected number of patients needing treatment with a non-special MRT unit within the Health Planning Area in the horizon year;

(iv) Multiply the number obtained in step (iii) above by the most recent two year average of treatment visits per patient for the respective planning area of each county to project the number of projected patient visits in the horizon year;

(v) Determine the percentage of total visits in each planning area attributable to (1) Simple treatment visits, (2) Intermediate treatment visits, (3) Complex treatment visits, (4) IMRT, and (5) SRS treatment visits performed on non-special equipment as based on a running average of the most recent two annual surveys for facilities located in each respective planning area. Prior to the 2008 survey year, the percentage of total visits in each planning area shall be based on the most recent annual survey for facilities located in each respective planning area;

(vi) Determine the number of projected equivalent visits in the horizon year for each planning area as follows:

A. Project the number of equivalent simple visits by multiplying the percentage obtained in step (v) for simple visits by the projected patient visits in the horizon year obtained in step (iv);

B. Project the number of equivalent intermediate visits by multiplying the percentage obtained in step (v) for intermediate visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for intermediate visits, 1.1;

C. Project the number of equivalent complex visits by multiplying the percentage obtained in step (v) for complex visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for complex visits, 1.3;

D. Project the number of equivalent IMRT visits by multiplying the percentage obtained in step (v) for IMRT visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for IMRT visits, 1.8;

E. Project the number of equivalent SRS visits by multiplying the percentage obtained in step (v) for SRS visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for SRS visits, 7.0; and

F. Sum the products obtained in step (vi)A. through step (vi)E.;

(vii) Calculate the number of needed non-special MRT units by dividing the number of projected equivalent visits obtained in step (iv)F. by 9,000, which represents the weighted equivalent capacity of a non-special MRT unit within a given year; and

(viii) Determine the net numerical unmet need for non-special MRT units by subtracting the total number of non-special MRT units currently existing or approved for use, not including units approved pursuant to the exception in section (3)(b)2. of this Rule, from the number of needed non-special MRT units obtained in step (vii).

2. Prior to approval of an additional non-special MRT unit in a planning area, the aggregate utilization rate for all existing non-special MRT units, not including units approved pursuant to the exception in section (3)(b)2. of this Rule, in that planning area shall equal or exceed eighty percent (80%) of capacity based on 9,000 weighted equivalent visits. For those existing non-special MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate.

(b) Exceptions to the need standard referenced in (3)(a) may be granted for applicants proposing any of the following:

1. To assure geographic access to non-special MRT services in rural areas when the proposed service is:

(i) to be located in a rural county;

(ii) to be located a minimum of 45 miles away from any existing or approved non-special MRT service; and

(iii) projected to serve a minimum of 150 patients per year. For purposes of this requirement, service projections must be submitted by the applicant using, at a minimum, state cancer registry data and documented cancer treatments within the service area.

2. To allow expansion of an existing service if the actual utilization of each radiation therapy unit within that service has exceeded ninety percent (90%) of optimal utilization over the most recent two years. Any such units approved pursuant to this exception shall not be included in the calculation of need and aggregate utilization for the applicable service delivery region but will be included in the Department non-special MRT unit inventory.

3. To allow the addition of a non-special MRT unit at the same defined location if the applicant has a substantial out-of-state patient base. 'Substantial out of state patient base' shall be defined as using at least thirty-three percent (33%) of capacity or 2,970 weighted equivalent visits at the applicant's own percentage of treatment visits weighted by treatment type using the statewide weighted equivalent factor for each non-special MRT unit over the most recent two years to treat patients who reside outside of the State of Georgia.

4. To remedy an atypical barrier to non-special MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded non-special MRT service shall document the impact on existing and approved services which already provide non-special MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded non-special MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service, whose current utilization is at or above eighty percent (80%), to a projected utilization of less than seventy percent (70%) within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit; or

2. decrease annual utilization of an existing service, whose current utilization is below eighty percent (80%), by ten percent (10%) or more within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing non-special MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing non-special MRT services, if any, within the planning area. An applicant proposing an additional non-special MRT unit pursuant to the exceptions to need standards referenced in (3)(b)2. shall not be required to document impact on existing and approved services as required by this paragraph.

(d) An applicant for a new or expanded non-special MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the non-special MRT service;

3. providing a written commitment to participate in the Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded non-special MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the non-special MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a Brachytherapy package;

3. Non-Special MRT capability including electron beam capability;

4. Capability to fabricate treatment aids; and

5. Access to brachytherapy;

(f) The applicant must provide a written commitment that physicians providing professional radiation oncology services at the MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff, or are eligible for and have an active pending application for privileges, of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

1. One (1) FTE board-certified or board-qualified physician trained in radiation oncology, which shall be available by continuous means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

2. One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with a special competence in radiation oncology physics; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

3. One (1) medical dosimetrist, who shall be a member of the radiation oncology team who has the knowledge of the overall characteristics and clinical relevance of radiation oncology treatment machines and equipment, is cognizant of procedures commonly used in brachytherapy and has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

4. Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); and who shall be on-site at all times of operation of the facility; and

5. One (1) program director, who shall be a board-certified physician trained in radiation oncology who may also be the physician required under (h)1.; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

(i) An applicant for a new or expanded non-special MRT service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

(4) **Standards for Special Purpose MRT.**

(a) The need for the addition of a special purpose MRT unit shall be determined through analysis of the capacity and utilization of the existing units of the same type in the planning area and an applicant's reasonable and documented projection of a minimum volume as follows:

Special MRT Equipment	**Capacity**	**Minimum Aggregate Utilization**	**Minimum Projected Volume**
Gamma Knife	500	80%	300 by 3rd Year of Operation
Heavy Particle Accelerator	4,000 per Gantry	80%	2,400 per Gantry by 3 rd Year of Operation
Dedicated SRS LINAC (including CyberKnife)	850	80%	510 by 3rd Year of Operation
OR-based IORT	350	80%	150 by 3rd Year of Operation

Where capacity is measured in annual procedures; where minimum aggregate utilization is the aggregate utilization rate for all existing special purpose MRT units of the same type (Gamma Knife utilization for Gamma Knife, etc.) in the planning area, except that for those existing special purpose MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate for special purpose equipment of the same type; and where the minimum projected volume is measured in procedures per year.

(b) Exceptions to the need standards referenced in (3)(a) may be granted for applicants proposing to remedy an atypical barrier to special purpose MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded special purpose MRT service shall document the impact on existing and approved services of the same type (Gamma Knife for Gamma Knife application, etc.) which already provide special purpose MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded special purpose MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service of the same type, whose current utilization is at or above seventy percent (70%), to a projected utilization of less than sixty percent (60%) within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit; or

2. decrease annual utilization of an existing service of the same type, whose current utilization is below seventy percent (70%), by ten percent 10% or more within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing special purpose MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing special purpose MRT services, if any, within the planning area.

(d) An applicant for a new or expanded special purpose MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the special purpose MRT service;

3. providing a written commitment to participate in the Medicaid and PeachCare for KidsT programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded special purpose MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the special purpose MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient; and

3. Capability to fabricate treatment aids as applicable.

(f) The applicant must provide written commitment that physicians providing professional radiation oncology services at the special purpose MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available;

1. For applicants seeking the addition of a Gamma Knife:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating a Gamma Knife and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating a Gamma Knife; and who shall be available on-site;

2. For applicants seeking the addition of a Heavy Particle Accelerator, Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists ("ARRT") or the American Registry of Clinical Radiography Technologists ("ARCRT"); who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times of operation of the facility;

3. For applicants seeking the addition of a dedicated SRS LINAC:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an SRS LINAC; and who shall be available on-site;

(iii) One (1) radiation therapy technologist, who shall be registered or eligible by the American Registry of Radiological Technologists or the American Registry of Clinical Radiography Technologists; who shall have received special training in operating an SRS LINAC; and who shall be on-site at all times of operation of the facility; and

4. For applicants seeking the addition of an OR-Based IORT unit:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site.

(i) An applicant for a new or expanded special purpose MRT service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.42

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Specific Review Considerations for Radiation Therapy Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: New Rule entitled "Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units" adopted. F. May 13, 2008; eff. June 2, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Department 125. BOARD OF CORRECTIONS

Chapter 125-1. ADMINISTRATION

Subject 125-1-1. ORGANIZATION

125-1-1-.09 Records

(1) The records of the Board of Corrections and the Department of Corrections are maintained by the Commissioner of the Department of Corrections at his office in Atlanta.

(2) The request should include the Requestor's name, mailing address, contact telephone number, and list of records requested. The Department of Corrections will provide a response within a reasonable amount of time, not to exceed three (3) business days of receipt. Reasonable fees, as allowed by the Open Records Act, may be charged for fulfillment of the request.

(3) (a) All institutional inmate files and central office inmate files of the Department of Corrections are classified as confidential state secrets and privileged under law, unless declassified in writing by the Commissioner. These records are subject to subpoena by a court of competent jurisdiction of this state.

(b) Offenders' medical and mental health records are subject to the provisions of HIPAA.

(c) Investigative files and intelligence information compiled by the Office of Professional Standards are classified as confidential state secrets and privileged under law, unless declassified in writing by the Commissioner.

(d) Access to all other records maintained by the Department of Corrections shall be subject to the limitations imposed by state and/or federal law.

(4) Requests for information may be made in person at the Office of Legal Services, Gibson Hall, 300 Patrol Road, Forsyth, GA 31029, in writing to the Office of Legal Services, P.O. Box 1529, Forsyth, GA 31029, by telephone to (478) 992-5240, or via email to open.records@gdc.ga.gov.

Cite as Ga. Comp. R. & Regs. R. 125-1-1-.09

AUTHORITY: O.C.G.A. §§ 42-2-2**,** 42-2-11**,** 42-5-36(c)**,** 50-18-70***, et seq*****.**

HISTORY: Original Rule entitled "Records" adopted as R. 415-1-1-.09. F. July 19, 1983; eff. August 8, 1983.

Amended: F. Apr. 11, 1985; eff. May 1, 1985; renumbered as R. 125-1-1-.09 of same title. F. June 28, 1985; eff. July 20, 1985, as specified by the Agency.

Amended: F. Feb. 6, 2003; eff. Feb. 26, 2003.

Amended: F. June 5, 2008; eff. June 25, 2008.

Amended: F. Mar. 2, 2022; eff. Mar. 22, 2022.

Department 160. RULES OF GEORGIA DEPARTMENT OF EDUCATION

Chapter 160-1.

Subject 160-1-4. GRANT PROGRAMS

160-1-4-.307 Computer Science Capacity II Grant

1. **Purpose of Grant.** This grant will support the development of computer science teacher capacity in public schools in Georgia that have not previously offered the AP Computer Science Principles course.

2. **Term and Conditions.** Grants are awarded through a competitive process to local educational agencies (LEA). Each recipient LEA shall use the grant funds for the growth and development of the teacher(s) identified in the application. The funds must be used for at least one of the following activities: paying for a Computer Science endorsement, paying for the summer AP Institute workshop, or paying for training with a curriculum or equipment provider. The funds may also be used pay a stipend to the identified teacher. Grant funds are one-time funds and must be expended during the fiscal year in which they are awarded. There is no allowability for carryover.

3. **Eligible Recipient(s).** All LEAs are eligible to apply.

4. **Criteria for Award.** Applications will be reviewed and scored by the Georgia Department of Education. Funding will be awarded based on rank (the highest score first) and available funding. Priority points will be awarded to rural LEAs, LEAs that have schools that have not offered the AP Computer Science Principles course, and LEAs that have schools that intend to offer the AP Computer Science Principles course in the school year immediately following the grant award.

5. **Directions and Deadlines for Applying.** Information regarding the application process, including the deadline, will be communicated to Career, Technical, and Agricultural Education Directors and Curriculum Directors. For additional information, please contact Bryan Cox, Lead Computer Science Program Specialist, Curriculum and Instruction, Georgia Department of Education, at bcox@doe.k12.ga.us.

Cite as Ga. Comp. R. & Regs. R. 160-1-4-.307

AUTHORITY: O.C.G.A. § 20-2-240**.**

HISTORY: Original grant description entitled "Computer Science Capacity II Grant" submitted Mar. 16, 2022.

Department 300. RULES OF GEORGIA DEPARTMENT OF LABOR

Chapter 300-2. EMPLOYMENT SECURITY LAW

Subject 300-2-4. UNEMPLOYMENT INSURANCE BENEFIT PAYMENTS

300-2-4-.08 Overpayments

(1) An individual shall be required to repay an overpayment of unemployment compensation unless a written application for waiver is filed with the Department and approved by the Commissioner or the Commissioner's designee.

(2) An application for waiver shall not be accepted for any overpayment the Department determined was the result of fraud attributable to the individual.

(3) An application for waiver shall not be approved if it is filed later than fifteen (15) calendar days following the release date of the Notice of Overpayment, provided, however, that the time limitation may be extended upon a showing of extenuating circumstances which prevented the filing of a timely application for waiver by the individual and such circumstances were beyond the individual's control.

(4) The Commissioner or the Commissioner's designee shall notify each individual in writing whether the application for waiver of overpayment has been approved or denied. The decision of the Commissioner or the Commissioner's designee shall become final unless the individual appeals the decision within 15 days after the notice was mailed or otherwise delivered to the individual.

(5) The Department shall suspend collection of an overpayment while an application for waiver of the same overpayment is pending.

(6) An application for waiver of overpayment of unemployment compensation shall be approved only if:

(a) The individual is determined to be without fault in the cause of the overpayment, regardless of whether such fault rises to the level of fraud; and

(b) Repayment of the overpayment is determined to be contrary to equity and good conscience.

(7) Repayment of the overpayment shall be contrary to equity and good conscience if:

1. It would cause financial hardship to the person for whom waiver is sought;

2. The recipient of the overpayment can show (regardless of their financial circumstances) that due to the notice that such payment would be made or because of the incorrect payment either they have relinquished a valuable right or changed positions for the worse; or

3. Recovery would be unconscionable under the circumstances.

(8) An application for waiver of overpayment shall specify why the individual was without fault in the cause of the overpayment and why repayment would be contrary to equity and good conscience, including supporting documentation.

(9) The Department shall consider each individual's waiver application separately on its own merits, with due consideration of the facts and circumstances of each individual case. When authorized by federal law and

regulations, and when it would not create a federal conformity issue, the Department may approve blanket waivers for groups of similarly situated individuals.

(10) Upon approval of an application for waiver, the Department shall refund any amounts that were collected towards the applicable overpayment prior to such approval, except when prohibited by state or federal law.

(11) A waiver of an unemployment insurance overpayment may be issued by the department in whole or in part upon the finding of a court of law having proper subject matter jurisdiction which rules that error existed in the information utilized to establish such overpayment, whether or not such overpayment was determined to be fraudulent in nature. Additionally, if a court finds repayment of an overpayment should be waived by virtue of discharge in bankruptcy under federal bankruptcy law, waiver will be granted.

(12) This rule shall apply to overpayments of all federal or state unemployment compensation programs administered by the Department, but only to the extent this rule is consistent with federal law and regulations, and would not create a federal conformity issue. An application for waiver of an overpayment of unemployment compensation shall not be approved when waiver would be prohibited by federal law or regulation, regardless of an individual's fault.

(13) Covid-19 Pandemic Overpayment Provisions.

(a) For any Notice of Overpayment issued prior to the effective date of this rule that established an overpayment for one or more weeks ending February 8, 2020, through June 26, 2021, the fifteen (15) day time limitation to file an application for waiver of overpayment shall be waived through June 30, 2022.

(b) An individual whose application for waiver of overpayment was denied prior to the effective date of this rule may request a redetermination; provided, however, that only overpayment weeks ending February 8, 2020, through June 26, 2021, shall be eligible for redetermination and the request for redetermination must be submitted to the Department before July 1, 2022. A redetermination with respect to eligible weeks shall be made in accordance with the provisions of this rule.

Cite as Ga. Comp. R. & Regs. R. 300-2-4-.08

AUTHORITY: O.C.G.A. §§ 34-2-6(a)(4), 34-8-70(b), 34-8-254(c); 34-8-197(b).

HISTORY: Original Rule entitled "Waiver of Overpayments" adopted F. Aug. 28, 1992; eff. Sept. 17, 1992.

Amended: F. Jun. 25, 1998; eff. July 15, 1998.

Amended: F. Jan. 10, 2012; eff. Jan. 30, 2012.

Repealed: New Rule entitled "Overpayments. Amended" adopted. F. Oct. 1, 2013; eff. Oct. 21, 2013.

Amended: F. Sep. 29, 2014; eff. Oct. 19, 2014.

Amended: F. Aug. 13, 2020; eff. Aug. 13, 2020, as specified by the Agency.

Amended: F. Feb. 9, 2021; eff. Mar. 1, 2021.

Amended: F. Dec. 28, 2021; eff. Jan. 1, 2022, as specified by the Agency.

Amended: F. Mar. 31, 2022; eff. Apr. 1, 2022, as specified by the Agency.

Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

Chapter 391-3. ENVIRONMENTAL PROTECTION

Subject 391-3-4. SOLID WASTE MANAGEMENT

391-3-4-.10 Coal Combustion Residuals

(1) Applicability.

(a) This Rule applies to the following:

1. Owners and operators of new and existing landfills and surface impoundments, including any lateral expansions of such units that dispose or otherwise engage in solid waste management of CCR generated from the combustion of coal at electric utilities and independent power producers. Unless otherwise provided in this Rule, these requirements also apply to disposal units located off-site of the electric utility or independent power producer.

2. All CCR units.

3. Any practice that does not meet the definition of a beneficial use of CCR.

(b) This Rule does not apply to the following:

1. Wastes, including fly ash, bottom ash, boiler slag, and flue gas desulfurization materials generated at facilities that are not part of an electric utility or independent power producer, such as manufacturing facilities, universities, and hospitals.

2. Fly ash, bottom ash, boiler slag, and flue gas desulfurization materials, generated primarily from the combustion of fuels (including other fossil fuels) other than coal, for the purpose of generating electricity unless the fuel burned consists of more than fifty percent (50%) coal on a total heat input or mass input basis, whichever results in the greater mass feed rate of coal.

3. CCR placement at active or abandoned underground or surface coal mines.

4. Municipal Solid Waste Landfills and Commercial Industrial Landfills that receive CCR.

(c) Standards for the Disposal of Coal Combustion Residuals in Landfills and Surface Impoundments 40 CFR 257.60 through 257.107, 80 Fed. Reg. 21468 (April 17, 2015); as amended at 80 Fed. Reg. 37988 (July 2, 2015), 81 Fed. Reg. 51807 (August 5, 2016), 83 Fed. Reg. 36451 (July 30, 2018), and 85 Fed. Reg. 53561 (August 28, 2020), are hereby incorporated.

(d) Any reference to 40 C.F.R. Parts in any provisions adopted by reference shall be construed to refer to the provisions contained in the following sections of these Rules:

Federal Regulation Reference	Georgia Rule Reference
40 C.F.R. Part 257.53	391-3-4-.10(2)
40 C.F.R. Parts 257.60 - 257.64	391-3-4-.10(3)
40 C.F.R. Parts 257.70 - 257.74	391-3-4-.10(4)
40 C.F.R. Parts 257.80 - 257.84	391-3-4-.10(5)
40 C.F.R. Parts 257.90 - 257.98	391-3-4-.10(6)

Federal Regulation Reference	Georgia Rule Reference
40 C.F.R. Parts 257.100 - 257.104	391-3-4-.10(7)
40 C.F.R. Parts 257.105 - 107	391-3-4-.10(8)

(2) Definitions.

(a) Definitions in 40 CFR 257.53 are incorporated by reference into this section and are applicable to CCR units with the following additions and revision:

1. "Dewatered Surface Impoundment" means a CCR surface impoundment that no longer receives CCR on or after October 19, 2015 and does not contain liquids on or after October 19, 2015.

2. "NPDES -CCR Surface Impoundment" means a CCR surface impoundment that no longer receives CCR on or after October 19, 2015 which still contains both CCR and liquids and is located at an electric utility or independent power producer that has ceased producing electricity prior to October 19, 2015.

3. "Inactive CCR Landfill" means a CCR landfill that no longer receive s CCR and other wastes on or after October 19, 2015.

4. The following text shall be substituted for the fourth condition in the definition of Beneficial use of CCR "(4) For unencapsulated use of CCR, the user must demonstrate to the Division and provide documentation to the Division that environmental releases to groundwater, surface water, soil, and air are comparable to or lower than those from analogous products made without CCR, or that environmental releases to groundwater, surface water, soil, and air will be at or below relevant regulatory and health-based benchmarks for human and ecological receptors during use."

(3) Location Restrictions.

(a) New CCR landfills, existing and new CCR surface impoundments, and all lateral expansions of CCR units must meet the location restrictions in 40 CFR 257.60, 40 CFR 257.61, 40 CFR 257.62, and 40 CFR 257.63.

(b) Existing or new CCR landfills, existing or new CCR surface impoundments, or lateral expansions of a CCR unit must meet the location restrictions in 40 CFR 257.64.

(c) For new and lateral expansions of CCR units, the hydrogeological evaluation for a specific site must be performed by a qualified groundwater scientist.

(d) For new and lateral expansions of CCR units, when the geological and hydrogeological data so indicate, the Division may specify greater separation distances to protect groundwater.

(e) Buffers: New CCR units and lateral expansions of CCR units must provide a 200-foot undisturbed buffer between the waste disposal boundary and the boundary of the permitted facility and a minimum 500-foot buffer between the waste disposal boundary and any occupied dwelling and the dwelling's operational private, domestic water supply well in existence on the date of the permit application. The 500-foot buffer may be reduced if the current owner of the dwelling provides a written waiver consenting to the waste disposal boundary being closer than 500 feet. No disposal or storage practices for waste shall take place in the buffer zones.

(4) Design Criteria.

(a) New CCR landfills and lateral expansions of CCR landfills shall be designed in accordance with 40 CFR 257.70.

(b) Existing CCR surface impoundments shall comply with liner design criteria in 40 CFR 257.71 and the structural integrity criteria in 40 CFR 257.73.

(c) New CCR surface impoundments and lateral expansions of CCR surface impoundments shall be designed and comply with requirements in 40 CFR 257.72 and 40 CFR 257.74.

(5) Operating Criteria.

(a) CCR landfills shall be operated in accordance with the criteria in 40 CFR 257.80, 40 CFR 257.81, and 40 CFR 257.84.

(b) CCR surface impoundments shall be operated in accordance with the criteria in 40 CFR 257.80, 40 CFR 257.82, and 40 CFR 257.83.

(c) The operation and use of the CCR unit shall be as stipulated in the solid waste handling permit.

(6) Groundwater Monitoring and Corrective Action.

(a) CCR units are subject to the groundwater monitoring and corrective action requirements in 40 CFR 257.90, 40 CFR 257.91, 40 CFR 257.93, 40 CFR 257.94, 40 CFR 257.95, 40 CFR 257.96, 40 CFR 257.97, and 40 CFR 257.98.

(b) When referenced in this Rule, Appendix III and Appendix IV constituents shall refer to those constituents as listed in Appendix III and IV of 40 CFR Part 257, Subpart D, 80 FR 21468, (Apr. 17, 2015), which are hereby incorporated by reference.

(c) The owner or operator of a CCR unit must submit a semi-annual report to the Division to coincide with the semi-annual sampling event. A qualified groundwater scientist must certify the report.

(d) The Division must provide concurrence with the following actions in order for them to be complete:

1. Groundwater monitoring system design

2. Groundwater sampling and analysis plan

3. Groundwater monitoring well installation

4. Alternate source demonstration

5. Selection of remedy

6. Completion of remedy

(e) The Director may require the analysis of additional parameters based on waste descriptions.

(f) An owner or operator of a CCR unit shall continue to monitor for Appendix I or II constituents if these constituents have previously been detected at statistically significant levels above background concentrations.

(g) Monitoring wells require replacement after two dry sampling events, unless an alternate schedule has been approved by the Division. A minor modification shall be submitted in accordance with Rule 391-3-4-.02 prior to the installation or decommissioning of monitoring wells. Well installation must be directed by a qualified groundwater scientist.

(7) Closure and Post-Closure Care.

(a) Inactive surface impoundments are subject to the requirements in 40 CFR 257.100.

1. The following additional requirements apply to inactive surface impoundments:

(i) Permitting requirements in Rule 391-3-4-.10(9)

(ii) Groundwater monitoring and corrective action requirements in Rule 391-3-4-.10(6)

2. CCR surface impoundments that complete closure through removal of CCR are subject only to the requirements in subparagraph (9)(c)6(v)(I) of Rule 391-3-4-.10.

(b) Closure or retrofit of existing, new, and lateral expansions of CCR units shall be conducted in accordance with 40 CFR 257.101, 40 CFR 257.102, and 40 CFR 257.103.

(c) The owner or operator must close the CCR unit in accordance with the written closure plan.

(d) A notice of intent to close must be provided to the Director after receipt of the final load of waste.

(e) Upon completion of closure activities, a professional engineer registered in Georgia shall prepare and submit a closure report to the Director. The closure report must be completed on forms provided by the Division. If the Director concurs with the closure report, closure will be deemed complete and the facility may begin the post-closure care period.

(f) Concurrent with the submission of this closure report to the Director, the owner or operator must submit confirmation to the Director that a notation on the property deed has been recorded. This recording must in perpetuity notify any potential purchaser of the property that the land has been used as a CCR unit and that its use is restricted under the post-closure care requirements of this Rule. This requirement does not apply to CCR units closed by removal.

(g) Post-Closure care for existing, new, and lateral expansions of CCR units shall be conducted in accordance with 40 CFR 257.104 with the following additions:

1. CCR units must comply with the conditions of the solid waste handling permit.

2. The release of CCR units from post-closure care must be approved by the Division.

(8) Recordkeeping, Notification, and Posting of Information to the Internet.

(a) The requirements of 40 CFR 257.105, 40 CFR 257.106, and 40 CFR 257.107 are incorporated by reference with the following addition:

1. Electronic mail sent to a designated EPD recipient is an authorized form of notification when approved by EPD.

(9) Permits.

(a) CCR Permit Applications: After the effective date of this Rule, owners and operators of all CCR units are required to submit to the director a permit application that meets the requirements of this Rule. Separate permits are required for each CCR unit.

1. Owners and operators of new CCR units are required to submit to the director a complete permit application prior to the initial receipt of CCR.

2. Owners and operators of existing and inactive CCR units shall submit a complete permit application no later than two years from the effective date of the Rule.

(b) All CCR unit permit applications must include the following:

1. A completed form designated by EPD.

2. Written verification that the site conforms to all local zoning or land use ordinances.

3. Property boundary survey and legal description.

4. Financial assurance mechanism meeting the criteria in Rule 391-3-4-.13.

5. A qualified professional engineer's certification that all application requirements have been met.

(c) Additional permit application requirements for CCR Units by Facility Type:

1. New CCR landfills or lateral expansion of CCR landfills

(i) Technical data and report to comply with location restrictions in 40 CFR 257.60, 40 CFR 257.61, 40 CFR 257.62, 40 CFR 257.63, and 40 CFR 257.64.

(ii) Siting report that meets the criteria specified in "Criteria for Performing Site Acceptability Studies for Solid Waste Landfills in Georgia", Circular 14, Appendix A. The report shall be prepared by a qualified groundwater scientist.

(iii) Plan and profile sheets of the disposal area. The plan and profile sheets shall include topographical maps at contour intervals of not more than five feet for the existing ground surface elevations, initial disposal area elevations, final disposal area elevations, and buffers.

(iv) Design of a liner and leachate collection system as required by 40 CFR 257.70.

(v) Quality assurance/quality control (QA/QC) plan for the construction of the liner system, leachate collection system, and the final cover system.

(vi) An operation plan that includes at a minimum:

(I) A fugitive dust plan in compliance with 40 CFR 257.80.

(II) A run-on and run-off control plan in compliance with 40 CFR 257.81.

(III) Inspection requirements in compliance with 40 CFR 257.84.

(IV) Identification of any uniquely associated wastes as listed in 40 CFR 261.4(b)(4), the estimated quantities generated by the facility, and a description of how these wastes will be managed.

(V) Procedures for compliance with recordkeeping, notification, and posting of information to the internet as required by 40 CFR 257.105, 40 CFR 257.106, and 40 CFR 257.107.

(VI) Procedures for updating all plans and assessments periodically as required by 40 CFR Part 257.

(vii) A groundwater monitoring plan in accordance with Rule 391-3-4-.10(6).

(viii) A closure and post-closure plan in accordance with Rule 391-3-4.10(7).

(ix) Any additional information that may be required by the Division.

2. New Surface Impoundments or lateral expansions of surface impoundments

(i) Technical data and report to comply with location restrictions in 40 CFR 257.60, 40 CFR 257.61, 40 CFR 257.62, 40 CFR 257.63, and 40 CFR 257.64.

(ii) Siting report that meets the criteria specified in "Criteria for Performing Site Acceptability Studies for Solid Waste Landfills in Georgia", Circular 14, Appendix A. The report shall be prepared by a qualified groundwater scientist.

(iii) Technical report for the hazardous potential classifications as outlined in 40 CFR 257.74 and the emergency action plan if required by 40 CFR 257.74.

(iv) For a new CCR surface impoundment that has a height of five feet or more and a storage volume of 20 acre-feet or more, or a surface impoundment with a height of 20 feet or more, the application shall include the following:

(I) Design and construction plan requirements in 40 CFR 257.74.

(II) Structural stability assessment as required by 40 CFR 257.74.

(III) Safety factor assessment as required by 40 CFR 257.74.

(v) Design of a liner system as required by 40 CFR 257.72.

(vi) Quality assurance/quality control (QA/QC) plan for the construction of the liner system, leachate collection system, and the final cover system.

(vii) An operation plan that includes at a minimum:

(I) A fugitive dust plan in compliance with 40 CFR 257.80.

(II) An inflow design flood control system in compliance with 40 CFR 257.82.

(III) Inspection requirements in compliance with 40 CFR 257.83.

(IV) Identification of any uniquely associated wastes as listed in 40 CFR 261.4(b)(4), the estimated quantities generated by the facility, and a description of how these wastes will be managed.

(V) Procedures for compliance with recordkeeping, notification, and posting of information to the internet as required by 40 CFR 257.105, 40 CFR 257.106, and 40 CFR 257.107.

(VI) Procedures for updating all plans and assessments periodically as required by 40 CFR Part 257.

(viii) A groundwater monitoring plan in accordance with Rule 391-3-4-.10(6).

(ix) A closure and post-closure plan in accordance with Rule 391-3-4-.10(7).

(x) Any additional information that may be required by the Division.

3. Existing CCR landfills

(i) Location restriction demonstration requirements in 40 CFR 257.64.

(ii) Description of how the CCR landfill's operating criteria requirements in 40 CFR 257.80, 40 CFR 257.81, and 40 CFR 257.84 are met.

(iii) Groundwater monitoring plan in accordance with 391-3-4-.10(6). Explanation of how groundwater monitoring and corrective action criteria requirements in 40 CFR 257.90, 40 CFR 257.91, 40 CFR 257.93, 40 CFR 257.94, 40 CFR 257.95, 40 CFR 257.96, 40 CFR 257.97, and 40 CFR 257.98 are met.

(iv) Explanation of how closure and post-closure care requirements in 40 CFR 257.101, 40 CFR 257.102, 40 CFR 257.103, and 40 CFR 257.104 will be met.

(v) Website address for information required to be posted by 40 CFR 257.105, 40 CFR 257.106, and 40 CFR 257.107.

4. Inactive CCR landfills must meet requirements subparagraphs (9)(c)3.(i) - (iv) of this Rule for an existing CCR landfill.

5. Existing Surface Impoundments

(i) Location restriction demonstrations required by 40 CFR 257.60, 40 CFR 257.61, 40 CFR 257.62, 40 CFR 257.63, and 40 CFR 257.64.

(ii) Description of the CCR surface impoundment's design criteria required by 40 CFR 257.71 and 40 CFR 257.73.

(iii) Description of how the CCR surface impoundment's operating criteria required by 40 CFR 257.80, 40 CFR 257.82, and 40 CFR 257.83 are met.

(iv) Groundwater monitoring plan in accordance with Rule 391-3-4-.10(6). Explanation of how groundwater monitoring and corrective action criteria required by 40 CFR 257.90, 40 CFR 257.91, 40 CFR 257.93, 40 CFR 257.94, 40 CFR 257.95, 40 CFR 257.96, 40 CFR 257.97, and 40 CFR 257.98 are met.

(v) Explanation of how closure and post-closure care requirements found in 40 CFR 257.101, 40 CFR 257.102, 40 CFR 257.103, and 40 CFR 257.104 will be met.

(vi) Website address for information required to be posted by 40 CFR 257.105, 40 CFR 257.106, and 40 CFR 257.107.

6. Inactive Surface Impoundments. An owner or operator of an inactive surface impoundment shall complete closure of the CCR unit as specified in 40 CFR 257.100, including:

(i) Technical data and report showing compliance with 40 CFR 257.100.

(ii) Technical report of geological and hydrogeological units within the disposal site.

(iii) Potentiometric surface map of the water table.

(iv) Siting report which includes identification of wetlands, floodplains, and seismic impact zones.

(v) Written closure plan that includes at a minimum:

(I) Narrative describing how the CCR unit will be closed including the elimination of free liquids and stabilization of remaining waste or by closure through removal of CCR.

(II) Identification of any pipes, utilities, or other penetrations through or beneath the impoundment. The inspection frequency and method of evaluation should be provided.

(II) Final cover analysis.

(vi) Stability analysis that, at a minimum, includes the following:

(I) On-site or local soil conditions that may result in significant differential settling.

(II) On-site or local geologic or geomorphologic features.

(III) On-site or local human-made features or events, both surface and subsurface.

(vii) Groundwater monitoring plan in accordance with Rule 391-3-4-.10(6).

(viii) Closure through removal of CCR is subject only to (v)(I) above and is not subject to the financial assurance requirements of Rule 391-3-4-.13.

7. NPDES - CCR Surface Impoundments

(i) Technical report of geological and hydrogeological units within the disposal site.

(ii) Potentiometric surface map of the water table.

(iii) Siting report which includes identification of wetlands, floodplains, and seismic impact zones.

(iv) Closure plan that includes at a minimum:

(I) Narrative describing how the CCR unit will be closed including the elimination of free liquids and stabilization of remaining waste or by closure through removal of CCR.

(II) Identification of any pipes, utilities, or other penetrations through or beneath the impoundment. The inspection frequency and method of evaluation should be provided.

(III) Final cover analysis.

(v) Stability analysis that at a minimum includes the following:

(I) On-site or local soil conditions that may result in significant differential settling.

(II) On-site or local geologic or geomorphologic features.

(III) On-site or local human-made features or events, both surface and subsurface.

(vi) Groundwater monitoring plan in accordance with Rule 391-3-4-.10(6).

(vii) Closure through removal of CCR is subject only to (iv)(I) above and is not subject to the financial assurance requirements of Rule 391-3-4-.13.

8. Dewatered Surface Impoundments

(i) Demonstration that closure procedures have minimized the threat to human health and the environment.

(ii) Stability analysis.

(iii) Final cover analysis.

(iv) Groundwater monitoring plan in accordance with Rule 391-3-4-.10(6).

(10) Financial Assurance.

(a) All CCR units must meet requirements in Rule 391-3-4-.13.

(11) Variances.

(a) A compliance schedule variance for dewatered surface impoundments and inactive CCR landfills not meeting the minimum criteria in 391-3-4-.10 may be considered upon the following:

1. A demonstration that no alternative units meeting the minimum requirement either on-site or off-site can be used to dispose of the CCR or non-CCR wastewater;

2. A demonstration that the owner or operator is unable to use other public or private alternatives to manage the waste in the non-compliant unit; and

3. The schedule of compliance must specify remedial measures and an enforceable sequence of actions or operations leading to compliance within a reasonable time not to exceed time frames as specified in 40 CFR 257.102.

4. Variances may be granted under Rule 391-3-4-.10 which are not less stringent than those found in 40 CFR 257.60 through 257.107.

Cite as Ga. Comp. R. & Regs. R. 391-3-4-.10

AUTHORITY: O.C.G.A. § 12-8-20 ***et seq*.**

HISTORY: Original Rule was filed on September 19, 1974; effective October 9, 1974.

Repealed: New Rule entitled "Special Solid Waste" adopted. F. Jun. 9, 1989; eff. Jun. 29, 1989.

Amended: F. Sept. 4, 1991; eff. Sept. 24, 1991.

Repealed: F. Jun. 7, 1993; eff. Jun. 27, 1993.

Adopted: New rule entitled "Coal Combustion Residuals." F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Note: Correction of non-substantive typographical error in paragraph (11). *"Variances may be granted under Rule 391-3-4-.10 which are not less stringent than those found in 40 CFR 257.60 through 257.107."* corrected to *"(b) Variances may be granted under Rule 391-3-4-.10 which are not less stringent than those found in 40 CFR 257.60 through 257.107."*, as requested by the Agency. Effective Aug. 10, 2018.

Amended: F. Mar. 22, 2022; eff. Apr. 11, 2022.

Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

Chapter 391-3. ENVIRONMENTAL PROTECTION

Subject 391-3-17. RADIOACTIVE MATERIALS

391-3-17-.04 Special Radiation Safety Requirements for Industrial Radiographic Operations

(1) **Purpose.**

The provisions of this Rule establish radiation safety requirements and certification procedures for persons utilizing radioactive materials for industrial radiography. Each licensee and certificate holder is responsible for ensuring compliance with these Rules, his license conditions, and Orders of the Director. Each licensee and certificate holder is also responsible for ensuring that persons performing activities under a license comply with the Rules, license conditions, and Orders of the Director.

(2) **Scope.**

(a) The provisions of this Rule are in addition to and not a substitution for the other requirements of this Chapter. The provisions of this Rule apply to all licensees who use radioactive materials for industrial radiography; provided, however, that nothing in this Rule shall apply to the use of radioactive materials in the healing arts.

(b) The licensee shall inform the Division within three days of work to be performed at temporary job sites within the State of Georgia. If the licensee was not given three days notice for a particular job site the licensee shall provide notification to the Division prior to starting work at the site. The following information is required in the notification: the location of the job site; the employing company; a point of contact for the employing company; the dates of the job; and the starting and ending times on the job site.

(3) **Definitions.** The definitions set forth for certain terms in Rule 391-3-17-.01 are applicable to those terms as used in this Rule. The following additional definitions also apply:

(a) "Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

(b) "ANSI" means American National Standards Institute.

(c) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source. (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when used as an exposure head.)

(d) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that radiation levels at every location on the exterior meet the conditions specified in Rule 391-3-17-.03(5)(i).

(e) "Certifying entity" means an independent certifying organization meeting the requirements in Appendix A of this Rule or an Agreement State regulatory program meeting the requirements in Appendix A, Parts II and III of this Rule.

(f) "Collimator" means a device used to limit the size, shape, and direction of the primary beam of radiation.

(g) "Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

(h) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

(i) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(j) "Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.

(k) "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.

(l) "Field station" means a facility from which sources of radiation may be stored or used and from which equipment is dispatched.

(m) "Guide tube" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

(n) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.

(o) "Independent certifying organization" means an independent organization that meets all of the criteria of Appendix A of this Rule.

(p) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

(q) "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

(r) "Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

(s) "Permanent radiographic installation" means a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed.

(t) "Personal supervision" means guidance and instruction provided to a radiographer's assistant by a radiographer who is present at the site, in visual contact with the radiographer's assistant while the radiographer's assistant is using radioactive material, and in such proximity that immediate assistance can be given if required.

(u) "Pigtail" see "Source assembly".

(v) "Pill" see "Sealed source".

(w) "Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

(x) "Radiation Safety Officer" means an individual named by the licensee who has a knowledge of, responsibility for, and authority to impose appropriate radiation protection rules, standards, and practices on behalf of the licensee and who meets the requirements of (15) of this Rule.

(y) "Radiographer" means any individual who performs or who, in attendance at the site where radioactive materials are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of this Chapter and all license conditions.

(z) "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in (16) of this rule.

(aa) "Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, radioactive materials, related handling tools, or radiation survey instruments in industrial radiography.

(bb) "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to an unshielded position for purposes of making a radiographic exposure (e.g. camera).

(cc) "Radiographic operations" means all activities performed with a radiographic exposure device. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries.

(dd) "Residential location" means any area where structures in which people live or lodge are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

(ee) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

(ff) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(gg) "Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

(hh) "Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in Rule 391-3-17-.03(5)(i) of this Chapter.

(ii) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ball stop to secure the source in the shielded position.

(jj) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

(kk) "Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

(ll) "Storage container" means a shielded device in which sealed sources are secured and stored.

(mm) "Temporary job site" means any location where radiographic operations are performed and where sources of radiation may be stored other than the location(s) listed specifically on the license.

(nn) "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the U.S. Department of Transportation.

(oo) "Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

(4) **Licensing Requirements for Industrial Radiography Operations.** The Director will approve an application for a specific license for the use of licensed material if the applicant meets the following requirements:

(a) The applicant satisfies the general requirements specified in Rule 391-3-17-.02(8), as applicable, and any special requirements contained in this Rule;

(b) The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of .04(16):

1. After April 18, 2004, the applicant need not describe the initial training and examination program for radiographers in the subjects outlined in .04(16)(g).

2. The applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in .04(16)(g).

(c) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

(d) The applicant submits written operating and emergency procedures as described in .04(17);

(e) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six months as described in .04(16)(e);

(f) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(g) The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in .04(15)(a);

(h) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. The description must include the:

1. Methods of collecting the samples;

2. Instruments to be used;

3. Methods of analyzing the samples; and

4. Qualifications of the individual who analyzes the samples.

(i) If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in .04(8)(b) and .04(19)(g)4.;

(j) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

(k) The applicant identifies the location(s) where all records required by this and other Rules in this Chapter will be maintained;

(l) If a license application includes underwater radiography the applicant must submit a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and

3. Methods for gas-tight encapsulation of equipment; and

(m) If an application includes offshore platform and/or lay-barge radiography the applicant must submit a description of:

1. Transport procedures for radioactive material to be used in industrial radiographic operations;

2. Storage facilities for radioactive material; and

3. Methods for restricting access to radiation areas.

(5) **Performance Requirements for Radiography Equipment.** Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) Each radiographic exposure device, source assembly or sealed source and all associated equipment must meet the requirements specified in American National Standards Institute (ANSI) N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). (This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402 and from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036, Telephone (212) 642-4900. Copies of the document are available for inspection at the Department of Natural Resources, Environmental Protection Division, Radioactive Materials Program, 4244 International Parkway, Suite 120, Atlanta, Georgia 30354 or current address.)

(b) In addition to the requirements specified in (5)(a) of this Rule, the following requirements apply to radiographic exposure devices, source changers, source assemblies or sealed sources:

1. Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the:

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model number (or product code) and serial number of the sealed source;

(iv) Manufacturer of the sealed source; and

(v) Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71.

3. Modification of any radiographic exposure devices, source changers, source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in .04(5)(a) and (5)(b) the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for routine operation or to source changers:

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

4. Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER - RADIOACTIVE." The label must not interfere with the safe operation of the exposure device or associated equipment.

5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

6. Guide tubes must be used when moving the source out of the device.

7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

9. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of .04(5).

(e) Notwithstanding (5)(a) equipment used in industrial radiographic operations need not comply with section 8.9.2(c) of the Endurance Test in ANSI N432-1980 if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

(6) **Equipment Control. Limits on External Radiation Levels From Storage Containers and Source Changers.** The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at one meter from any exterior surface with the sealed source in the shielded position.

(7) **Locking and Storage of Radiographic Devices, Storage Containers, and Source Changers.**

(a) Each radiographic exposure device shall be provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of a sealed source from its shielded position. The exposure device and/or its container shall be kept locked[1] at all times except when not under the direct surveillance of a radiographer or a radiographer's assistant except at a permanent radiographic installations as stated in .04(21).

(b) Each sealed source storage container and source changer shall be provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be and kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer of radiographer's assistant.

(c) Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.

(d) During radiographic operations the sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. A survey shall be performed to determine that the sealed source is in the shielded position.

(e) Storage Precautions.

1. Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

2. Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This Rule does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with (7)(e)3. of this Rule and if the vehicle does not constitute a permanent storage location as described in (7)(e)4. of this Rule.

3. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing the radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in Rule .03(5)(i) of this Chapter at the exterior surface of the vehicle.

(i) If this vehicle is parked in a residential location a 360° survey of the vehicle must be performed before leaving the vehicle unattended to ensure that radiation levels do not exceed the limits specified in Rule .03(5)(i) of this Chapter.

(ii) An unattended vehicle shall have the name, local address, and local telephone number of the person responsible for the vehicle, posted on it in a conspicuous place on the vehicle.

4. A storage or use location is considered permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

(i) Telephone service is established by the licensee;

(ii) Industrial radiographic services are advertised for or from the location;

(iii) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

(8) **Radiation Survey Instruments.**

(a) The licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this Rule and Rule 391-3-17-.03(7)(a)1. and 2. Instrumentation required herein shall have a range such that two milliroentgens per hour through one Roentgen per hour can be measured.

(b) The licensee shall have each radiation survey instrument required under .04(4)(d) calibrated:

1. By a person licensed or certified by the Director, another Agreement State, or the U.S. Nuclear Regulatory Commission to perform such service;

2. At energies appropriate for the licensee's use;

3. At intervals not to exceed six months and after each instrument servicing, except for battery changes;

4. To demonstrate an accuracy within ±20 percent; and

5. At two points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and at approximate points for digital instruments.

(c) The licensee shall maintain records of the results of the instrument calibrations in accordance with .04(25).

(9) **Leak Testing and Replacement of Sealed Sources.**

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source shall be performed only by persons specially authorized to do so by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State.

(b) The opening, repair, or modification of any sealed source shall be performed only by persons specially authorized to do so by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State.

(c) Testing and Record keeping Requirements

1. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved by the Division, the U.S. Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcuries (185 bequerel) of radioactive material on the test sample and must be performed by a person specifically authorized by the Division, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

2. The licensee shall maintain records of the leak test in accordance with .04(26)

3. Unless a sealed source is accompanied by a certificate from a transferor that shows that it has been leak tested within the six months before the transfer, it shall not be used by the licensee until tested for leakage. Sealed sources authorized for storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.

4. Any test conducted pursuant to the requirements of (9)(c)1. and 3. of this Rule which reveals the presence of 0.005 microcuries (185 bequerel) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Division Rules. A report shall be filed, within five (5) days after obtaining results of the test, with the Division, describing the equipment involved, the test results, and the corrective action taken.

5. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 0.005 microcuries (185 becquerel) of radioactive material on the test sample and must be performed by a person specifically authorized by the Division, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with .04(26).

(10) **Quarterly Inventory.**

(a) Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and devices containing depleted uranium received or possessed under the license.

(b) The licensee shall maintain records of the quarterly inventories in accordance with .04(27)

(11) **Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.**

(a) The licensee shall perform visual and operability checks on survey meters radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

1. The equipment is in good working condition;

2. The sources are adequately shielded; and

3. Required labeling is present.

(b) Survey instrument operability must be performed using check sources or other appropriate means.

(c) If equipment problems are found, the equipment must be removed from service until repaired.

(d) Each licensee shall have written procedures for and perform inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(e) The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(f) Records of equipment problems and of any maintenance performed under .04(11)(c) and (d) shall be maintained in accordance with .04(29).

(12) **Permanent Radiographic Installations.**

(a) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have either:

1. An entrance control of the types described in Rule 391-3-17-.03(9)(a)1., or .03(9)(a)2. that causes the radiation level upon entry into the area to be reduced; or

2. Both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.

(b) The alarm system shall be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in .04(12)(a) must be tested monthly. If an entrance control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven day period, provided the licensee implements the continuous surveillance requirements of .04(21) and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms and records of repairs must be maintained in accordance with .04(30).

(13) **Labeling, Storage, and Transportation.**

(a) The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard

trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION *

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES [or " NAME OF COMPANY"]

* --- or "DANGER"

(b) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Rule 391-3-17-.06.

(c) Radiographic exposure devices, source changers, and storage containers, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

(d) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(e) The licensee's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material for temporary job site use.

(14) **Conducting Industrial Radiographic Operations.**

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of .04(16)(c). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(b) All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless otherwise specifically authorized by the Division.

(c) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(d) A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Division.

(15) **Radiation Safety Officer.** A Radiation Safety Officer (RSO) shall be designated on every industrial radiography license issued by the Director. The Radiation Safety Officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(a) The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

1. Completion of the training and testing requirements of .04(16);

2. 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

3. Formal training in the establishment and maintenance of a radiation protection program.

(b) The Division will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(c) The specified duties of the RSO include, but are not limited to, the following:

1. Establishing and overseeing all operating, emergency, and ALARA procedures, and to review them regularly to ensure that the procedures are current and conform with these Rules;

2. Overseeing and approving all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

3. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with these Rules, including any corrective measures when levels of radiation exceed established limits;

4. Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by this Chapter;

5. Ensuring that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

6. Investigating and reporting to the Division each known or suspected case of radiation exposure to an individual, or radiation level detected, in excess of limits established by this Chapter and each theft or loss of source(s) of radiation, to determine the cause and to take steps to prevent its recurrence;

7. Having a thorough knowledge of management policies and administrative procedures of the licensee;

8. Assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

9. Maintaining records as required by this Chapter;

10. Ensuring the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

11. Ensuring that inventory and inspection and maintenance programs are performed in accordance with (10) and (11) of this Rule;

12. Ensuring that personnel are complying with this Chapter, the conditions of the license, and the operating and emergency procedures of the licensee.

(16) **Training.**

(a) The licensee shall not permit any individual to act as a radiographer until such individual has received at least 40 hours of training in the subjects outlined in .04(16)g, in addition to on the job training consisting of hands- on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of this Rule. The on the job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material.

(b) In addition, the licensee may not permit any individual to act as a radiographer until the individual:

1. Has received copies of and instruction in the requirements described in the regulations contained in this Rule, and applicable sections of Rules 391-1-7-.03, .06, and .07, in the license under which the radiographer will perform industrial radiography, and the licensee's operating and emergency procedures;

2. Has demonstrated an understanding of items in .04(16)(b)1. by successful completion of a written or oral examination;

3. Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in .04(16)(b)3. by successful completion of a practical examination.

(c) The licensee may not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in the requirements described in these regulations contained in this Rule, and applicable sections of Rules 391-3-17-03, .06, and .07, in the license under which the radiographer's assistant will perform industrial radiography, and the licensee's operating and emergency procedures;

2. Has demonstrated an understanding of items in .04(16)(c)1. by successful completion of a written or oral examination;

3. Under the personal supervision of a radiographer, has received training in the use of the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in .04(16)(c)3. by successful completion of a practical examination.

(d) The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in .04(16)(e)4., the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Division's Rules, the license, and operating and emergency procedures are followed. The inspection program must:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of .04(16)(b)3. and the radiographer's assistant must demonstrate knowledge of the training requirements of .04(16)(c)3. by a practical examination before these individuals can next participate in a radiographic operation.

3. The Division may consider alternative in those situations where the individual serves as both radiographer and radiation safety officer.

4. In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

(f) The licensee shall maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with .04(31).

(g) The licensee shall include the following subjects required in .04(16)(a):

1. Fundamentals of Radiation Safety including:

(i) Characteristics of gamma and x-radiation.

(ii) Units of radiation dose (rem or Sievert) and quantity of radioactivity (Curie or becquerel).

(iii) Significance of radiation dose:

(I) Radiation protection standards;

(II) Biological effects of radiation dose; and

(III) Case histories of radiography accidents.

(iv) Levels of radiation from sources of radiation.

(v) Methods of controlling radiation dose:

(I) Working time;

(II) Working distances; and

(III) Shielding.

2. Radiation Detection Instrumentation including.

(i) Use of radiation survey instruments:

(I) Operation;

(II) Calibration; and

(III) Limitations.

(ii) Survey techniques.

(iii) Use of personnel monitoring equipment including but not limited to:

(I) Film badges;

(II) Thermoluminescent dosimeters (TLDs);

(III) Pocket dosimeters;

(IV) Alarm ratemeters; and

(V) Optically stimulated luminescent devices.

3. Radiographic Equipment to be Used including:

(i) Remote handling equipment.

(ii) Operation and control of radiographic exposure equipment, remote handling equipment, storage containers, and sealed sources, including pictures or models of source assemblies (pigtails).

(iii) Storage control, and disposal of sources of radiation; and transport containers and source changers.

(iv) Collimators.

4. Inspection and maintenance of equipment.

5. The Requirements of Pertinent Federal and State Regulations.

6. The Licensee's Written Operating and Emergency Procedures.

7. Case histories of accidents in radiography.

(h) Licensees will have one year from the effective date of this rule to comply with the additional training requirements specified in .04(16)(b)1. and .04(16)(c)1.

(17) **Operating and Emergency Procedures.**

(a) The operating and emergency procedures of the licensee shall include, as a minimum, instruction in the following:

1. Appropriate handling and use of sources of radiation so that no individual is likely to be exposed to radiation doses in excess of the limits established in Rule 391-3-17-.03, "Standards for Protection Against Radiation";

2. Methods and occasions for conducting radiation surveys;

3. Methods for posting and controlling access to radiographic areas;

4. Methods and occasions for locking and securing sealed sources;

5. Personnel monitoring and the use of personnel monitoring equipment;

6. Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Rule .06 of this Chapter;

7. The inspection, maintenance and operability checks of radiographic exposure devices, survey instruments, alarming ratemeters, transport containers, and storage containers.

8. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;

9. The procedure(s) for identifying and reporting defects and noncompliance, as required by .04(37);

10. The procedure for notifying proper persons in the event of an accident or incident;

11. Minimizing exposure of individuals in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

12. Source recovery procedure if licensee will perform source recoveries; and

13. Maintenance of records.

(b) The licensee shall maintain copies of current operating and emergency procedures in accordance with .04(32) and .04(36).

(18) **Supervision of Radiographer's Assistants.**

(a) Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment, or a sealed source, or conducts radiation surveys required by (20)(b) and (c) of this Rule to determine that the sealed source has

returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include:

1. The radiographer's physical presence at the site where the sealed sources are being used;

2. The ability of the radiographer to give immediate assistance if required; and

3. The radiographer's direct observation of the assistant's performance of the operations referred to in .04(18) of this Rule.

(19) **Personnel Monitoring Control.**

(a) The licensee shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct-reading dosimeter, an alarming ratemeter, and a personal monitoring device. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use the use of an alarming ratemeter is not required.

1. Pocket dosimeters shall have a range from zero to 200 milliroentgens (2 millisieverts) and shall be recharged daily or at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

2. Each personal monitoring device shall be assigned to and worn by only one individual.

3. Personal monitoring devices must be exchanged at periods not to exceed one month. After replacement each personal monitoring device must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. If circumstances exist which make it impossible to return each personal monitoring device within 14 calendar days, such circumstances must be documented and available for review by the Division.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be read and exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with .04(33).

(c) Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed one year for correct response to radiation, and records must be maintained in accordance with .04(33). Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure**.**

(d) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 200 mrem (2 millisieverts), the personal monitoring device must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter may be started within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with .04(33).

(e) If a personal monitoring device is lost or damaged, the worker shall cease work immediately until a replacement personal monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the personal monitoring device. The results of the calculated exposure and the time period for which the personal monitoring device was lost or damaged must be included in the records maintained in accordance with .04(33).

(f) Reports received from personal monitoring devices shall be retained in accordance with .04(33).

(g) Each alarm ratemeter must:

1. Be checked to ensure that the alarm functions properly prior to use at the start of each shift;

2. Emit an alarm signal at a preset dose-rate of 500 mr (5 mSv) per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate.

3. Require special means to change the preset alarm function; and

4. Be calibrated at periods not to exceed one year for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with .04(33).

(20) **Radiation Surveys.** The license shall:

(a) Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of .04(8);

(b) Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey shall be to determine that the sealed source has been returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

(c) Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in .04(3), to ensure that the sealed source is in its shielded position; and

(d) Maintain records in accordance with .04(34).

(21) **Surveillance.** During each radiographic operation, the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Rule .01 of this Chapter, except at permanent radiographic installations where all entryways are locked and the requirements of .04(12) are met.

(22) **Posting.** Notwithstanding any provisions of Rule 391-3-17-.03(12)(c) all areas in which industrial radiography is being performed shall be conspicuously posted as required by Rule 391-3-17-.03(12)(b)1. and 2.

(23) **Records for Industrial Radiography.** Each licensee shall maintain a copy of its license, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Division, or until the Director terminates the license.

(24) **Records of Receipt and Transfer of Sources of Radiation.**

(a) Each licensee shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for three years after it is made.

(b) These records must include the date, the name of the individual making the record, radionuclide, number of curies (becquerels) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

(25) **Records of Radiation Survey Instruments.** Each licensee shall maintain records of the calibrations of its radiation survey instruments that are required under .04(8) and retain each record for three years after it is made.

(26) **Records of Leak Testing of Sealed Sources and Devices Containing DU.** Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of microcuries (becquerels). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

(27) **Records of Quarterly Inventory.**

(a) Each licensee shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by .04(10), and retain each record for three years.

(b) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of curies (becquerels) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

(28) **Utilization Logs.**

(a) Each licensee shall maintain utilization logs showing for each source of radiation the following information:

1. A description, including the make, model, and serial number the radiographic exposure device, transport, or storage container in which the sealed source is located;

2. The identity and signature of the radiographer to whom assigned;

3. The location and dates of use, including the dates removed and returned to storage; and

4. For permanent radiographic installations, the dates each radiographic exposure device is used.

(b) The licensee shall retain the logs required by .04(28)(a) for three years.

(29) **Records of Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.**

(a) Each licensee shall maintain records specified in .04(11) of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for three years after it is made.

(b) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

(30) **Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations.** Each licensee shall maintain records of alarm system and entrance control device tests required by .04(12) and retain each record for three years after it is made.

(31) **Records Of Training and Certification.** Each licensee shall maintain the following records for three years:

(a) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

(b) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

(32) **Copies of Operating and Emergency Procedures.** Each licensee shall maintain a copy of current operating and emergency procedures until the Director terminates the license. Superseded material must be retained for three years after the change is made.

(33) **Records of Personnel Monitoring.** Each licensee shall maintain the following exposure records specified in .04(19):

(a) Direct reading dosimeter readings and yearly operability checks required by .04(19)(b) and .04(19)(c) for three years after the record is made;

(b) Records of alarming ratemeter calibrations for three years after the record is made;

(c) Reports received from the personal dosimeter processor until the Director terminates the license; and

(d) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel monitoring device, until the Director terminates the license.

(34) **Records of Radiation Surveys.** Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in .04(20)(c). Each record must be maintained for three years after it is made.

(35) **Form of Records.** Each record required by these rules must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(36) **Location Of Documents and Records.**

(a) Each licensee shall maintain copies of records required by this Rule and other applicable Rules of this Chapter at the location specified in .04(4)(k).

(b) Each licensee shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary job site:

1. The license authorizing the use of sources of radiation;

2. Operating and emergency procedures as required by .04(32);

3. A copy of Rules .02, .03, .04 of this Chapter;

4. Survey records required by .04(34) and Rule .03(8) of this Chapter as applicable for the period of operation at the site;

5. Records of dosimeter readings as required by .04(33);

6. Valid radiographer's identification cards issued by a certifying entity for each radiographer working at the temporary job site or field location;

7. Evidence of the latest instrument calibration of the radiation survey instruments in use at the site as required by .04(25);

8. Utilization logs for each source of radiation dispatched from that location as required by .04(28);

9. Records of equipment problems identified in daily checks of equipment as required by .04(29)(a);

10. Records of alarm system and entrance control checks required by .04(30), if applicable;

11. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by .04(33);

12. The shipping papers for the transportation of radioactive materials required by Rule .06 of this Chapter; and

13. When operating under reciprocity pursuant to Rule 391-3-17-.02(20) of this Chapter, a copy of the applicable Agreement State license or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

(37) **Notifications.**

(a) In addition to the reporting requirements specified in 10 CFR 30.50 and in Rule 391-3-17.03 of this Chapter, each licensee shall provide a written report to the Division within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

1. Unintentional disconnection of the source assembly from the control cable.

2. Inability to retract the source assembly to its fully shielded position and secure it in this position.

3. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function.

(b) The licensee shall include the following information in each report submitted under (37)(a)1. of this Rule and in each report of overexposure submitted under Rule 391-3-17-.03(15)(c) which involves failure of safety components of radiography equipment:

1. A description of the equipment problem;

2. Cause of each incident, if known;

3. Name of the manufacturer and model number of equipment involved in the incident;

4. Place, time, and date of the incident;

5. Actions taken to establish normal operations;

6. Corrective actions taken or planned to prevent recurrence; and

7. Qualifications of personnel involved in the incident.

(c) Any licensee conducting radiographic operations or storing sources of radiation at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the Division prior to exceeding the 180 days.

(38) **[Reserved]**

(39) **[Reserved]**

(40) **Reciprocity.**

(a) All reciprocal recognition of licenses by the Director will be granted in accordance with Rule 391-3-17-.02(20) of this Chapter.

(b) Reciprocal recognition by the Director of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in .04(3);

2. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by .04(16)(a);

3. The applicant presents the certification to the Division prior to entry into the state; and

4. No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

(c) Certified individuals who are granted reciprocity by the Director shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of .04(16)(a).

(41) **Specific Requirements for Radiographic Personnel Performing Industrial Radiography.**

(a) The licensee shall supply the following at the job site:

1. At least one operable, calibrated survey instrument for each exposure device in use;

2. A current whole body personal dosimeter for each individual;

3. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations;

4. An operable, calibrated alarm ratemeter with preset dose-rate of 500 mr (5 mSv) per hour for each person performing radiographic operations using a radiographic exposure device; and

5. The appropriate barrier ropes and signs.

(b) Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

(c) Industrial radiographic operations shall not be performed if any of the items in .04(41)(a) or .04(41)(b) are not available at the job site or are inoperable.

(d) Each licensee shall provide as a minimum two-person crews, i.e., two radiographers or a radiographer assistant who is under the personal supervision of a radiographer, when sources of radiation are used at temporary job sites.

(e) No individual other than a radiographer or a radiographer assistant who is under the personal supervision of a radiographer shall manipulate controls or operate equipment used in industrial radiographic operations.

(f) During an inspection by the Division, the Division inspector may terminate an operation if any of the items in .04(41)(a) are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.

(g) Special Requirements for Enclosed Radiography. Systems for enclosed radiography designed to allow admittance of individuals shall:

1. Comply with all applicable requirements of this Rule and Rule 391-3-17-.03(5)(i); and

2. Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in .04(41)(g)1. Records of these evaluations shall be maintained for inspection by the Division for a period of two years after the evaluation.

(h) Prohibitions. Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the Director.

APPENDIX A

I. **Requirements for an Independent Certifying Organization.**

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

2. Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;

3. Have a certification program open to non-members, as well as members;

4. Be an incorporated, nationally-recognized organization that is involved in setting national standards of practice within its fields of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. **Requirements for Certification Programs.**

All certification programs must:

1. Require applicants for certification to (a) receive training in the topics set forth in .04(16)(g) or equivalent State or Nuclear Regulatory Commission regulations, and (b) satisfactorily complete a written examination covering these topics;

2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

(a) Received training in the topics set forth in .04(16)(g) or equivalent State or Nuclear Regulatory Commission regulations;

(b) Satisfactorily completed a minimum period of on-the-job training as specified in .04(16)(a); and

(c) Received verification by a State licensee or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;

5. Provide a certification period of not less than three years nor more than five years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. **Requirements for Examinations.**

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in .04(16)(g) or equivalent State or Nuclear Regulatory Commission requirements;

2. Written in a multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in .04(16)(g).

[1] If a keyed lock, the key must be removed at all times.

Cite as Ga. Comp. R. & Regs. R. 391-3-17-.04

AUTHORITY: O.C.G.A. § 31-13-1 **et seq.**

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391-3-17-.05 Use of Radionuclides in the Healing Arts

(1) **Purpose and Scope.** This Rule, 391-3-17-.05, establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this Rule are in addition to, and not in substitution for, others in these regulations unless specifically exempted. All numbered and lettered references within this Rule refer to parts of this Rule, unless stated otherwise.

(2) **Definitions.**

(a) "Accredited institution," means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.

(b) "Address of use," means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

(c) "Area of use," means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

(d) "Authorized medical physicist," means an individual who:

1. Meets the requirements in Rules .05(23)(a) and .05(27); or

2. Is identified as an authorized medical physicist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission or Agreement State; or

3. Is identified as an authorized medical physicist on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

(e) "Authorized nuclear pharmacist," means a pharmacist who:

1. Meets the requirements in Rules .05(24)(a) and .05(27); or

2. Is identified as an authorized nuclear pharmacist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission or Agreement State; or

3. Is identified as an authorized nuclear pharmacist on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

(f) "Authorized user," means a physician, dentist, or podiatrist who:

1. Meets the requirements in Rule .05(27) and .05(43)(a), .05(47)(a), .05(52)(a), .05(53)(a), .05(54)(a), .05(63)(a), .05(66)(a), or .05(84)(a); or

2. Is identified as an authorized user on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission or Agreement State; or

3. Is identified as an authorized user on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

(g) "Brachytherapy," means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

(h) "Brachytherapy source," means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(i) "Client's address," means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with Rule .05(38).

(j) "Dedicated check source," means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

(k) "Dentist," means an individual licensed to engage in the practice dentistry under the Authority of O.C.G.A. 43-11-40.

(l) "Diagnostic clinical procedures manual," means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

(m) "High dose-rate remote afterloader," (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rad) per hour at the treatment site.

(n) "Low dose-rate remote afterloader," (LDR) means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rad) per hour at the treatment site.

(o) "Management," means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

(p) "Manual brachytherapy," means a type of therapy in which brachytherapy sources are manually applied or inserted.

(q) "Medical institution," means an organization in which several medical disciplines are practiced.

(r) "Medical use," means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(s) "Medium dose-rate remote afterloader," (MDR) means a device that remotely delivers a dose rate of greater than 2 gray (200 rad), but less than, or equal to, 12 gray (1200 rad) per hour at the treatment site.

(t) "Misadministration," means an event that meets the criteria in Rule .05(115)(a).

(u) "Mobile medical service," means the transportation of radioactive material or its medical use at the client's address.

(v) "Nuclear medicine technologist," means an individual who meets the requirements of Rule .05(25)(a) and, is under the supervision of an authorized user, to prepare or administers radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.

(w) "Nuclear medicine technology," means the science and art of in vivo and in vitro detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.

(x) "Output," means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(y) "Patient intervention," means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(z) "Pharmacist," means any individual who is licensed to practice Pharmacy in this State by the Georgia State Board of Pharmacy.

(aa) "Physician," means any person who is licensed to engage in the practice of medicine under the Authority of O.C.G.A. 43-34-20 or the limited practice of medicine under O.C.G.A. 43-35-1.

(bb) "Podiatrist," means an individual licensed by the appropriate authority to practice podiatry in the state of Georgia.

(cc) "Positron Emission Tomography (PET) radionuclide production facility" is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(dd) "Preceptor," means an individual who provides, directs or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, an Associate Radiation Safety Officer or a Radiation Safety Officer.

(ee) "Prescribed dosage," means the specified activity or range of activity of radioactive drug as documented:

1. In a written directive; or

2. In accordance with the directions of the authorized user for procedures performed pursuant to Rule .05(41), (44) and (48).

(ff) "Prescribed dose," means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, the total dose and dose per fraction as documented in the written directive;

3. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(gg) "Pulsed dose-rate remote afterloader," (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

2. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(hh) "Radiation Safety Officer," means an individual who:

1. Meets the requirements in Rule .05(22)(a) or .05(22)(c)1. And .05(27); or

2. Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Division for similar types and uses of radioactive material.

(ii) "Radiation therapist," means an individual who meets the requirements of Rule .05(25)(b) and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

(jj) "Radiation therapy technology," means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

(kk) "Radioactive drug," means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

(ll) "Sealed source," means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(mm) "Sealed Source and Device Registry," means the national registry that contains the registration certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(nn) "Stereotactic radiosurgery," means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a treatment site.

(oo) "Structured educational program," means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(pp) "Teletherapy," as used in this Rule, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(qq) "Temporary jobsite," as used in this Rule, means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

(rr) "Therapeutic dosage," means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(ss) "Therapeutic dose," means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(tt) "Treatment site," means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(uu) "Type of use," means use of radioactive material as specified under Rule .05(41), (44), (48), (55), (65), (67) or (85).

(vv) "Unit dosage," means a dosage that:

1. Is obtained or prepared in accordance with the regulations for uses described in Rule .05(41), (44), (48); and

2. Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(ww) "Written directive," means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Rule .05(19).

(xx) "Associate Radiation Safety Officer," means an individual who:

1. Meets the requirements in 391-3-17-.05(22) and .05(27); and

2. Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

(yy) "Ophthalmic physicist," means an individual who:

1. Meets the requirements in 391-3-17-.05(27) and 391-3-17-.05(64)(c)2.; and

2. Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the Commission or an Agreement State;

(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Commission master material licensee; or

(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

(3) **Maintenance of Records.** Each record required by Rule .05 must be legible throughout the retention period specified by each Division Rule. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(4) **Provisions for Research Involving Human Subjects.** A licensee may conduct research involving human subjects using radioactive material provided:

(a) That the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Division license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(b) The research involving human subjects authorized in .05(4)(a) shall be conducted using radioactive material authorized for medical use in the license; and

(c) Nothing in Rule .05(4) relieves licensees from complying with the other requirements in Rule .05.

(5) **U.S. Food and Drug Administration, Federal, and State Requirements.** Nothing in Rule .05 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

(6) **Implementation.**

(a) A licensee shall implement the provisions in Rule .05 on July 1, 2003.

(b) When a requirement in Rule .05 differs from the requirement in an existing license condition, the requirement in Rule .05 shall govern.

(c) Any existing license condition that is not affected by a requirement in Rule .05 remains in effect until there is a license amendment or license renewal.

(d) If a license condition exempted a licensee from a provision of Rule .05 on July 1, 2003, it will continue to exempt a licensee from the corresponding provision in Rule .05.

(e) If a license condition cites provisions in Rule .05 that will be deleted on July 1, 2003, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(f) Licensees shall continue to comply with any license condition that requires it to implement procedures required by Rule .05(70), (76), (77) and (78) until there is a license amendment or renewal that modifies the license condition.

(7) **License Required.**

(a) A person may manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Director, the Nuclear Regulatory Commission or an Agreement State, or as allowed in Rule .05(7)(b) or (7)(c).

(b) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in Rule .05 under the supervision of an authorized user as provided in Rule .05(18), unless prohibited by license condition.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in Rule .05 under the supervision of an authorized nuclear pharmacist or authorized user as provided in Rule .05(18), unless prohibited by license condition.

(8) **Application for License, Amendment, or Renewal.**

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of radioactive material as described in Rule .05(41), (44), (48), (55), (65), (67) or (85) must be made by:

1. Filing an original Application for Radioactive Materials License, and

2. Submitting procedures required by sections Rule .05(70), (76), (77), and (78), as applicable.

(c) A request for a license amendment or renewal must be made by:

1. Submitting an original in letter format.

2. Submitting procedures required by sections Rule .05(70), (76), (77) and (78), as applicable.

(d) In addition to the requirements in (8)(b) and (8)(c), an application for a license or amendment for medical use of radioactive material as described in (85) of Rule .05 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Rule .05(1) through Rule .05(40), as well as any specific information on:

1. Radiation safety precautions and instructions;

2. Training and experience of proposed users;

3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(e) The applicant or licensee shall also provide any other information requested by the Division in its review of the application.

(f) An applicant that satisfies the requirements specified in Rule .02(10)(b) may apply for a Type A specific license of broad scope.

(9) **Mobile Medical Service Administrative Requirements.**

(a) The Director shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(b) Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the clinic's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

(c) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(d) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(e) A licensee providing mobile medical services shall retain the letter required in (9)(b) in accordance with Rule .05(97).

(f) A mobile medical service licensee shall maintain on each mobile unit:

1. The current operating and emergency procedures;

2. A copy of the license;

3. Copies of the letter required by .05(9)(b);

4. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

5. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

(g) A mobile medical service licensee shall maintain records required by Rules .03 and .05 of this Chapter at a location within the Division's jurisdiction that is:

1. A single address of use:

(i) Identified as the records retention location; and

(ii) Staffed at all reasonable hours by individual(s) authorized to provide the Division with access for purposes of inspection; or

2. When no address of use is identified on the license for records retention, the mobile unit:

(i) Identified in the license; and

(ii) Whose current client's address schedule and location schedule is reported to the Division.

(10) **License Amendments.** A licensee shall apply for and must receive a license amendment:

(a) Before it receives, prepares or uses radioactive material for a type of use that is permitted under Rule .05, but that is not authorized on the licensee's current license issued pursuant to Rule .05;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is:

1. For an authorized user, an individual who meets the requirements in Rule .05(27) and (43)(a), Rule .05(47)(a), (52)(a), (53)(a), (54)(a), (63)(a), (64)(a), (66)(a), or (84)(a) or;

2. For an authorized nuclear pharmacist, an individual who meets the requirements in Rule .05(24)(a) and (27);

3. For an authorized medical physicist, an individual who meets the requirements in Rule .05(23)(a) and (27);

4. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Division that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

5. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

(c) Before it changes Radiation Safety Officers, except as provided in (15)(c);

(d) Before it receives radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except as specified in (11)(b)4.;

(f) Before it changes the address(es) of use identified in the application or on the license;

(g) Before it changes statements, representations, and procedures which are incorporated into the license; and

(h) Before it releases licensed facilities for unrestricted use.

(11) **Notifications.**

(a) A licensee shall provide to the Division a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist, pursuant to (10)(b).

(b) A licensee shall notify the Division by letter no later than 30 days after:

1. A Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;

2. The licensee's mailing address changes;

3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Rule .02(13)(b) of these regulations; or

4. The licensee has added to or changed the areas where radioactive material is used in accordance with Rule .05(41) and (44).

(12) **Exemptions Regarding Type A Specific Licenses of Broad Scope.** A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(a) The provisions of (8)(d) of these regulations, regarding the need to file an amendment to the license for medical uses of radioactive material, as described in .05(85);

(b) The provisions of (10)(b) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;

(c) The provisions of (10)(e) regarding additions to or changes in the areas of use at the addresses specified in the license;

(d) The provisions of .05(11)(a) regarding notification to the Division for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and

(e) The provisions of .05(21)(a) regarding suppliers for sealed sources.

(13) **License Issuance.**

(a) The Director shall issue a license for the medical use of radioactive material if:

1. The applicant has filed Application for Radioactive Materials License in accordance with the instructions in .05(8);

2. The applicant has paid any applicable fee;

3. The applicant meets the requirements of Rule .02 of this Chapter; and

4. The Director finds the applicant equipped and committed to observe the safety standards established by the Division in these Rules for the protection of the public health and safety.

(b) The Director shall issue a license for mobile services if the applicant:

1. Meets the requirements in .05(13)(a); and

2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with .05(37).

(14) **Specific Exemptions.** The Director may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Rule .05 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

General Administrative Requirements

(15) **Authority and Responsibilities for the Radiation Protection Program.**

(a) In addition to the radiation protection program requirements of Rule .03(4), a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Division;

2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist, and

3. Radiation protection program changes that do not require a license amendment and are permitted under .05(16);

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in .05(15)(e), provided the licensee takes the actions required in .05(15)(b), (d), (e) and (h). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

(d) A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3. Stop unsafe operations; and,

4. Verify implementation of corrective actions.

(f) Licensees that are authorized for two or more different types of radioactive material use under Rule .05(48), (55), (67), and (85), or two or more types of units under Rule .05(67) shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(g) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each required meeting in accordance with Rule .05(86)(c).

(h) A licensee shall retain a record of actions taken pursuant to Rule .05(15)(a), (15)(b) and (15)(d) in accordance with Rule .05(86)(a) and (b).

(16) **Radiation Protection Program Changes.**

(a) A licensee may revise its radiation protection program without Division approval if:

1. The revision does not require an amendment under Rule .05(10);

2. The revision is in compliance with the regulations and the license;

3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and

4. The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with Rule .05(87).

(17) **Duties of Authorized User and Authorized Medical Physicist.**

(a) A licensee shall assure that only authorized users for the type of radioactive material use:

1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;

2. Direct, as specified in Rule .05(18) and (19), or in license conditions, the administration of radioactive material for medical use to patients or human research subjects; and

3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with Rule .05(7)(b) and (7)(c) and (18).

(b) A licensee shall assure that only authorized medical physicists perform, as applicable:

1. Full calibration measurements as described in Rule .05(73), (74), and (75);

2. Periodic spot checks as described in Rule .05(76), (77), and (78); and

3. Radiation surveys as described in Rule 5(80).

(18) **Supervision.**

(a) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by Rule .05(7)(b) shall:

1. In addition to the requirements in Rule .07(3) of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the medical use of radioactive material.

(b) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Rule .05(7)(c), shall:

1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of Rule .05, and license conditions.

(c) Unless physical presence is required in other sections of Rule .05, a licensee who permits supervised activities under Rule .05(18)(a) and (18)(b) shall require an authorized user to be immediately available to communicate with

the supervised individual, and when a written directive is required, be able to be physically present within one hour of notification; and

(d) A licensee that permits supervised activities under Rule .05(18)(a) and (18)(b) is responsible for the acts and omissions of the supervised individual.

(19) **Written Directives.**

(a) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 µCi), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

2. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

3. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(b) The written directive must contain the patient or human research subject's name and the following:

1. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

2. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

3. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

4. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

5. For all other brachytherapy including LDR, MDR, and PDR:

(i) Prior to implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose), and date; or

6. For permanent implant brachytherapy:

(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date.

(c) The licensee shall retain the written directive in accordance with Rule .05(88).

(20) **Procedures for Administrations Requiring a Written Directive.**

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. The patient's or human research subject's identity is verified before each administration; and

2. Each administration is in accordance with the written directive.

(b) The procedures required by Rule .05(20)(a) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;

2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

3. Checking both manual and computer-generated dose calculations;

4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Rule .05(67);

5. Determining if a medical event, as defined in Rule .05(115), has occurred; and

6. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(c) A licensee shall retain a copy of the procedures required under subparagraph (a) in accordance with 391-3-17-.05(20) and (88).

(21) **Suppliers for Sealed Sources or Devices for Medical Use.** For medical use, a licensee may only use:

(a) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Rule .02 of this Chapter or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(b) Sealed sources or devices non-commercially transferred from Rule .05 licensee or a Nuclear Regulatory Commission or an Agreement State medical use licensee.

(22) **Training for Radiation Safety Officer.** Except as provided in Rule .05(26), the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in Rule .05(15) to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rule. 05(22)(d), and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. (i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. (i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(I) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in Rule .05(26), .05(47) or .05(52); and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b) 1. Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Radiation biology; and

(V) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Nuclear Regulatory Commission, Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission, Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive byproduct material. The full-time radiation safety experience must involve the following;

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

(III) Securing and controlling radioactive material;

(IV) Using administrative controls to avoid mistakes in the administration of radioactive material;

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(VI) Using emergency procedures to control radioactive material; and

(VII) Disposing of radioactive material; or

2. This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in subparagraphs (b)1. and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c) 1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under Rule .05(23)(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or Associate Radiation Safety Officer and who meets the requirements in .05(22)(d); or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or an Agreement State license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in subparagraph .05(22)(d); or

3. Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in subparagraph .05(22)(d).

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

(23) **Training for Authorized Medical Physicist.** Except as provided in Rule .05(26) the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in .05(23)(c) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have 2 years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in Rule .05(26), .05(63) or .05(84); and

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b) 1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in .05(23)(b)1. and .05(23)(c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in Rule .05(23), .05(26), or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(24) **Training for an Authorized Nuclear Pharmacist.** Except as provided in Rule .05(26), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

2. Hold a current, active license to practice pharmacy;

3. Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

4. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(b) 1. Has completed 700 hours in a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving:

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha or beta-emitting radionuclides;

(III) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(IV) Using administrative controls to avoid misadministrations in the administration of radioactive material; and

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in Rule .05(24)(b)1. and has achieved a level of competency sufficient to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist and operate a nuclear pharmacy, and

(c) Licensed as a Nuclear Pharmacist by the Georgia Board of Pharmacy.

(25) **Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists.**

(a) The licensee shall require a nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in:

(i) Nuclear Medicine by the Nuclear Medicine Technology Certification Board;

(ii) Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine; or,

2. Is board eligible to take the CNMT or ARRT(N) examinations; or,

3. Has successfully completed a training program in nuclear medicine which has resulted in a certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,

4. Has performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or,

5. Has completed 80 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) Administering dosages to patients or human research subjects; and

(iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a nuclear medicine technologist.

(b) The licensee shall require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or

2. Is board eligible to take the ARRT(T) examination; or,

3. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology[1]; or,

4. Has performed as a full-time radiation therapist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or

5. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Assisting the authorized user in simulating the patient for treatment;

(III) Preparing the patient for treatment;

(IV) Implementing treatment plans as prescribed by the authorized user;

(V) Providing written documentation of treatment setup and patient treatments;

(VI) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;

(VII) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;

(VIII) Delivering doses to patients or human research subjects under the supervision of the authorized user;

(IX) Preparing, implanting, and removing sealed sources;

(X) Delivering dose to patients or human research subjects;

(XI) Maintaining running inventories of material on hand;

(XII) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,

(XIII) Properly implementing emergency procedures and

(iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a radiation therapist.

(c) Individuals working as nuclear medicine technologists or radiation therapists prior to July 1, 2003 for a facility holding a Division license need not comply with the training requirements of this section.

(d) The licensee shall maintain records of the above training as specified in Rule .05(100).

(26) **Provisions for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.**

(a) 1. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on a Division, Nuclear Regulatory Commission or Agreement State license or on a permit issued by the Division, Nuclear Regulatory commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of this rule, need not comply with the training requirements of Rules .05(22), .05(23), or .05(24), respectively except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in Rule .05(22)(d) or .05(23)(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of Rule .05(22) to be identified as a Radiation Safety Officer or as an Associate

Radiation Safety Officer on a Division, U.S. Nuclear Regulatory Commission or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Rule .05(23), for those materials and uses that these individuals performed on or before October 24, 2005.

4. A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Rules .05(22), .05(23) or .05(24), respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b) 1. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Division, Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Division, Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before March 17, 2020, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05 (54.1), .05(63). .05(64), .05(66), and .05(84), respectively.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Division, Nuclear Regulatory Commission or Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Division, Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized on or before October 24, 2005, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05 (54.1), .05(63). .05(64), .05(66), and .05(84), as follows:

(i) For uses authorized under Rules .05(41) or .05(44), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under Rule .05(48), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under Rules .05(55) or .05(67), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under Rules .05(65), a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05 (54.1), .05(63). .05(64), .05(66), and .05(84) respectively, when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on the Division licenses for the same uses for which these individuals are authorized.

(27) **Recentness of Training.** The training and experience specified in Rule .05 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

GENERAL TECHNICAL REQUIREMENTS

(28) **Quality Control of Diagnostic Equipment.** Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures that have been approved by the Division. The licensee shall conduct quality control procedures in accordance with written procedures.

(29) **Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.**

(a) For direct measurements performed in accordance with Rule .05(31), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(b) A licensee shall test the instrumentation required in Rule .05(29)(a) in accordance with nationally recognized standards or the manufacturer's instructions.

(c) The tests required in Rule .05(29)(b) shall include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

(d) A licensee shall retain a record of each instrument test required by Rule .05(29) in accordance with Rule .05(91).

(30) **Calibration of Survey Instruments.**

(a) A licensee shall ensure that the survey instruments used to show compliance with Rule .05 and Rule .03 of this Chapter, have been calibrated before first use, annually, and following any repair that will affect the calibration.

(b) To satisfy the requirements of Rule .05(30)(a), the licensee shall:

1. Calibrate all required scale readings up to 10 millisievert (1,000 mrem) per hour with a radiation source;

2. Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisievert (2 and 1,000 mrem) per hour; and

(iii) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked; and

3. Conspicuously note on the instrument the date of calibration.

(c) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.

(d) A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each survey instrument calibration in accordance with Rule .05(92).

(31) **Determination of Dosages of Radioactive Material for Medical Use.**

(a) A licensee shall determine and record the activity of each dosage prior to medical use.

(b) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission or Agreement State.

(c) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission or Agreement State.

(d) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by Rule .05(31)(a) through (31)(c) in accordance with Rule .05(93).

(32) **Authorization for Calibration, Transmission and Reference Sources.** Any person authorized by Rule .05(7) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission or Agreement State and that do not exceed 1.11 gigabecquerel (30 mCi) each;

(b) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerel (15 mCi);

(c) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

1. 7.4 megabecquerel (200 µCi); or

2. 1,000 times the quantities in Schedule B of Rule .02(21)(b) of this Chapter; and

(d) Technetium-99m in amounts as needed.

(33) **Requirements for Possession of Sealed Sources and Brachytherapy Sources.**

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Division.

(b) A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with Rule .03 of this Chapter.

2. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Division, an Agreement State, or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(c) If the leak test reveals the presence of 185 becquerel (0.005 µCi) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Rules .02 and .03 of this Chapter; and

2. File a report with the Division within 5 days of receiving the leak test results in accordance with Rule .05(117).

(d) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with Rule .05(94).

(34) **Labels.** Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(35) **Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

(36) **Surveys for Ambient Radiation Dose Rate and Contamination.**

(a) Except as provided in Rule .05(36)(h), a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by Rule .05(36)(a) and (b) so as to be able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by Rule .05(36)(a) and (36)(b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by Rule .05(36)(e) so as to be able to detect contamination on each wipe sample of 33.3 becquerel (2,000 dpm).

(g) A licensee shall establish removable contamination action levels for the surveys required by Rule .05(36)(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by Rule .05(36)(a) in area(s) where patients or human research subjects are confined when they cannot be released pursuant to Rule .05(37).

(i) A licensee shall retain a record of each survey in accordance with Rule .05(95)

(37) **Release of Individuals Containing Radioactive Drugs or Implants.**

(a) A licensee may authorize the release of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

(b) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including oral and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the potential consequences, if any, of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with Rule .05(96).

(d) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with Rule .05(96).

(e) Notwithstanding Rule .05(37)(a), the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

(f) The licensee shall immediately notify the Division in accordance with Rule .05(118) if a patient departs prior to an authorized release.

(g) The licensee shall notify the Division in accordance with Rule .05(119):

1. When they are aware that a patient containing radioactive material and who has been released in accordance with Rule .05(37) dies; and,

2. If it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

(38) **Mobile Medical Service Technical Requirements.** A licensee providing mobile medical service shall:

(a) Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

(b) Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

(d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

(e) Check survey instruments for consistent response with a dedicated check source before use at each client's address;

(f) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Rule .03 of this Chapter;

(g) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Division for compliance with airborne release standards; and,

(h) Retain a record of each survey required by Rule .05(38)(f) in accordance with Rule .05(97)(b).

(39) **Storage and Control of Volatiles and Gases.**

(a) A licensee shall store volatile radioactive materials and radioactive gases in the shippers' radiation shield and container.

(b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.

(c) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Rule .03 of this Chapter.

(d) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(e) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

(40) **Decay-in-Storage.**

(a) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

1. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

2. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and

3. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(b) For radioactive material disposed in accordance with (40)(a) of this section, the licensee shall retain a record of each disposal in accordance with Rule .05(98).

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL WRITTEN DIRECTIVE NOT REQUIRED

(41) **Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required.** A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or

(c) Obtained from and prepared by a Division, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

(42) **Possession of Survey Instrument.** A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with Rule .05(30).

(43) **Training for Uptake, Dilution, and Excretion Studies.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a unsealed radioactive material for the uses authorized under Rule .05(41) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in Rule .05(43)(c)1.(i) through .05(43)(c)1.(ii)(VI); and

2. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under Rule .05(47) or .05(52) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rules .05(26), (43), (47) or (52) or equivalent Agreement State or Nuclear Regulatory Commission requirements, involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) Administering dosages to patients or human research subjects; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(43)(c)1. and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule .05(41). The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(43)(c)1.

(44) **Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.** A licensee may use, for imaging and localization studies, any radioactive material (except aerosol or gaseous forms) prepared for medical use, in quantities that do not require a written directive as described in Rule .05(19) that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or

(c) Obtained from and prepared by the Division, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA, or

(e) Provided the conditions of Rule .05(39) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Division.

(45) **Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

(a) A licensee shall not administer to humans a radioactive drug containing:

1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of Mo-99 per mCi of Tc-99m); or

2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride); or

3. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82);

(b) To demonstrate compliance with Rule .05(45)(a), the licensee preparing radioactive drugs from radionuclide generators shall:

1. Measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with subparagraph .05(45)(a);

2. Before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with subparagraph .05(45)(a).

(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with Rule .05(99).

(d) A licensee shall report immediately to the Division each occurrence of radionuclide contaminant concentration exceeding the limits specified in Rule .05(45)(a).

(46) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(47) **Training for Imaging and Localization Studies.** Except as provided in Rule .05(26), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Rule .05(44) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in (c)1.(i) through (c)1.(ii)(VII) of this rule; and

2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is listed as an authorized user under Rule .05(52) and meets the requirements in .05(47)(c)1.(ii)(VII) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes, at a minimum:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use;

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Rule .05(26), .05(47) or .05(47)(c)1.(ii)(VII) and Rule .05(52), or equivalent Agreement State or Nuclear Regulatory Commission requirements. An authorized nuclear pharmacist who meets the requirements in 391-3-17-.05(24) or 391-3-17-.05(26) may provide the supervised work experience for subparagraph .05(47)(c)1.(ii)(VII). Work experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) Administering dosages to patients or human research subjects; and

(VII) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(47)(c)1. and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rules .05(41) and .05(44).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(47)(c)1.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL WRITTEN DIRECTIVE REQUIRED

(48) **Use of Unsealed Radioactive Material for Which a Written Directive is Required.** A licensee may use any unsealed radioactive material identified in subparagraph (52)(b)1.(ii)(VII) prepared for diagnostic or therapeutic medical use for which a written directive is required that has been:

(a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or (52), or an individual under the supervision of either as specified in Rule .05(26); or

(c) Obtained from and prepared by the Division, Nuclear Regulatory Commission or Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

(49) **Safety Instruction.** In addition to the requirements of Rule .07(3) of this Chapter:

(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with Rule .05(37). The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;

2. Visitor control to include the following:

(i) Routine visitation to hospitalized individuals in accordance with Rule .03 of this Chapter;

(ii) Contamination control;

(iii) Waste control; and

(iv) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101).

(50) **Safety Precautions.**

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with Rule .05(37), a licensee shall:

1. Quarter the patient or the human research subject either in:

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received radiopharmaceutical therapy and who cannot be released in accordance with Rule .05(37); and,

2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

3. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) The Radiation Safety Officer, or his designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Division in accordance with Rule .05(119) if it is possible that any individual could receive exposures in excess of the limits in Rule .03(5)(i) of this Chapter as a result of the deceased's body.

(51) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(52) **Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.** Except as provided in Rule .05(26), the licensee shall require an authorized user of radioactive material for the uses authorized under Rule .05(48) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State, and who meets the requirements of Rule .05(52)(b)1(ii)(VII). (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in Rule .05(52)(b)1.(i) through .05(52)(b)1.(ii)(V). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(b) 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(52) or equivalent Agreement State, or Nuclear Regulatory Commission requirements. The work experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.

(VI) Reserved.

(VII) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised work experience required by Rule .05(52)(b)1.(ii):

(i) Oral administration of less than or equal to 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131, for which a written directive is required;

(ii) Oral administration of greater than 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131[2];

(iii) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV, for which a written directive is required; and/or

(iv) Parenteral administration of any other radionuclide, for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(52)(b)1., and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule .05(48).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(52)(b)1.

(53) **Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerel (33 millicurie) for which a Written Directive is Required.** Except as provided in Rule .05(26), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerel (33 millicurie), for which a written directive is required, to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in .05(53)(c)1. and .05(53)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under Rule (52) for uses listed in (52)(b)1.(ii)(VII)(i) or (ii), or (54), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), (53) or (54), or equivalent Agreement State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b) must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(i) or (ii); the work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(53)(c)1. and (53)(c)2. and is able to independently fulfill the radiation safety-related duties as an authorized user for medical uses authorized under .05(48).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral

Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(53)(c)1. and 2.

(54) **Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerel (33 millicurie) for which a Written Directive is Required.** Except as provided in Rule .05(26), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerel (33 millicurie), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in Rules .05(54)(c)1. and .05(54)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under Rule .05(52) for uses listed in Rule .05(52)(b)1.(ii)(VII)(ii), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), or (54), or equivalent Agreement State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(ii); the work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(54)(c)1. and .05(54)(c)2. and is able to independently fulfill the duties as an authorized user for medical uses authorized under Rule .05(48). The written attestation must be signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(52), or .05(54), or equivalent Agreement State or Nuclear Regulatory Commission requirements. The preceptor authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(ii).

(54.1) Except as provided in Rule .05(26) the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under Rule .05(52) for uses listed in 05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(b) Is an authorized user under Rules .05(63), .05(84), or equivalent Agreement State or Nuclear Regulatory Commission requirements and who meets the requirements in .05(54.1)(d); or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State under Rules .05(63) or .05(84), and who meets the requirements in paragraph .05(54.1)(d).

(d) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rules .05(26), .05(52), .05 (54.1) or equivalent Agreement State or Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Rule .05(52) or .05 (54.1) must have experience in administering dosages as specified in 05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in .05(54.1)(d)1. and (d)2. and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive.

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (52), (54.1) or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (52) or (54.1), or equivalent Agreement State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(54.1)(d)1. and 2.

Manual Brachytherapy

(55) **Use of Sealed Sources for Manual Brachytherapy.** A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

(56) **Surveys After Source Implant and Removal.**

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

(57) **Brachytherapy Sources Inventory.**

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with Rule .05(103).

(58) **Safety Instruction.** In addition to the requirements of Rule .07(3) of this Chapter:

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with Rule .05(37). Instruction must be commensurate with the duties of the personnel and shall include the following:

1. Size and appearance of the brachytherapy sources;

2. Safe handling and shielding instructions;

3. Patient or human research subject control;

4. Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with Rule .03(5)(i)1.(i) of this Chapter; and

(ii) Visitation authorized in accordance with Rule .03(5)(i)2. of this Chapter; and

5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Division in accordance with Rule .05(119) if it is possible for any individual to receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101).

(59) **Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.**

(a) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with Rule .05(37), a licensee shall:

1. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

1. Dislodged from the patient; or

2. Lodged within the patient following removal of the source applicators.

(c) Radiation Safety Officer, or his designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

(60) **Calibration Measurements of Brachytherapy Sealed Sources.**

(a) Prior to the first medical use of a brachytherapy sealed source on or after July 1, 2003, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of Rule .05(72)(a);

2. Determine source positioning accuracy within applicators; and

3. Use published protocols accepted by nationally recognized bodies to meet the requirements of Rule .05(60)(a)1. and .05(60)(a)2.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with Rule .05(60)(a).

(c) A licensee shall mathematically correct the outputs or activities determined in Rule .05(60)(a) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(d) An authorized medical physicist shall perform or review the calculation measurements made pursuant to Rule .05(60)(a), (60)(b), or (60)(c).

(e) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with Rule .05(60)(a), (60)(b), and (60)(c).

(f) A licensee shall retain a record of each calibration in accordance with Rule .05(104).

(g) A licensee shall retain a record of decay calculations required by Rule .05(60)(e) in accordance with Rule .05(105).

(61) **Therapy-related Computer Systems.** The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine radioactive source positions from radiographic images.

(62) **Possession of Survey Instruments.** A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(63) **Training for Use of Manual Brachytherapy Sources.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under Rule .05(55) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in .05(26), (63) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution authorized to use byproduct material under Rule .05(55), involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Checking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of material on hand;

(V) Using administrative controls to prevent a misadministration involving the use of radioactive material; and

(VI) Using emergency procedures to control radioactive material; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(63) or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by Rule .05(63)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rules .05(63)(b)1. and (63)(b)2. and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under in Rule .05(55).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.

(64) **Training for Ophthalmic Use of Strontium-90.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under Rule .05(55) to be a physician who:

(a) Is an authorized user under Rule .05(63) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or,

(b) 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice, and that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow-up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(63) or .05(64) or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in Rule .05(64)(b)1. and 2., and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

(c) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subparagraph .05(64)(d) are performed by either:

1. An authorized medical physicist; or

2. An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and

(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(I) The creation, modification, and completion of written directives;

(II) Procedures for administrations requiring a written directive; and

(III) Performing the calibration measurements of brachytherapy sources as detailed in Rule (.05)(60).

(d) The individuals who are identified in subparagraph .05(64)(c) must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Rule (.05)(60); and

2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subparagraph .05(64)(c) will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(e) Licensees must retain a record of the activity of each strontium-90 source in accordance with Rule (.05)(105).

Sealed Sources For Diagnosis

(65) **Use of Sealed Sources and Medical Devices for Diagnosis.**

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(20)(a) are met.

(66) **Training for Use of Sealed Sources for Diagnosis and Medical Devices for Diagnosis.** Except as provided in Rule .05(26), the licensee shall require the authorized user of a diagnostic sealed source for the use in a device authorized under Rule .05(65) to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rules .05(66)(c) and .05(66)(d) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user for uses listed in Rule .05(44) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

Photon-Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(67) **Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.**

(a) A licensee must only use sealed sources:

1. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of Rule .05(21)(a) are met.

(68) **Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.**

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(b) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

(69) **Installation, Maintenance, Adjustment, and Repair.**

(a) Only a person specifically licensed by the Director, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Director, an Agreement State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Director, an Agreement State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with Rule .05(106).

(70) **Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or when unattended;

2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

3. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by Rule .05(70)(a)4. must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by Rule .05(70)(a)4.; and

2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) 1. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

2. A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(i) The procedures identified in Rule .05(70)(a)4.; and

(ii) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by Rule .05(70)(d), in accordance with Rule .05(101).

(g) A licensee shall retain a copy of the procedures required by subparagraphs .05(70)(a)4. and (d)2.(ii).

(71) **Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

2. Cause the source(s) to be shielded promptly when an entrance door is opened; and

3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in Rule .05(71)(a) through (71)(e), a licensee shall:

1. For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

2. For high dose-rate remote afterloader unit, require:

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

4. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(g) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

1. Remains in the unshielded position; or

2. Lodges within the patient following completion of the treatment.

(72) **Dosimetry Equipment.**

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

2. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been inter-compared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the inter-comparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the inter-comparison result to change the calibration factor. When inter-comparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with Rule .05(72)(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in Rule .05(72)(a).

(c) The licensee shall retain a record of each calibration, inter-comparison, and comparison in accordance with Rule .05(107).

(73) **Full Calibration Measurements on Teletherapy Units.**

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding 1 year.

(b) To satisfy the requirement of Rule .05(73)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(73)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by Rule .05(73)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in Rule .05(73)(b)1. for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by Rule .05(73)(a) and physical decay corrections required by Rule .05(73)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(74) **Full Calibration Measurements on Remote Afterloader Units.**

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

3. At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of Rule .05(74)(a), full calibration measurements must include, as applicable, determination of:

1. The output within +/- 5 percent;

2. Source positioning accuracy to within +/- 1 millimeter;

3. Source retraction with backup battery upon power failure; and

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Rule .05(74)(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(d) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output.

(e) A licensee shall make full calibration measurements required by Rule .05(74)(a) in accordance with published protocols accepted by nationally recognized bodies.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with Rule .05(74)(a) through (74)(e).

(g) A licensee shall mathematically correct the outputs determined in Rule .05(74)(b)1. of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by Rule .05(74)(a) and physical decay corrections required by Rule .05(74)(g) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(75) **Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.**

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of Rule .05(75)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent;

2. Relative helmet factors;

3. Isocenter coincidence;

4. Timer accuracy and linearity over the range of use;

5. On-off error;

6. Trunnion centricity;

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

8. Helmet microswitchs;

9. Emergency timing circuits; and

10. Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(75)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by Rule .05(75)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in Rule .05(75)(b)1. at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by Rule .05(75)(a) and physical decay corrections required by Rule .05(75)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(76) **Periodic Spot-Checks for Teletherapy Units.**

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy, and timer linearity over the range of use;

2. On-off error;

3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b); and

6. The difference between the measurement made in Rule .05(76)(a)5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by Rule .05(76)(a) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;

2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

4. Viewing and intercom systems;

5. Treatment room doors from inside and outside the treatment room; and

6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in Rule .05(76)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by Rule .05(76)(a) and (76)(d), in accordance with Rule .05(109).

(77) **Periodic Spot-Checks for Remote Afterloader Units.**

(a) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

1. At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and

3. After each source installation.

(b) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in Rule .05(77)(a). The authorized medical physicist need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of Rule .05(77)(a), spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;

4. Emergency response equipment;

5. Radiation monitors used to indicate the source position;

6. Timer accuracy;

7. Clock (date and time) in the unit's computer; and

8. Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in Rule .05(77)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by Rule .05(77)(d) in accordance with Rule .05(110).

(78) **Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;

2. At the beginning of each day of use; and

3. After each source installation.

(b) The licensee shall have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in Rule .05(78)(a); and

2. Review the results of each spot-check required by Rule .05(78)(a)1. within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of Rule .05(78)(a)1., spot-checks must, at a minimum:

1. Assure proper operation of:

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitchs;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

2. Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b);

(ii) The difference between the measurement made in Rule .05(78)(c)2.(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of Rule .05(78)(a)2. and (78)(a)3., spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Timer termination;

5. Radiation monitors used to indicate room exposures; and

6. Emergency off buttons.

(e) A licensee shall arrange for prompt repair of any system identified in Rule .05(78)(c) that is not operating properly.

(f) If the results of the checks required in Rule .05(78)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by Rule .05(78)(c) and (78)(d) in accordance with Rule .05(111).

(79) **Additional Technical Requirements for Mobile Remote Afterloader Units.**

(a) A licensee providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

2. Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by Rule .05(77), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

5. Radiation monitors used to indicate room exposures;

6. Source positioning (accuracy); and

7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in Rule .05(79)(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in Rule .05(79)(b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by Rule .05(79)(b) in accordance with Rule .05(112).

(80) **Radiation Surveys.**

(a) In addition to the survey requirements in Rule .03(8) of this Chapter, a person licensed pursuant to Rule .05 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by Rule .05(80)(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by Rule .05(80)(a) of this section in accordance with Rule .05(113).

(81) **Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism and other safety components.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Director, an Agreement State or the Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with Rule .05(114).

(82) **Therapy-Related Computer Systems.** The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(83) **Possession of Survey Instruments.** A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(84) **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a sealed source for a use authorized under Rule .05(67) to be a physician who:

(a) Is certified by a medical specialty board whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission, and who meets the requirements in .05(84)(c). (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b) 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution that is authorized to use radioactive materials in Rule .05(67), involving:

(I) Reviewing full calibration measurements and periodic spot checks;

(II) Preparing treatment plans and calculating treatment doses and times;

(III) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(V) Checking and using survey meters; and

(VI) Selecting the proper dose and how it is to be administered; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by Rule .05(84)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(84)(b)1. and .05(84)(b)2., and .05(84)(c), and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status; and

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (84), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (84), or equivalent Agreement State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

(85) **Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.** A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Rule .05 if:

(a) The applicant or licensee has submitted the information required by Rule .05(8)(b), (8)(c) and (8)(d); and

(b) The applicant or licensee has received written approval from the NRC or an Agreement State in a license and uses the material in accordance with the regulations and specific conditions the NRC or Agreement State considers necessary for the medical use of the material.

Records

(86) **Records of Authority and Responsibilities for Radiation Protection Programs.**

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with Rule .05(15)(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by Rule .05(15)(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by Rule .05(15)(b). The record must include the signature of the Radiation Safety Officer and licensee management.

(c) The minutes of each Radiation Safety Committee meeting held in accordance with Rule .05(15)(g) shall include:

1. The date of the meeting;

2. Members present;

3. Members absent; and

4. Summary of deliberations and discussions.

(87) **Records of Radiation Protection Program Safety Changes.** A licensee shall retain a record of each radiation protection program change made in accordance with Rule .05(16)(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(88) **Records of Written Directives.** A licensee shall retain a copy of each written directive as required by Rule .05(19) for 3 years.

(89) **Records of Misadministrations.** A licensee shall retain a record of misadministrations reported in accordance with Rule .05(115) for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(90) **Record of a Dose to an Embryo/Fetus or a Nursing Child.** A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with Rule .05(116) for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(91) **Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.** A licensee shall maintain a record of instrument calibrations required by Rule .05(29) for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(92) **Records of Survey Instrument Calibrations.** A licensee shall maintain a record of instrument calibrations required by Rule .05(30) for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(93) **Records of Dosages of Unsealed Radioactive Material for Medical Use.** A licensee shall maintain a record of dosage determinations required by Rule .05(31) for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.11 MBq (30 µCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(94) **Records of Possession of Sealed Sources and Brachytherapy Sources.** A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Rule .05(33)(d) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(95) **Records of Surveys for Ambient Radiation Exposure Rate.** A licensee shall retain a record of each survey required by Rule .05(36) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(96) **Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.**

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release,

(b) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by Rule .05(37)(b) were provided to a breast-feeding woman.

(97) **Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.**

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by Rule .05(9)(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by Rule .05(38)(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(98) **Records of Decay-in-Storage.** A licensee shall maintain records of the disposal of licensed materials, as required by Rule .05(40), for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(99) **Records of Radionuclide Purity.** A licensee shall maintain a record of the radionuclide contaminant concentration tests required by Rule .05(45) for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcurie/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

(100) **Records of Training.** A licensee shall maintain records of training required by Rule .05(25) for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

(101) **Records of Safety Instruction and Training.** A licensee shall maintain a record of safety instructions and training required by Rules .05(49), (58) and (70) for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(102) **Records of Radiation Surveys of Patients and Human Research Subjects.** A licensee shall maintain a record of the surveys required by Rule .05(56) and (68) for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(103) **Records of Brachytherapy Source Inventory.**

(a) A licensee shall maintain a record of brachytherapy source accountability required by Rule .05(57) for 3 years.

(b) For temporary implants, the record must include:

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use;

2. The number and activity of unused sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage; and

3. The number and activity of temporarily implanted sources removed from the patient or human research subject, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

2. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

3. The number and activity of sources permanently implanted in the patient or human research subject.

(104) **Records of Calibration Measurements on Brachytherapy Sources.** A licensee shall maintain a record of the calibrations on brachytherapy sources required by Rule .05(60) for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(105) **Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.** The licensee shall maintain a record of the activity of a strontium 90 source required by Rule .05(60) for the life of the source. The record must include the date and initial activity of the source as determined under Rule .05(60), and for each decay calculation, the date, and the source activity and the signature of the authorized medical physicist.

(106) **Records of Installation, Maintenance, Adjustment, and Repair.** A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by Rule .05(69) for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(107) **Records of Dosimetry Equipment.**

(a) A licensee shall retain a record of the calibration, inter-comparison, and comparisons of its dosimetry equipment done in accordance with Rule .05(72) for the duration of the license.

(b) For each calibration, inter-comparison, or comparison, the record must include:

1. The date;

2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by Rule .05(72)(a) and (72)(b);

3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an inter-comparison; and

4. The names of the individuals who performed the calibration, inter-comparison, or comparison.

(108) **Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.**

(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by Rule .05(73), (74) and (75) for 3 years.

(b) The record must include:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

3. The results and assessments of the full calibrations;

4. The results of the autoradiograph required for low dose-rate remote afterloader units; and

5. The signature of the authorized medical physicist who performed the full calibration.

(109) **Records of Periodic Spot-Checks for Teletherapy Units.**

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Rule .05(76) for 3 years.

(b) The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

3. An assessment of timer linearity and constancy;

4. The calculated on-off error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

6. The determined accuracy of each distance measuring and localization device;

7. The difference between the anticipated output and the measured output;

8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(110) **Records of Periodic Spot-Checks for Remote Afterloader Units.**

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by Rule .05(77) for 3 years.

(b) The record must include, as applicable:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

3. An assessment of timer accuracy;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(111) **Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Rule .05(78) for 3 years.

(b) The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

3. An assessment of timer linearity and accuracy;

4. The calculated on-off error;

5. A determination of trunnion centricity;

6. The difference between the anticipated output and the measured output;

7. An assessment of source output against computer calculations;

8. Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(112) **Records of Additional Technical Requirements for Mobile Remote Afterloader Units.**

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by Rule .05(79) for 3 years.

(b) The record must include:

1. The date of the check;

2. The manufacturer's name, model number, and serial number of the remote afterloader unit;

3. Notations accounting for all sources before the licensee departs from a facility;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

5. The signature of the individual who performed the check.

(113) **Records of Surveys of Therapeutic Treatment Units.**

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Rule .05(80) for the duration of use of the unit.

(b) The record must include:

1. The date of the measurements;

2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the individual who performed the test.

(114) **Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.**

(a) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Rule .05(81) for the duration of use of the unit.

(b) The record must contain:

1. The inspector's radioactive materials license number;

2. The date of inspection;

3. The manufacturer's name and model number and serial number of both the treatment unit and source;

4. A list of components inspected and serviced, and the type of service; and

5. The signature of the inspector.

Reports

(115) **Reports and Notifications of Misadministrations.**

(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug or the wrong radionuclide for brachytherapy procedures;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(i) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(ii) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4. For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(I) The wrong radionuclide;

(II) The wrong individual or human research subject;

(III) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(IV) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify the Division by telephone no later than the next calendar day after discovery of the misadministration.

(d) The licensee shall submit a written report to the Division within 15 days after discovery of the misadministration.

1. The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

(g) A licensee shall retain a record of a misadministration in accordance with Rule .05(89). A copy of the record required under Rule .05(89) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

(116) **Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.**

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

1. Is greater than 50 mSv (5 rem) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the Division no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

(d) The licensee shall submit a written report to the Division within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

1. The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken, or are planned, to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under Rule .05(116)(a) or (116)(b), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with Rule .05(90). A copy of the record required under Rule .05(90) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(117) **Reports of Leaking Sources.** A licensee shall file a report with the Division within 5 days if a leakage test required by Rule .05(33) reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(118) **Reports of Patient Departure Prior to Authorized Release.**

(a) A licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under Rule .05(37)(a).

(b) The licensee shall submit a written report to the Division within 30 days after discovery of the unauthorized departure. The written report must include:

1. The licensee's name;

2. The date and time of the unauthorized departure;

3. The projected date and time when release would have occurred;

4. The address of the patient's or human research subject's home or anticipated destination following departure;

5. The radionuclide, chemical and physical form and calculated activity at time of release;

6. The apparent reason(s) for the departure prior to authorized release; and

7. A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(119) **Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.**

(a) The licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of limits specified in Rule .03(5)(i) of this Chapter as a result of the deceased's body.

(b) The licensee shall submit a written report to the Division within 30 days after discovery that the patient or human research subject referenced in (119)(a) has died. The written report must include:

1. The licensee's name;

2. The date of death;

3. The radionuclide, chemical and physical form and calculated activity at time of death; and,

4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisievert (500 mrem).

(120) **Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.**

(a) The licensee shall notify by telephone the Georgia Department of Natural Resources, Environmental Protection Division and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 391-3-17-.05(45)(a) at the time of generator elution. The telephone report to the Georgia EPD must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(b) By an appropriate method listed in 391-3-17-.01(13), the licensee shall submit a written report to Georgia Department of Natural Resources, Environmental Protection Division within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subparagraph .05(120)(a).

[1] "Essentials and guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.

[2] Experience with at least 3 cases in category (VII)(ii) also satisfies the requirement in category (VII)(i).

Cite as Ga. Comp. R. & Regs. R. 391-3-17-.05

AUTHORITY: O.C.G.A. § 31-13-1 *et seq.*

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Repealed: New Rule of same title adopted. F. May 30, 2003; eff. July 1, 2003, as specified by the Agency.

Amended: F. Oct. 17, 2008; eff. Nov. 6, 2008.

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Amended: New title, "Use of Radionuclides in the Healing Arts." F. June 1, 2017; eff. June 21, 2017.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Feb. 26, 2020; eff. Mar. 17, 2020.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-17-.06 Transportation of Radioactive Material

(1) **General.**

(a) Purpose. The Regulations in this Rule, 391-3-17-.06, establish requirements for packaging, preparation for shipment, and transportation of radioactive material.

(b) Scope. This Rule applies to any licensee authorized by specific or general license issued by the Director, Agreement State, or NRC to receive, possess, use, or transfer licensed material to a carrier for transport of the material outside the site of usage as specified in the license, or transports that material on public highways or public access roads. No provision of this part authorizes possession of licensed material.

(2) **Requirement for License.** No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Director or as exempted in (4).

(3) **Definitions.** As used in this Rule, the following definitions apply:

(a) "A_1" and "A_2" mean, respectively, the maximum activity of special form radioactive material (A_1) and the maximum activity of radioactive material, other than special form material, LSA, and SCO material (A_2), permitted in a Type A package.

(b) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(c) "Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.

(d) "Certificate of Compliance (CoC)" means the certificate issued by the U.S Nuclear Regulatory Commission, which approves the design of a package for the transportation of radioactive material.

(e) "Close reflection by water" means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

(f) "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

(g) "Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(h) "Containment system" means the assembly components of the packaging intended to retain the radioactive material during transport.

(i) "Conveyance" means:

1. For transport by public highway or rail any transport vehicle or large freight container;

2. For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

3. For transport by any aircraft.

(j) "Criticality Safety Index (CSI)" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in 391-3-17-.06(11) and (12) and 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

(k) "Deuterium" means deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5,000.

(l) "DOT" means the U.S. Department of Transportation.

(m) "Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.[1]

(n) "Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Neither natural nor depleted uranium is fissile material.[2] Unirradiated natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

(o) "Graphite" means graphite with a boron equivalent content less than five (5) parts per million and density greater than 1.5 grams per cubic centimeter.

(p) "Indian Tribe" means an Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

(q) "Licensed material" means byproduct, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to the regulations in 10 CFR or this Chapter, respectively.

(r) "Low specific activity material" means radioactive material with limited specific activity which is nonfissile or is excepted under 391-3-17-.06(4)(f), and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. The LSA material must be in one of three groups:

1. LSA-I

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides; or

(ii) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form; or

(iii) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 391-3-17-.06(23).

2. LSA-II

(i) Water with tritium concentration up to 20.0 Ci/L (0.8 TBq/liter); or

(ii) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

3. LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc);

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1 A_2; and

(iii) The estimated average specific activity of the solid, excluding any shielding material, does not exceed $2x10^{-3}$ A_2/g.

(s) "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

(t) "Maximum normal operating pressure" means the maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(u) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(v) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material."

(w) "Nuclear waste" means a quantity of source, byproduct or special nuclear material[3] required to be in US Nuclear Regulatory Commission-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

(x) "Optimum interspersed hydrogenous moderation" means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

(y) "Package" means the packaging together with its radioactive contents as presented for transport.

1. "Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package" means a fissile material packaging together with its fissile material contents.

2. "Type A package" means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.

3. "Type B package" means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lb/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR Part 71 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in .06(8).

(z) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this Rule. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(aa) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

(bb) "Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71 for purposes of this Rule.

(cc) "Special form radioactive material" means radioactive material that satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 in.); and

3. It satisfies the requirements specified by the Nuclear Regulatory Commission in 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR 71, revised as of January 1, 1983), and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR 71, revised as of January 1, 1996), and constructed prior to April 1, 1998, may continue to be used. A special form material that was successfully tested before September 10, 2015 in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form must meet requirements of this definition applicable at the time of its design or construction.

(dd) "Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(ee) "Spent nuclear fuel or Spent fuel" means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one (1) year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(ff) "Surface Contaminated Object (SCO)" means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

1. SCO-I: A solid object on which:

(i) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-4} microcurie/cm^2 (4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-5} microcurie/cm^2 (0.4 Bq/cm^2) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1.0 microcurie/cm^2 ($4x10^4$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 ($4x10^3$ Bq/cm^2) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1.0 microcurie/cm^2 ($4x10^4$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 ($4x10^3$ Bq/cm^2) for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(i) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-2} microcurie/cm^2 (400 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-3} microcurie/cm^2 (40 Bq/cm^2) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcurie/cm^2 ($8x10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm^2 ($8x10^4$ Bq/cm^2) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcurie/cm^2 ($8x10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm^2 ($8x10^4$ Bq/cm^2) for all other alpha emitters.

(gg) "Transport index" means the dimension-less number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transportation index is the number expressing the maximum radiation level in millirem per hour at 1 meter from the external surface of the package.

(hh) "Tribal official" means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

(ii) "Type A package" means a packaging that, together with its radioactive contents limited to A_1 or A_2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding required by this Rule under normal conditions of transport as demonstrated by the tests set forth in 49 CFR 173.465 or 173.466, as appropriate.

(jj) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table 4, "A_1 and A_2 Values for Radionuclides" or may be determined by procedures described in (23) of this Rule.

(kk) "Type B package" is defined in Rule 391-3-17-.01(2)(ttt).

(ll) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

(mm) "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

(nn) "Unirradiated uranium" means uranium containing not more than $2x10^3$ Bq of plutonium per gram of uranium-235, not more than $9x10^6$ Bq of fission products per gram of uranium-235, and not more than $5x10^{-3}$ grams of uranium-236 per gram of uranium-235.

(oo) "Uranium-natural, depleted, enriched" means:

1. Natural uranium means uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

2. Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

3. Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(pp) "Contamination" means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm^2 (1x10-5 $\mu Ci/cm^2$) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 (1x10-6 $\mu Ci/cm^2$) for all other alpha emitters.

1. Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport

2. Non-fixed contamination means contamination that can be removed from a surface during normal conditions of transport

(4) **Exemptions.**

(a) Common and contract carriers, freight forwarders, and warehousemen who are subject to the requirements of the U.S. Department of Transportation (DOT) in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section C-023.9.0, and the U.S. Postal Service, are exempt from the requirements of this Rule and as stated in 10 CFR 30.13 to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to (2) of this Rule and other applicable requirements of these Regulations.

(b) Any licensee is exempt from the requirements of this Rule to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcurie per gram (70 Bq/gm).

(c) Any physician licensed by Georgia to dispense drugs in the practice of medicine is exempt from Rule .06 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under Rule .05.

(d) A licensee is exempt from the requirements of Rule .06 with respect to shipment or carriage of the following low-level materials:

1. Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in Table 5 and 7.

2. Materials for which the activity concentration is not greater than the activity concentration values specified in Table 5 and 7, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table 5 and 7.

3. Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in 391-3-17-.06(3)(pp).

(e) A licensee is exempt from the requirements of Rule .06, other than .06(5) and .06(17), with respect to shipment or carriage of the following packages, providing the packages do not contain any fissile material, or the material is exempt from classification as fissile material in .06(4)(f):

1. A package that contains no more than a Type A quantity of radioactive material;

2. A package transported within the United States that contains no more than 20 Ci (0.74 TBq) of special form plutonium-244; or

3. A package contains LSA or SCO radioactive material, provided that the LSA or SCO material has an external radiation dose of less than or equal to 1 rem/hr (10 mSv/hr) at a distance of 3 meters from the unshielded material or that the package contains only LSA-I or SCO-I material.

(f) Fissile material meeting the requirements of at least one of the following six paragraphs in this part are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of this part, except as noted.

1. Individual package containing two (2) grams or less of fissile material.

2. Individual or bulk packaging containing fifteen (15) grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

3. Low concentrations of solid fissile material commingled with solid nonfissile material, provided that (i) there is at least 2,000 grams of solid nonfissile material for every gram of fissile material, and (ii) there is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

4. Uranium enriched in uranium-235 to a maximum of one (1) percent by weight, and with a total plutonium and uranium-233 content of up to one (1) percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five (5) percent of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

5. Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two (2) percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

6. Packages containing, individually, a total plutonium mass of not more than 1,000 grams, of which not more than twenty (20) percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(5) **Transportation of Licensed Material.**

(a) Each licensee who transports licensed material outside the site of usage, as specified in a Division license, or where transport is on public highway, or public access road, or who delivers licensed material to a carrier for transport, shall:

1. Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the US Department of Transportation (DOT).

(i) The licensee shall particularly note DOT regulations in the following areas:

(I) Packaging - 49 CFR Part 173, Subparts A and B and I.

(II) Marking and Labeling - 49 CFR Part 172: Subpart D, and §§ 49 CFR 172.400 through 172.407, §§ 172.436 through 172.440 of Subpart E.

(III) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556 and Appendices B and C.

(IV) Accident Reporting - 49 CFR Part 171: §§ 171.15 and 171.16.

(V) Shipping Papers and Emergency Information - 49 CFR Part 172, Subpart C and Subpart G.

(VI) Hazardous material employee training - 49 CFR Part 172: Subpart H.

(VII) Security Plans - 49 CFR Part 172: Subpart I.

(VIII) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

(ii) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(I) Rail - 49 CFR Part 174, Subparts A through D and K.

(II) Air - 49 CFR Part 175.

(III) Vessel - 49 CFR Part 176, Subparts A through F and M.

(IV) Public Highway - 49 CFR Part 177 and Parts 390 through 397.

2. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with Rule 391-3-17-.03(12)(f).

(b) If, for any reason, the regulations of the DOT are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 170-189 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

(6) **General Licenses for Carriers.**

(a) A general license is hereby issued to any common or contract carrier not exempt under (4) to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[4]

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(c) Persons who transport radioactive material pursuant to the general licenses in (6)(a) or (b) are exempt from the requirements of Rules 391-3-17-.03 and .07 to the extent that they transport radioactive material.

(7) **General License: NRC-Approved Packages.**

(a) A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the U.S. Nuclear Regulatory Commission (NRC).

(b) Each licensee issued a general license under .06(7)(a) shall:

1. Possess a copy of the specific license, certificate of compliance, or other approval of the package and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Comply with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of this Rule;

3. Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.71(a), the licensee's name and license number and the package identification number specified in the package approval.

(c) This general license applies only to a licensee who has a quality assurance program required by the Georgia Department of Natural Resources Radioactive Materials Program satisfying the provisions of (22).

(d) The general license in (7)(a) applies only when the package approval authorizes use of the package under this general license.

(e) For a Type B or fissile material package the design of which was approved by NRC before April 1, 1996 the general license is subject to additional restrictions of 10 CFR 71.19.

(8) **[Reserved].**

(9) **General License: DOT Specification Container.**

(a) A general license is issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(b) This general license applies only to a licensee who:

1. Has a copy of the specification;

2. Complies with the terms and conditions of the specification and the applicable requirements of this Rule; and

3. Has a quality assurance program required by (22).

(c) The general license in (9)(a) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States, except by multilateral approval, as defined in DOT regulations at 49 CFR 173.403.

(10) **General License: Use of Foreign-Approved Package.**

(a) A general license is issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

(b) This general license applies only to international shipments.

(c) This general license applies only to a licensee who:

1. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this Rule; and

3. Has a quality assurance program approved by the Georgia Department of Natural Resources, Environmental Protection Division, Radioactive Materials Program satisfying the requirements of (22).

(11) **General License: Fissile Material, Limited Quantity per Package.**

(a) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) This general license applies only to a licensee who has a quality assurance program required by (22).

(c) This general license applies only when a package contains no more than a Type A quantity of fissile material and contains less than 500 grams total of beryllium, graphite, or hydrogenous material enriched in deuterium.

(d) 1.

This general license applies only to packages containing fissile material that are labeled with a Criticality Safety Index (CSI), defined as

$$CSI = 10\left[\frac{grams\ of\ \square^{235}U}{X} + \frac{grams\ of\ \square^{233}U}{Y} + \frac{grams\ of\ Pu}{Z}\right]$$

where the values of X, Y, and Z used in the CSI equation must be taken from Tables 1 or 2, as appropriate. If Table 2 is used to obtain the value of X, then the values for the terms for uranium-233 and plutonium must be assumed to be zero. Table 1 values for X, Y, and Z must be used to determine the CSI if:

i. Uranium-233 is present in the package;

ii. The mass of plutonium exceeds one (1) percent of the mass of uranium-235;

iii. The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

iv. Substances having a moderating effectiveness (i.e., an average hydrogen density greater than water) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

2. In all cases, the Criticality Safety Index must be rounded up to one decimal place and may not exceed 10.0.

3. For a shipment of multiple packages containing fillies material, the sum of the CSIs must be less than or equal to 50 (for shipment on a non-exclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

Table 1

Mass Limits for General License Packages Containing Mixed Quantities Of Fissile Material or Uranium-235 of Unknown Enrichment

Fissile Material	Fissile Material mass mixed with moderating substances having an average hydrogen density less than or equal to water (in grams)	Fissile Material mass mixed with moderating substances having an average hydrogen density greater than water[(a)] (in grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

(a) - When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substances has an average hydrogen density greater than water.

Table 2

Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment

Uranium Enrichment in weight percent of ^{235}U not exceeding	Fissile Material mass of ^{235}U (X) (in grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408*
1.35	480*
1	1,020*
0.92	1,800*

*- Pursuant to the Division's agreement with the USNRC, jurisdiction extends only to 350 grams of uranium-235.

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(12) **General License: Plutonium-Beryllium Special Form Material.**

(a) A general license is hereby issued to any licensee to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. The material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) This general license applies only when all of the following requirements are met:

1. The package contains no more than a Type A quantity of radioactive material.

2. The package contains less than 1,000 grams of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.

(c) 1. This general license applies only to packages that are labeled with a Criticality Safety Index, calculated by:

$CSI = (10 / 24) \times (\text{grams } ^{239}Pu + \text{grams } ^{241}Pu)$

where the CSI value is less than or equal to 100 and must be rounded up to the first decimal place.

2. For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(d) The general license has a quality assurance program required by (22).

(13) **Assumptions as to Unknown Properties of Fissile Material.** When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that will cause the maximum neutron multiplication.

(14) **External Radiation Standards For All Packages.**

(a) Except as provided in (14)(b), each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 200 mrem/hr (2 mSv/hr) at any point on the external surface of the package, and the transport index does not exceed 10.

(b) A package that exceeds the radiation level limits specified in (14)(a) must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

1. 200 mrem/hr (2 mSv/hr) on the external surface of the package, unless the following conditions are met, in which case the limit is 1,000 mrem/hr (10 mSv/hr):

(i) The shipment is made in a closed transport vehicle;

(ii) The package is secured within the vehicle so that its position remains fixed during transportation; and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

2. 200 mrem/hr (2 mSv/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

3. 10 mrem/hr (0.1 mSv/hr) at any point two (2) meters (80 inches) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point two (2) meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

4. 2 mrem/hr (0.02 mSv/hr) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with Rule 391-3-17-.03(8)(b).

(c) For shipments made under the provisions of (14)(b), the shipper will provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

(d) The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

(15) **Preliminary Determinations.** Prior to the first use of any packaging for the shipment of radioactive material:

(a) The licensee shall ascertain that the determinations in 10 CFR 71.85(a) through (c) have been made.

(16) **Routine Determinations.** Prior to each shipment of licensed material, the licensee shall determine that:

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(h) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified by 10 CFR 71.45;

(i) The level of non-fixed radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable.

1. The level of non-fixed radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in (16)(i)2., the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 3 at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in Table 3.

2. In the case of packages transported as exclusive use shipments by rail or highway only, the non-fixed radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in (16)(i)1. The levels at the beginning of transport must not exceed the levels in (16)(i)1.;

Table 3

Non-Fixed (Removable) External Radioactive Contamination-Wipe Limits

	Maximum Permissible limits		
Contaminant	µCi/cm2	dpm/cm^2	Bq/cm^2
Beta-/gamma-emitting radionuclides; and low toxicity alpha emitters.....	10^{-5}	22	0.4
All other alpha-emitting radionuclides.....	10^{-6}	2.2	0.04

(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirem per hour (2 mSv/hr) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.

(k) For package transported as exclusive use by rail, highway, or water, radiation levels external to the package may exceed the limits specified in (16)(j). but shall not exceed any of the following:

1. 200 millirem per hour (2 mSv/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1,000 millirem per hour (10 mSv/hr):

(i) The shipment is made in a closed transport vehicle,

(ii) Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

2. 200 millirem per hour (2 mSv/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle, or, in the case of a flat-bed style vehicle with a personnel barrier[5], at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle;

3. 10 millirem per hour (0.1 mSv/hr) at any point 2 meters from the vertical planes represented by the outer lateral surfaces of the vehicle; or in the case of a flat-bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and

4. 2 millirem per hour (0.02 mSv/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with 391-3-17-.07(3) of this Chapter; and

(l) A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 185 degrees Fahrenheit (85 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

(m) A package may not incorporate a feature intended to allow continuous venting during transport.

(17) **Air Transport of Plutonium.** Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Rule or included indirectly by citation of the DOT regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

(a) The plutonium is contained in a medical device designed for individual human application;

(b) The plutonium is contained in a material in which the specific activity is not greater than the activity concentration values for plutonium as specified in Table 7, and in which the radioactivity is essentially uniformly distributed;

(c) The plutonium is shipped in a single package containing no more than an A2 quantity of plutonium in any isotope or form and is shipped in accordance with (5); or

(d) The plutonium is shipped in a package specifically authorized, in the certificate of compliance, issued by the Nuclear Regulatory Commission, for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the US Department of Transportation regulations applicable to the air transport of plutonium.

(18) **Opening instructions.** Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with Rule 391-3-17-.03(12)(f).

(19) **Shipment Records.** Each licensee shall maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under (4), showing, where applicable:

(a) Identification of the packaging by model number;

(b) Verification that there were no significant defects in the packaging, as shipped;

(c) Volume and identification of coolant;

(d) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(e) Date of the shipment;

(f) Name and address of the transferee;

(g) Address to which the shipment was made; and

(h) Results of the determinations required by (16) and the conditions of the package approval.

(i) The licensee shall make available to the Division for inspection, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(j) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by 391-3-17-.06(15) and 10 CFR 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.

(k) For each item of irradiated fissile material —

1. Identification by model number and serial number;

2. Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

3. Any abnormal or unusual condition relevant to radiation safety;

(l) For fissile packages and for Type B packages, any special controls exercised.

(20) **Reports.** The licensee shall report to the Division within 30 days:

(a) Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and

(b) Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.

(21) **Advance Notification of Transport of Nuclear Waste.**

(a) As specified in paragraphs (b), (c), and (d) of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee[6], of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

1. As specified in paragraphs (b), (c), and (d) of this section, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (d)3.(iii) of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is also required when:

1. The licensed material is required to be in Type B packaging for transportation;

2. The licensed material is being transported into, within, or through, a state en route to a disposal facility or to a collection point for transport to a disposal facility; and

3. The quantity of licensed material in a single package exceeds the least of the following:

(i) 3000 times the A1 value of the radionuclides as specified in Table 7, for special form radioactive material;

(ii) 3000 times the A2 value of the radionuclides as specified in Table 7 for normal form radioactive material; or

(iii) 27,000 Ci (1000 TBq);

(c) Each advance notification required by .06(21)(a) shall contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);

3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

4. The seven-day period during which arrival of the shipment at state boundaries or Tribal reservation boundaries is estimated to occur;

5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

6. A point of contact with a telephone number for current shipment information.

(d) Procedures for Submitting Advance Notification:

1. The notification required by .06(21)(a) shall be made in writing to the office of each appropriate governor, or governor's designee, to the office of each appropriate Tribal official or Tribal official's designee, and to the Division.

2. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

3. A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(i) [Reserved]

(ii) The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the Federal Register on or about June 30th to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes, including telephone and mailing addresses of Tribal official's designees, is available on the NRC Web site at: https://scp.nrc.gov/special/designee.pdf.

4. A copy of the notification shall be retained by the licensee for three years.

(e) A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.

(f) Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and to the Division.

1. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled. The licensee shall retain a copy of the notice as a record for 3 years.

(22) **Quality Assurance Requirements.**

This paragraph describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this paragraph, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

(a) Unless otherwise authorized by the Division, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations,

and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

(b) The licensee shall identify the material and components to be covered by the quality assurance program.

(c) Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.

(d) Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Division of its quality assurance program.

(e) The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of three years after shipment.

(f) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of rule 391-3-17-.04(11)(d) and (e) or equivalent NRC or Agreement State requirement, is deemed to satisfy the requirements of 391-3-17-.06(7) and .06(22)(g).

(g) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 391-3-17-.06(22) and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(h) Approval of program.

1. Before the use of any package for the shipment of licensed material subject to this paragraph, each licensee shall obtain Division approval of its quality assurance program. Using an appropriate method listed in 391-3-17-.06(22), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: Georgia Department of Natural Resources/Environmental Protection Division, Radioactive Materials Program, at 4244 International Parkway, Suite 120, Atlanta, Georgia 30354.

(i) Quality Assurance Organization

1. The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

2. The quality assurance functions are:

(i) Assuring that an appropriate quality assurance program is established and effectively executed; and

(ii) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(j) Changes to Quality Assurance Programs

1. Each quality assurance program approval holder shall submit, in accordance with the requirements of 391-3-17-.01(13) and 391-3-17-.06(19), a description of a proposed change to its Georgia Department of Natural Resources Radioactive Materials Program approved quality assurance program that will reduce commitments in the program description as approved by the Georgia Department of Natural Resources Radioactive Materials Program. The

quality assurance program approval holder shall not implement the change before receiving Georgia Department of Natural Resources Radioactive Materials Program approval.

(i) The description of a proposed change to the Georgia Department of Natural Resources Radioactive Materials Program approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of 391-3-17-.06(22).

(ii) [Reserved]

2. Each quality assurance program approval holder may change a previously approved quality assurance program without prior Georgia Department of Natural Resources Radioactive Materials Program approval, if the change does not reduce the commitments in the quality assurance program previously approved by the Georgia Department of Natural Resources Radioactive Materials Program. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Georgia Department of Natural Resources Radioactive Materials Program every 24 months, in accordance with 391-3-17-.01(13). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

(i) The use of a quality assurance standard approved by the Georgia Department of Natural Resources Radioactive Materials Program that is more recent than the quality assurance standard in the applicant's current quality assurance program at the time of the change;

(ii) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(iii) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(iv) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

(v) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

3. Each quality assurance program approval holder shall maintain records of quality assurance program changes.

(k) Quality Assurance Records

1. The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by 391-3-17-.06(22)(j), the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for 3 years beyond the date when the licensee last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded.

(23) Determination of A_1 and A_2.

(a) Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table 4. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

(b) 1. For individual radionuclides whose identities are known but are not listed in Table 4, the A_1 and A_2 values contained in Table 5 may be used. Otherwise, the licensee shall obtain prior Division approval of the A_1 and A_2 values for radionuclides not listed in Table 4, before shipping the material.

2. For individual radionuclides whose identities are known but are not listed in Table 7, the exempt material activity concentration and exempt consignment activity values contained in Table 5 may be used. Otherwise, the licensee shall obtain prior Division approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table 7, before shipping the material.

(c) In calculations of A_1 and A_2 for a radionuclide not in Table 4, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 and A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days, or greater than of the parent nuclide, the parent and those daughters nuclides shall be considered as a mixture of different nuclides.

(d) Mixtures of radionuclides.

1. For mixture of radionuclides whose identities and respective activities are known, following conditions apply:

(i) For a special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i in special form, and A_1(i) is the A_1 value for radionuclide i.

(ii) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i in normal form, and A_2(i) is the A_2 value for radionuclide i.

(iii) If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

where B(i) is the activity of radionuclide i as special form radioactive material, A_1(i) is the A_1 value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and A_2(j) is the A_2 value for radionuclide j.

(iv) Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

A_1 for mixture =

$$\frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture and A_1 (i) is the appropriate A_1 value for radionuclide i.

(v) Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

A_2 for mixture =

$$\frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and A_2(i) is the appropriate A_2 value for radionuclide i.

(e) The exempt activity concentration for mixtures of radionuclides may be determined as follows:

Exempt activity concentration for mixture =

$$\frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction activity concentration of radionuclide i in the mixture and [A](i) is the activity concentration for exempt material containing radionuclide i.

(f) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

Exempt consignment activity limit for mixture =

$$\frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and [A] is the activity limit for exempt consignments for radionuclide i.

(g) 1. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped, and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying formulas above. Groups may be based on the total alpha activity and the total

beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

2. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped, and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph 391-3-17-.06(23). Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

Table 4- A_1 and A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195		$1.0X10^{1}$	$2.7X10^{2}$	6.0	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Ba-133		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	9.4	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	8.1	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	1.9	$5.2X10^{1}$
Bi-210		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g) (Ci/g)	
Bk-247	Berkelium (97)	8.0	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	8.1	$6.1X10^{1}$	$1.6X10^{3}$
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6
Cf-252		$1.0X10^{-1}$	2.7	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	4.0	$1.1X10^{2}$	4.0	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g) (Ci/g)	
Cs-137 (a)		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	3.2	$8.7X10^{1}$
Cu-64	Copper (29)	6.0	$1.6X10^{2}$	1.0	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	8.1	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short lived)		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g) (Ci/g)	
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192		[c]1.0	[c]$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-79	Krypton (36)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
Kr-81		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		8.0	$2.2X10^{2}$	8.0	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		9.0	$2.4X10^{2}$	9.0	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	1.1
Mo-99 (a) (h)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{7}$	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	8.8	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	6.0	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g) (Ci/g)	
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^{1}$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	5.4	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	5.2	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	1.4	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g)	(Ci/g)
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g) (Ci/g)	
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-10}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T (H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g) (Ci/g)	
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (medium lung absorption) (a) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a), (d),		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity (TBq/g) (Ci/g)	
(e), (f)							
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d), (e), (f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table 6	See Table 6
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table	See Table
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$^{6}6.3X10^{3}$	$^{5}1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (70)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$
Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days as listed in Table 4-A.

[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq).

[c] The activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

[h] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

TABLE 4-A- DAUGHTER NUCLIDES WITH HALF-LIVES LESS THAN 10 DAYS

Parent Nuclide	Daughter Nuclide(s)						
Mg-28	Al-28						
Ca-47	Sc-47						
Ti-44	Sc-44						
Fe-52	Mn-52m						
Fe-60	Co-60m						
Zn-69m	Zn-69						
Ge-68	Ga-68						
Rb-83	Kr-83m						
Sr-82	Rb-82						
Sr-90	Y-90						
Sr-91	Y-91m						
Sr-92	Y-92						
Y-87	Sr-87m						
Zr-95	Nb-95m						
Zr-97	Nb-97m,	Nb-97					
Mo-99	Tc-99m						
Tc-95m	Tc-95						
Tc-96m	Tc-96						
Ru-103	Rh-103m						
Ru-106	Rh-106						
Pd-103	Rh-103m						
Ag-108m	Ag-108						
Ag-110m	Ag-110						
Cd-115	In-115m						
In-114m	In-114						
Sn-113	In-113m						
Sn-121m	Sn-121						
Sn-126	Sb-126m						
Te-127m	Te-127						
Te-129m	Te-129						
Te-131m	Te-131						

Parent Nuclide	Daughter Nuclide(s)						
Te-132	I-132						
I-135	Xe-135m						
Xe-122	I-122						
Cs-137	Ba-137m						
Ba-131	Cs-131						
Ba-140	La-140						
Ce-144	Pr-144m,	Pr-144					
Pm-148m	Pm-148						
Gd-146	Eu-146						
Dy-166	Ho-166						
Hf-172	Lu-172						
W-178	Ta-178						
W-188	Re-188						
Re-189	Os-189m						
Os-194	Ir-194						
Ir-189	Os-189m						
Pt-188	Ir-188						
Hg-194	Au-194						
Hg-195m	Hg-195						
Pb-210	Bi-210						
Pb-212	Bi-212,	Tl-208,	Po-212				
Bi-210m	Tl-206						
Bi-212	Tl-208,	Po-212					
At-211	Po-211						
Rn-222	Po-218,	Pb-214,	At-218,	Bi-214,	Po-214		
Ra-223	Rn-219,	Po-215,	Pb-211,	Bi-211,	Po-211,	Tl-207	
Ra-224	Rn-220,	Po-216,	Pb-212,	Bi-212,	Tl-208,	Po-212	
Ra-225	Ac-225,	Fr-221,	At-217,	Bi-213,	Tl-209,	Po-213,	Pb-209
Ra-226	Rn-222,	Po-218,	Pb-214,	At-218,	Bi-214,	Po-214	
Ra-228	Ac-228						
Ac-225	Fr-221,	At-217,	Bi-213,	Tl-209,	Po-213,	Pb-209	
Ac-227	Fr-223						
Th-228	Ra-224,	Rn-220,	Po-216,	Pb-212,	Bi-212,	Tl-208,	Po-212
Th-234	Pa-234m,	Pa-234					
Pa-230	Ac-226,	Th-226,	Fr-222,	Ra-222,	Rn-218,	Po-214	
U-230	Th-226,	Ra-222,	Rn-218,	Po-214			
U-235	Th-231						
Pu-241	U-237						
Pu-244	U-240,	Np-240m					
Am-242m	Am-242,	Np-238					
Am-243	Np-239						
Cm-247	Pu-243						
Bk-249	Am-245						

TABLE 5 — GENERAL VALUES FOR A_1 AND A_2

Contents	A_1		A_2		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
Only beta or gamma emitting	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{1}	2.7×10^{-10}	1×10^{4}	2.7×10^{-7}

TABLE 5 — GENERAL VALUES FOR A_1 AND A_2								
radionuclides are known to be present								
Alpha emitting nuclides, but no neutron emitters, are known to be present[a]	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
Neutron emitting nuclides are known to be present or no relevant data are available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

[a] If beta or gamma emitting nuclides are known to be present, the A_1 value of 0.1 TBq (2.7 Ci) should be used.

TABLE 6 - ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment[1] wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}

[1] The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

Table 7 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	**Element and atomic number**	**Activity concentration for exempt material (Bq/g)**	**Activity concentration for exempt material (Ci/g)**	**Activity limit for exempt consignment (Bq)**	**Activity limit for exempt consignment (Ci)**
Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-79	Krypton (36)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Kr-81		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{1}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
T (H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b),(d)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b), (d), (e), (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b), (d), (e), (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (natural) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less) (g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a] [Reserved]

[b] Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

[c] [Reserved]

[d] These values apply only to compounds of uranium that take the chemical form of UF6, UO2F2 and UO2(NO3)2 in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO3, UF4, UCl4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

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AUTHORITY: O.C.G.A. § 31-13-1 ***et seq.***

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Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-17-.09 Licensing and Radiation Safety Requirements for Irradiators

(1) **Purpose and scope.**

(a) This Rule, 391-3-17-.09, contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This Rule also contains radiation safety requirements for operating irradiators. The requirements of this Rule are in addition to other requirements of this Chapter. In particular, the provisions of Rules 391-3-17-.02, .03, and .07 apply to applications and licenses subject to this Rule. Nothing in this Rule relieves the licensee from complying with other applicable Federal, State, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) The Regulations in this Rule apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 500 rads (5 Grays) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Rule.

(c) This Rule does not apply to self-contained dry-source-storage irradiators (those in which both the source and the areas subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

(d) Any sealed source licensed pursuant to this Rule shall have a solubility equal to or less than the solubility of cobalt-60 metal in water.

(2) **Definitions.**

(a) "Annually" means once every 12 calendar months or no later than the last day of the same calendar month of the following year.

(b) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

(c) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials.

(d) "Irradiator operator" means an individual who has successfully completed the training and testing described in (5)(a) of this Rule and is authorized by the terms of the license to operate the irradiator without a supervisor present.

(e) "Large irradiator" means an irradiator where radiation dose rates exceeding 500 rads (5 Grays) per hour exist at one meter from the sealed radioactive sources in air or in water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(f) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(g) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(h) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(i) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

(j) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(k) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(l) "Radiation Safety Officer" means an individual with responsibility for the overall Radiation Safety Program at the facility.

(m) "Sealed source" means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(n) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than ten percent, as designated by the U.S. Geological Survey.

(o) "Solubility of one liquid or solid in another" means the mass of a substance contained in the solution which is in equilibrium with an excess of the substance.

(p) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(3) **Specific Licensing Requirements.**

(a) Application for a specific license.

1. A person, as defined in Rule 391-3-17-.01 may file an application for a specific license authorizing the use of sealed sources in large irradiators in accordance with Rule .02 of this Chapter.

2. A separate license is required for each large irradiator, radiation room, or underwater irradiator.

(b) Specific licenses for large irradiators. The Director will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

1. The applicant shall satisfy the general requirements specified in Rule 391-3-17-.02 and the requirements contained in this Rule.

2. The applicant shall describe its training for irradiator operators that shall include, at a minimum, the following:

(i) A minimum of 40 hours of classroom training;

(ii) A minimum of 160 hours of on-the-job training;

(iii) Safety reviews;

(iv) The means the applicant will use to test each operator's understanding of and ability to comply with the Division's Rules and licensing requirements and the irradiator operating and emergency procedures; and

(v) Minimum training and experience of personnel who may provide training.

3. The applicant shall submit an outline or summary of the written operating and emergency procedures listed in this Rule that describes the radiation safety aspects of the procedures.

4. The application shall describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The applicant shall also describe the training and experience required for the position of Radiation Safety Officer.

5. The application must include a description of the access control system required by (4)(b) of this Rule, the radiation monitors required by (4)(e) of this Rule, the method of detecting leaking sources required by (5)(e) of this Rule including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

6. The applicant shall provide assurance that any radioactive source not used in the irradiation process shall be removed from the irradiator pool and disposed of or returned to the manufacturer.

7. If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Division for approval. The procedures must include the following:

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

(iii) Pertinent experience of the individual who analyzes the samples.

8. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at his facility, the loading or unloading must be done by an organization specifically licensed by the Director, an Agreement State, or the U.S. Nuclear Regulatory Commission to load or unload irradiator sources.

9. The applicant shall perform the following operational tests to ensure proper functioning of all equipment and safety devices before the irradiator is loaded with sources:

(i) Interlock and radiation safety systems;

(ii) Pool integrity and plumbing;

(iii) Source rack mechanical positioning system;

(iv) Source rack movement and position sensing systems;

(v) Source rack electrical control system;

(vi) Uninterruptible electrical power supply for radiation monitoring warning systems;

(vii) Fire protection system;

(viii) Emergency systems for returning a stuck source rack into the pool;

(ix) Systems used for transferring sources to and from transport vehicles; and

(x) Product conveyor system.

10. The applicant shall describe the operational inspection and maintenance program, including the frequency of the checks required by (5)(f) of this Rule.

11. The roof plug opening or removable shielding providing access for the loading and removal of sources shall be large enough to accommodate the largest applicable transportation cask.

(c) The applicant shall not begin construction of a new irradiator facility prior to the issuance of a license by the Director. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of site, site surveys or soil testing, site preparation, site excavation, and other similar tasks. Any activities undertaken prior to the issuance of license with respect to the requirements of this Chapter shall be at the risk of the applicant and have no bearing on the issuance of a license in accordance with this Chapter.

(d) Applications for exemptions.

1. The Director may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this Rule that it determines are authorized by law and will not endanger public health, safety, or property.

2. Any application for a license or for an amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this Rule. The Division will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

(e) Request for written statements.

1. After the filing of the original application, the Division may request further information necessary to enable the Director to determine whether the application should be granted or denied.

2. Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Division's request, submit written statements or other sufficient information to enable the Director to determine whether the license should be modified, suspended, or revoked.

(4) **Design and Performance Requirements for Irradiators.**

(a) Performance criteria for sealed sources.

1. Requirements. Sealed sources installed after January 1, 1994:

(i) Must have a certificate of registration issued under 10 CFR 32.210;

(ii) Must be doubly incapsulated;

(iii) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(iv) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(v) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the following tests:

2. Temperature. The test source must be held at 40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

3. Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.

4. Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from height of 1 meter onto the test source.

5. Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

6. Puncture. A 50-gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

7. Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

(b) Access control.

1. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they are reliable and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

2. Each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause

the sources to return to their full shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained in how to respond to the alarm and prepared to promptly render or summon assistance.

3. A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in (4)(b)2. of this Rule. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

4. Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

5. Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

6. Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed with a present time after activation of the control.

7. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "Very High radiation area," but the sign may be removed, covered, or otherwise made inoperable when the sources are fully shielded.

8. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if the shield is not placed properly or by an operating procedure requiring inspection including documentation of inspection, of shielding before operation.

9. Panoramic irradiators shall not operate if the requirements in (4)(b) of this Rule are not met.

10. Underwater irradiators must have a personnel access barrier around the pool, which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

(c) Shielding.

1. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 millirems (0.02 millisievert) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 millirems (0.02 millisievert) per hour must be locked, roped off, or posted and not entered without written approval or in the physical presence of the Radiation Safety Officer.

2. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 2 millirems (0.02 millisievert) per hour when the sources are in the fully shielded position.

3. The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 2 millirems (0.02 millisievert) per hour and at 5 centimeters from the shield must not exceed 20 millirems (0.02 millisievert) per hour.

(d) Fire protection.

1. The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

2. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

(e) Radiation monitors.

1. Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

2. For pool irradiators, the licensee shall provide a means to detect radioactive contamination in pool water each day the irradiator operates. The means may be either an on-line radiation monitor on the pool water purification system or an analysis of pool water. If the licensee uses an on-line radiation monitor, the detection of above normal background radiation levels must activate the alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. If a false alarm due to background radiation occurs, the alarm set-point must be increased. Activation of the alarm must automatically cause the water purification system to shut off. However, the licensee may reset the alarm set-point to a higher level if necessary to operate the pool purification system to clean up contamination in the pool as specifically provided in written emergency procedures.

3. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

(f) Control of source movement.

1. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

2. The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

3. The control console of a panoramic irradiator must have an emergency control that promptly returns the sources to the shielded position.

4. Each control for a panoramic irradiator must be clearly marked as to its function.

(g) Irradiator pools.

1. For licenses initially issued after January 1, 1994, irradiator pools must either:

(i) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(ii) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

2. For licenses initially issued after January 1, 1994, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

3. A means must be provided to replenish water losses from the pool.

4. A visible indicator must be provided in a clearly visible location to indicate the pool water level is below the normal low water level or above the normal high water level.

5. Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 micromhos per centimeter or less and with a clarity so that the sources can be seen clearly.

6. A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

7. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 2 millirems (0.02 millisievert) per hour.

(h) Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

(i) Power failures.

1. If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

2. The lock on the door of the radiation room of a panoramic irradiator shall not be deactivated by a power failure.

3. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

(j) Design requirements.

Irradiators whose construction begins after January 1, 1994, must meet the design requirements of this section.

1. Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of (4)(c) of this Rule. If the irradiator will use more than 5 million Curies (1.85 x 1017 becquerels) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

2. Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure that it is adequate to support the weight of the facility shield walls.

3. Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed

sources, that all outlets or pipes meet the requirements of (4)(c)2. of this Rule, and that metal components are metallurgically compatible with other components in the pool.

4. Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of (4)(g) of this Rule. The system must be designed so that water leading from the system does not drain to unrestricted areas without being monitored.

5. Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by (4)(e)1. of this Rule. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under (5)(e)2. of this Rule, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

6. Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

7. Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of (4)(b) of this Rule.

8. Fire protection. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

9. Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

10. Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

11. Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

12. Product carriers. For irradiators utilizing product carriers, the basic design of the carrier shall prevent the carrier from opening or coming into contact with the source rack or protective barrier. The basic design shall be submitted to the Division for approval.

13. Floor penetrations. All floor penetrations, including expansion joints, floor joints, and drains, shall not allow the uncontrolled release of water, which has not been analyzed for its radioactive content, from the radiation room.

14. Lift mechanisms. The lift mechanisms for the source rack and source transport cask must be designed for working and breaking strength to safely lift a source transport cask and sources into and out of the irradiator pool.

15. Ventilation. All radiation rooms in a panoramic irradiator shall be maintained under negative pressure. Any exhaust from radiation rooms shall be through a high-efficiency nuclear air cleaning system. This system shall consist of standard roughing and absolute (HEPA) filters that have been tested in line in accordance with and has met the requirements of ANSI N510.

(k) Construction monitoring and acceptance testing.

The requirements of (4)(k) of this Rule must be met for irradiators whose construction begins after January 1, 1994. Additionally, the requirements for shielding, (4)(k)1., foundations, (4)(k)2., pool integrity, (4)(k)3., and wiring, (4)(k)11. of this Rule must be certified by a registered professional engineer. The requirements must be met prior to loading sources.

1. Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

2. Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

3. Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of (4)(f)2. of this Rule.

4. Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

5. Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by (4)(e)1. of this Rule. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm, if used, to meet (4)(e)2. of this Rule. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by (4)(e)2. of this Rule.

6. Source racks. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in (4)(h) of this Rule are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

7. Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

8. Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

9. Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

10. Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

11. Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(5) **Operation of Irradiators.**

(a) Training.

1. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in the following:

(i) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Division's dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

(ii) The requirements of this Rule and Rule 391-3-17-.07 that are applicable to the irradiator;

(iii) The operation of the irradiator;

(iv) Those operating and emergency procedures listed in (5)(b) of this Rule that the individual is responsible for performing; and

(v) Case histories of accidents or problems involving irradiators.

2. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received, consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

3. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

4. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

(i) Changes in operating and emergency procedures since the last review, if any;

(ii) Changes in Regulations and license conditions since the last review, if any;

(iii) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(iv) Relevant results of inspections of operator safety performance;

(v) Relevant results of the facility's inspection and maintenance checks; and

(vi) A drill to practice an emergency or abnormal event procedure.

5. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that the Regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

6. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the Radiation Safety Officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, and procedures or parts of procedures listed in (5)8. of this Rule that they are expected to perform or comply with, and their proper response to alarms required in this Rule. Tests may be oral.

7. Individual who must be prepared to respond to alarms required by (4)(b)2., (4)(b)10., (4)(d)1., (4)(e)1., and (5)(e)2. of this Rule shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

(b) Operating and emergency procedures.

1. The licensee shall have and follow written operating procedures for the following:

(i) Operation of the irradiator, including entering and leaving the radiation room;

(ii) Use of personnel dosimeters;

(iii) Surveying the shielding of panoramic irradiators;

(iv) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(v) Leak testing of sources;

(vi) Inspection and maintenance checks required by (5)(f) of this Rule;

(vii) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(viii) Inspection of movable shielding required by (4)(b)8. of this Rule, if applicable.

2. The licensee shall have and follow emergency or abnormal event procedures, appropriate to the irradiator type, for the following:

(i) Source stuck in the unshielded position;

(ii) Personnel overexposures;

(iii) A radiation alarm from the product exit portal monitor or pool monitor;

(iv) Detection of leaking sources, pool contamination, or alarm cause by contamination of pool water;

(v) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(vi) A prolonged loss of electrical power;

(vii) A fire alarm or explosion in the radiation room;

(viii) An alarm indicating unauthorized entry into the radiation room, area around the pool, or another alarm area;

(ix) Natural phenomena, including an earthquake, tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(x) The jamming of the automatic conveyor system.

3. The licensee may revise operating and emergency procedures without Division approval only if all of the following conditions are met:

(i) The revisions do not reduce the safety of the facility,

(ii) The revisions are consistent with the outline or summary of procedures submitted with the license application,

(iii) The revisions have been reviewed and approved by the Radiation Safety Officer, and

(iv) The users or operators are instructed and tested on the revised procedures before they are put into use.

(c) Personnel monitoring.

1. Irradiator operators shall wear a personnel monitoring device while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel monitoring device processor must be capable of detecting high energy photons in the normal and accident dose ranges. Each personnel monitoring device must be assigned to and worn only by one individual. Film Badges must be replaced at least monthly and all other personnel monitoring devices must be processed at least quarterly.

2. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are use to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

(d) Radiation surveys.

1. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operations after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rate.

2. If the radiation levels specified in (4)(c) of this Rule are exceeded, the facility must be modified to comply with the requirements of (4)(c) of this Rule.

3. Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20 percent of the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

4. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR Part 20 , Table 2, Column 2 or Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage".

5. Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level of less than 0.5 millirem (0.005 millisievert) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 millirem (0.005 millisievert) per hour.

(e) Detection of leaking sources.

1. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Division, an Agreement State, or the U.S. Nuclear Regulatory Commission. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 0.005 microcurie (200 becquerels) of radioactive material and must be performed by a person approved by the Division, an Agreement State, or the U.S. Nuclear Regulatory Commission to perform the test.

2. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

3. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by the Division, Agreement State, or U.S. Nuclear Regulatory Commission licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by the Division, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B to 20.1001 to 20.2401 of 10 CFR 20.

(f) Inspection and maintenance.

1. The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(i) Operability of each aspect of the access control system required by (4)(b) of this Rule.

(ii) Functioning of the source position indicator required by (4)(f) of this Rule.

(iii) Operability of the radiation monitor for radioactive contamination in pool water required by (5)(e)2. of this Rule using a radiation check source, if applicable.

(iv) Operability of the over-the-pool radiation monitor at underwater irradiators as required by (4)(e)3. of this Rule.

(v) Operability of the product exit monitor required by (4)(e)1. of this Rule.

(vi) Operability of the emergency source return control required by (4)(e)3. of this Rule.

(vii) Leak-tightness of systems through which pool water circulates (visual inspection).

(viii) Operability of the heat and smoke detectors and extinguisher system required by (4)(d) of this Rule (but without turning extinguishers on).

(ix) Operability of the means of pool water replenishment required by (4)(g)3. of this Rule.

(x) Operability of the indicators of high and low pool water levels required by (4)(g)4. of this Rule.

(xi) Operability of the intrusion alarm required by (4)(b)10. of this Rule, if applicable.

(xii) Functioning and wear of the system, mechanism, and cables used to raise and lower sources.

(xiii) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by (4)(h) of this Rule.

(xiv) Amount of water added to the pool to determine if the pool is leaking.

(xv) Electrical wiring on required safety systems for radiation damage.

(xvi) Pool water conductivity measurements and analysis as required by (5)(g)2. of this Rule.

2. Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

(g) Pool water purity.

1. The pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 micromhos per centimeter under normal circumstances. If pool water conductivity rises above 20 micromhos per centimeter, the licensee shall take prompt actions to lower the pool water conductivity, and shall take corrective actions to prevent future recurrences.

2. The licensee shall measure the pool water conductivity frequently enough, but not less than weekly, to assure that the conductivity remains below 20 micromhos per centimeter. Conductivity meters must be calibrated at least annually.

(h) Attendance during operation.

1. Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:

(i) Whenever the irradiator is operated using an automatic product conveyor system; and

(ii) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

2. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in (5)(a)7. of this Rule must be onsite.

3. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in (5)(a)6. and 7. of this Rule. Static irradiations may be performed without a person present at the facility.

4. Irradiator operators shall not be on duty more than 12 hours in any 24-hour period without at least 8 hours uninterrupted rest, unless an emergency exists and prior authorization has been given by the Division.

(i) Entering and leaving the radiation room.

1. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source while entering the radiation room. The survey meter must be of a type that does not saturate and read zero at high radiation dose rates.

2. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(i) Visually inspect the entire radiation room to verify that no one else is in it; and

(ii) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

3. During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by (4)(e)3. of this Rule is operating with backup power.

(j) Irradiation of explosive or flammable materials.

1. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Division. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

2. Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Division. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

(6) **Records.**

(a) Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified:

1. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Director terminates the license for documents not superseded.

2. Records of each individual's training, tests, and safety reviews provided to meet the requirements of (5)(a)1,. 2., 3., 4., 5., and 7. of this Rule for 3 years after the evaluation.

3. Records of the annual evaluations of the safety performance of irradiator operators required by (5)(a)5. of this Rule for 3 years after the evaluation.

4. A copy of the current operating and emergency procedures required by (5)(b) of this Rule until superseded or the Director terminates the license. Records of the Radiation Safety Officer's review and approval of changes in procedures as required by (5)(b)3.iii of this Rule are to be retained for 3 years from the date of the change.

5. Personnel monitoring results required by (5)(c) of this Rule shall be retained until the Director terminates each pertinent license requiring the record. Upon termination of the license, the licensee shall permanently store records on Division Form, "Occupational Radiation Exposure History", or equivalent, or shall make provisions with the Division for transfer to the Division.

6. Records of radiation surveys required by (5)(d) of this Rule for three years from the date of the survey.

7. Records of radiation survey meter calibrations required by (5)(d) of this Rule and pool water conductivity meter calibrations required by (5)(g)2. of this Rule until three years from the date of calibration.

8. Records of the results of leak tests required by (5)(e)1. of this Rule and the results of contamination checks required by (5)(e)2. of this Rule for three years from the date of each test.

9. Records of inspection and maintenance checks required by (5)(f) of this Rule for three years.

10. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

11. Records of the receipt, transfer, and disposal of all licensed sealed sources for three years after the transfer or disposal of the sealed source.

12. Records of the design checks required by (4)(j) of this Rule and the construction control checks as required by (4)(k) of this Rule until the license in terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

13. Records related to decommissioning of the irradiator as required by Rule 391-3-17-.02(8)(g)8.

(b) Reports.

1. In addition to the reporting requirements in other Rules of this Chapter, the licensee shall report the following events if not reported under other Rules of this Chapter:

(i) Source stuck in an unshielded position.

(ii) Any fire or explosion in a radiation room.

(iii) Damage to the source racks.

(iv) Failure of the cable or drive mechanism used to move the source racks.

(v) Inoperability of the access control system.

(vi) Detection of a radiation source by the product exit monitor.

(vii) Detection of radioactive contamination attributable to licensed radioactive material.

(viii) Structural damage to the pool liner or walls.

(ix) Abnormal water loss or leakage from the source storage pool.

(x) Pool water conductivity exceeding 100 micromhos (100 µS) per centimeter.

2. The report must include a telephone report within 24 hours and a written report within 30 days as described in Rule 391-3-17-.03(14)(b).

Cite as Ga. Comp. R. & Regs. R. 391-3-17-.09

AUTHORITY: O.C.G.A. § 31-13-1 **et seq.**

HISTORY: Original Rule entitled "Enforcement" adopted. F. May 2, 1991; eff. May 22, 1991.

Repealed: New Rule entitled "Licensing and Radiation Safety Requirements for Irradiators" adopted. F. Feb. 24,1994; eff. Mar. 16, 1994.

Amended: F. Oct. 4, 1994; eff. Oct. 24, 1994.

Amended: F. Mar. 29, 2002; eff. Apr. 18, 2002.

Amended: F. May 11, 2016; eff. May 31, 2016.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

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Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

Chapter 391-3. ENVIRONMENTAL PROTECTION

Subject 391-3-20. ENHANCED INSPECTION AND MAINTENANCE

391-3-20-.01 Definitions

The following terms as used in these rules shall have the meaning hereinafter respectively ascribed, except that to the extent terms are not defined in these rules, the Act's definitions control; and provided that definitions within any subsequent rule or subdivision thereof, which are expressly made applicable to the rule or subdivision within which they appear, shall apply for purposes of such specific rule or subdivision thereof.

(a) "Act" means O.C.G.A. § 12-9-40 et seq., as amended, "The Georgia Motor Vehicle Emission Inspection and Maintenance Act."

(b) "Calibration" means, in the case of the Georgia Analyzer System (GAS), the process of establishing or verifying that the test values of the GAS emissions bench are accurate by using the applicable calibration gases. In the case of a fuel cap tester, "calibration" means the process of verifying that the measured pressure drop over time is between the upper and lower control limits.

(c) "Certificate" means the license issued by the Director to a person authorizing him or her to perform emission inspections in accordance with the requirements of the Act and this Chapter.

(d) "Certificate of Authorization" means a certificate issued by the Director to each establishment or location designated as an official emission inspection station.

(e) "Certificate of Emissions Inspection" means an official certificate that exhaust emissions, evaporative emissions, emission control equipment, and on-board diagnostic equipment have been inspected and approved in accordance with the Act and this Chapter. Such certificates will be furnished to official emission inspection stations by EPD to be completed and issued by such stations to the owner or operator of a responsible motor vehicle upon inspection and approval certifying that such responsible motor vehicle has been inspected and complies with the inspection and maintenance required by the Act and this Chapter.

(f) "DLC" means the data or diagnostic link connector for a vehicle's on-board diagnostic system.

(g) "Dedicated data transmission line" means a unique communication line identifiable by a transmitted digital identification number which allows the Vehicle Information Database or (VID) to identify the Georgia Analyzer System (GAS) unit communicating with the VID.

(h) "Department" means the Department of Natural Resources.

(i) "Diagnostic Trouble Codes (DTC)" means that for vehicles equipped with on-board diagnostic (OBD) computer systems, a five digit code that is associated with a specific test of the OBD system.

(j) "Director" means the Director of the Environmental Protection Division of the Department of Natural Resources.

(k) "E-Certs" means blank Electronic Certificates of Emission Inspection that are pre-purchased by official emissions inspection stations for the purpose of performing emission inspections.

(l) "Emission Inspection" means all tests and inspections required by the Act and this Chapter, including an on-board diagnostic system check, a fuel cap test, a tampering inspection, and an exhaust emissions test where applicable.

(m) "Emissions Inspector Certification Training Program Manual", means the manual supplied to inspectors during their initial and re-certification classes; the most current version of this manual is available on the Georgia Clean Air Force website at www.cleanairforce.com.

(n) "Emission Recall Compliance Check" means determining whether a recall campaign has been issued by the original equipment manufacturer of a vehicle.

(o) "E-VIN" means the Electronic Vehicle Identification Number embedded in the OBD computer system on 1996 and later model year vehicles.

(p) "EPD" means the Environmental Protection Division of the Georgia Department of Natural Resources.

(q) "Exhaust Emission Test" means the determination of the amount of specified gases in a vehicle's exhaust by use of the 2-speed idle (TSI) test.

(r) "Fleet Vehicle" means a motor vehicle owned or leased by a person engaged in a commercial activity, utility service, or government service; or a motor vehicle offered for sale, rent, or lease at a business which is licensed to sell, rent, or lease motor vehicles.

(s) "Fuel Cap Test" means the determination of the ability of the fuel cap(s) to retain pressure.

(t) "Gas Calibration" means the calibration of the Georgia Analyzer System (GAS) by the use of a manufactured calibration gas.

(u) "Georgia Analyzer System" (GAS) means the test systems approved by EPD for use in performing emission inspections in Georgia in accordance with the Act and this Chapter.

(v) "Georgia Analyzer System Hardware and Software Specifications" (GAS Specs) means the Georgia Analyzer System Hardware and Software Specifications, Phase V, August 31, 2016, which contains the hardware and software requirements for a GAS.

(w) "Georgia's Clean Air Force" (GCAF) means the partnership between EPD and the Management Contractor to implement Georgia's Enhanced Motor Vehicle Emission Inspection and Maintenance Program (I/M Program).

(x) "Grandfathered Vehicle" means a vehicle manufactured outside of the United States and certified to meet foreign emission standards, but which has subsequently been legally imported into the United States and is subject to the provisions of the Act and this Chapter. Such vehicles are approved by EPD to comply with alternative tail pipe emission standards for that Model Year vehicle.

(y) "Gray Market Vehicle" means vehicles which are manufactured for use outside of, and imported into, the United States.

(z) "GVWR" means the gross vehicle weight rating, i.e., the weight of the vehicle and contents when loaded to its maximum capacity, as established by the vehicle manufacturer.

(aa) "Hot Rod" means a vehicle in which the original engine has been replaced with an engine from another manufacturer, or with a different type of engine from the same manufacturer which was never installed in that model vehicle. For the purposes of this definition, a different type of engine will include engines with a different number of cylinders from any engine which was originally installed in that make of vehicle. It will not include engines of the same family, e.g., Chevrolet V8s of 283, 305, 327, 350 and 400 cubic inch displacement, nor will it include engines different from the original, but which were also installed in that make of vehicle, e.g., gasoline for diesel engine

swaps in General Motors or Volkswagen vehicles, or V8 for V6 swaps where both engines were installed in that model vehicle by the manufacturer for retail sale.

(bb) "Idle RPM" means for vehicles equipped with a manual transmission, the manufacturer's recommended engine speed with the transmission in neutral or with the clutch disengaged. For vehicles equipped with an automatic transmission, idle revolutions per minute (RPM) means the manufacturer's recommended engine speed with the transmission in neutral or park.

(cc) "Inspection Term" means the period of time a certificate of emission inspection shall be considered valid. The specific period of an inspection term is established in this Chapter.

(dd) "Inspector" means a person certified by the Director to perform emission inspections in accordance with the requirements of the Act and this Chapter.

(ee) "Kit Car" means a motor vehicle which does not utilize a chassis from a vehicle certified by the manufacturer to meet emission control standards or for which the original manufacturer's identification has been eliminated due to the replacement of the vehicle's body with one of a different make and/or style.

(ff) "Light Duty Truck" means any motor vehicle with a GVWR of 8500 pounds or less which has a vehicle curb weight of 6,000 pounds or less and which has a basic vehicle frontal area of 45 square feet or less, which is:

1. Designed primarily for purposes of transportation of property or is a derivation of such a vehicle, or

2. Designed primarily for transportation of persons and has a capacity of more than 12 persons, or

3. Available with special features enabling off-street or off-highway operation and use.

(gg) "Light Duty Vehicle" means a passenger car or passenger car derivative, capable of seating 12 passengers or less with a GVWR of 8500 pounds or less.

(hh) "Management Contractor" means the person, corporation or entity under contract to design and operate the data management system and to perform other functions for the I/M Program.

(ii) "Malfunction Indicator Light (MIL)" means a light on the dashboard of OBD equipped vehicles that notifies the driver that an emission related fault has been detected and the vehicle should be repaired as soon as possible.

(jj) "Non-conforming Vehicle" means vehicles that were not built to standards set by the EPA.

(kk) "On-Board Diagnostic (OBD) System" means a computer system installed on 1996 or later model year vehicles as required by Section 202(m) of the Clean Air Act (42 U.S.C. 7521) which is designed to identify engine or primary emission control component problems which cause excess emissions.

(ll) "On-Board Diagnostic (OBD) System Check" means the determination of readiness codes and diagnostic trouble codes stored within the memory of the on-board diagnostic system.

(mm) "Primary Emission Control Component" means the catalytic converter, air injection system, exhaust gas recirculation system or other major component, as determined by the Director, which is installed on a vehicle primarily for the purpose of emission control.

(nn) "Public Vehicle" means a motor vehicle that is not a fleet vehicle.

(oo) "Recognized Repair Technician" means any person professionally engaged in vehicle repair, employed by an ongoing business whose purpose is vehicle repair or possessing a nationally recognized certification for vehicle emission related diagnosis and repair.

(pp) "Responsible Motor Vehicle" means any motor vehicle defined as a light duty vehicle or a light duty truck, excluding any motor vehicle exempted from the Act and this Chapter such as vehicles not in a Covered County as defined in 391-3-20-.02.

(qq) "Revolutions per Minute" (RPM) means the number of times the crankshaft of an engine makes a complete 360 degree turn in one minute (60 seconds).

(rr) "State-Certified Emissions Inspection Station" means a facility that has met all the qualifications of this Act and this Chapter and is certified by the Director.

(ss) "Station Owner" means the individual, partnership, firm, corporation, association, municipality, governmental agency, lessee, or other entity having ownership of or control of the daily operation of an inspection station.

(tt) "Tampering Inspection" means the determination of whether the catalytic converter(s) as installed by the original manufacturer has been removed from the vehicle or modified.

(uu) "Time Extension" means any time extension as defined in section "Extensions and Reciprocal Inspections." of these rules and issued by EPD, the Management Contractor or an authorized agent of EPD to the owner of a responsible motor vehicle certifying that such owner and vehicle have met the requirements in the Act and this Chapter for extending the time to comply with the emission inspection requirement.

(vv) "Vehicle" means a motor vehicle.

(ww) "Vehicle Information Database" (VID) means the data collection and management system for Georgia's Enhanced Motor Vehicle Emission Inspection and Maintenance Program (I/M Program) that contains current and historical program data. The VID is comprised of data collection tables, including the table of inspection records. The term "VID" is used to refer to the VID as a whole or to any part, e.g., Enforcement database, Audit database, Emission Inspections database, and Waiver database.

(xx) "Waiver" means the official form issued by EPD, the Management Contractor or an authorized agent of EPD to the owner of a responsible motor vehicle certifying that such owner and vehicle have met the requirements in the Act and this Chapter for obtaining a waiver of the emission inspection requirement.

(yy) "2-speed idle (TSI) test" means an exhaust emission test where the vehicle under test is run at an idle revolutions per minute (RPM) speed and a higher RPM speed as defined in the GAS Specs.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.01

AUTHORITY: O.C.G.A. § 12-9-40***, et seq*****.**

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Amended: F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.01 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

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Amended: F. Oct. 23, 1998; eff. Nov. 12, 1998.

Amended: F. June 18, 1999; eff. July 8, 1999.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 5, 2003; eff. Dec. 25, 2003.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. Dec. 21, 2006; eff. Jan. 10, 2007.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.04 Emission Inspection Procedures

(1) Prior to performing an emission inspection, the inspector shall determine whether the vehicle has leaking fluids, is overheating, or is otherwise unsafe to inspect. The inspector shall not perform an emission inspection on any vehicle which is unsafe to inspect.

(2) Inspectors shall perform a complete emission inspection on any responsible motor vehicle presented for an initial inspection, in accordance with the requirements of the Act and this Chapter and the procedures as prompted by the GAS, including the following:

(a) For OBD equipped vehicles.

1. A tampering inspection.

2. An OBD system check. On occasion, when activated by EPD, the GAS will prompt the inspector at the conclusion of the OBD system check to perform the 2-speed idle test to collect exhaust emission data. The exhaust emission data will not be used to determine Pass/Fail results of the vehicle.

3. A fuel cap test.

(b) For non-OBD equipped vehicles.

1. A tampering inspection.

2. An exhaust emission test. The inspector may perform a 2-speed idle test on vehicles as prompted by the GAS.

3. A fuel cap test.

(c) For grandfathered vehicles.

1. A tampering inspection. The inspector shall perform a tampering inspection only for those vehicles given grandfathered status by EPD that were originally equipped with a catalytic converter by the vehicle manufacturer or that have been subsequently equipped with a catalytic converter.

2. An exhaust emission test. The inspector shall perform a 2-speed idle test on all vehicles that have been given grandfathered status by EPD.

3. A fuel cap test.

(3) The station owner and inspector shall take all reasonable precautions to avoid damage to vehicles during the emission inspection.

(4) EPD may require alternate procedures for certain types or classes of vehicles when it determines that such alternate procedures are necessary to safely and effectively inspect such vehicles.

(5) Emission inspections may be performed on any vehicle when done "at motorist's request," for reasons such as performing a reciprocal inspection for a motorist to meet the emission inspection requirements in his or her state of residence, as allowed by the Georgia Analyzer System software. The inspection procedure to be performed by certified inspectors shall be as prompted by the GAS.

(6) Inspectors shall perform a reinspection of the portions previously failed during an emission inspection on any vehicle presented for an after repairs inspection, in accordance with the requirements of the Act and this Chapter and the procedures as prompted by the GAS.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.04

AUTHORITY: O.C.G.A. § 12-9-40***, et seq*.**

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Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.04 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

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Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Aug. 27, 1998; eff. Sept. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 10, 2002; eff. Dec. 30, 2002.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

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391-3-20-.05 Emission Standards

(1) An inspector shall not perform a tampering inspection, an exhaust emission test, a fuel cap test, or an OBD system check on a vehicle which:

(a) has a missing exhaust system, or

(b) is unsafe to inspect.

(2) The inspector shall not issue a Certificate of Emission Inspection indicating an overall passing result for the emission inspection unless the inspector has inspected the vehicle in accordance with the requirements of the Act and this Chapter and the vehicle has passed the tampering inspection, the OBD system check, the fuel cap test, and the exhaust emissions test where applicable.

(a) The vehicle shall pass the tampering inspection if:

1. the catalytic converter(s) has not been removed or disconnected;

2. no catalytic converter was installed by the original equipment manufacturer as determined from the vehicle emission control label;

3. in the case of a vehicle which has been converted from a single exhaust system to a dual exhaust system and a catalytic converter(s) was part of the original single exhaust system configuration, a catalytic converter has been installed in each pipe of the dual exhaust system;

4. in the case of a hot rod for which either the original vehicle or the replacement engine was equipped with a catalytic converter(s), a catalytic converter(s) has been installed; or

5. a catalytic converter(s) installed by the original equipment manufacturer has been removed and replaced with another catalytic converter(s).

(b) The vehicles shall pass the OBD system check if:

1. the Georgia Analyzer System (GAS) is able to communicate with the vehicle's OBD system;

2. the MIL illuminates with the ignition key in the "on" position and the engine not running, which is known as Key On Engine Off (KOEO);

3. the OBD system does not command the MIL to illuminate with the ignition key in the on position with the engine running;

4. all nonexempt OBD system monitors, as specified in the GAS, are set to "ready";

5. the OBD system does not contain any fault codes which command the MIL to illuminate, as specified by the vehicle manufacturer, indicating problems with the emissions control parameters monitored by the OBD system; and

6. the MIL does not illuminate with the ignition key in the "on" position and the engine running, which is known as Key On Engine Running (KOER).

(c) The vehicle shall pass the fuel cap test if:

1. the vehicle's primary fuel cap and, when equipped, one secondary fuel cap, holds pressure in accordance with the standard established by the GAS; and

2. where a vehicle has two or more fuel caps, each fuel cap is present.

(d) The vehicle shall pass the exhaust emission test if:

1. in the case of a vehicle subject to a 2-speed idle test any simultaneous pair of values for hydrocarbons and carbon monoxide, in each mode, do not exceed the exhaust levels established in the GAS, and the combined value for carbon monoxide and carbon dioxide is equal to or more than the minimum combined value established in the GAS; or

2. in the case of a gray market vehicle, kit car, hot rod, or non-conforming vehicle that has been given grandfathered status by EPD under this Chapter, any simultaneous pair of values for hydrocarbon and carbon monoxide, in each mode of the 2-speed idle test, do not exceed the exhaust levels established in the GAS for 1975 model year vehicles, or for the model year of the vehicle, and the combined value for carbon monoxide and carbon dioxide is equal to or more than the minimum combined value established in the GAS.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.05

AUTHORITY: O.C.G.A. § 12-9-40***, et seq*.**

HISTORY: Original Rule entitled "Emission Standards" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.05 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: ER. 391-3-20-0.38-.05 adopted. F. Dec. 5, 1997; eff. Dec. 3, 1997, the date of adoption.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. June 18, 1999; eff. July 8, 1999.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.09 Inspection Station Requirements

(1) Classes of stations - There shall be two classes of inspection stations: regular inspection stations and fleet inspection stations. Regular inspection stations shall be public inspection stations and may inspect no more than ten (10) vehicles per year which are owned incidental to the operation of the business.

(a) Regular Inspection Stations

1. A regular inspection station is authorized to inspect any vehicle subject to the I/M Program.

(b) Fleet Inspection Stations

1. Vehicle owners who operate a fleet vehicle may apply for a Certificate of Authorization under this Chapter to inspect their own fleet vehicles, but must meet certain additional requirements beyond those established for public regular inspection stations. Fleet inspection stations are only allowed to inspect fleet vehicles that they own or operate. No inspection of public vehicles is allowed by a fleet inspection station.

(2) General Requirements for Inspection Stations

(a) Persons wishing to obtain or renew a Certificate of Authorization to operate one or more inspection stations shall apply to EPD in a format established by EPD. One application must be submitted for each inspection station. Each application shall include all information required by the Director to determine that the proposed inspection station will meet the requirements of the Act and this Chapter and shall identify all persons having any ownership, financial and/or operational interest in the station. Additional information that may be requested includes, but is not limited to:

1. Explicit permission of all persons having any financial or operational interest in the station, as named in the application, authorizing the director to conduct a background check, including criminal history, on the named individuals;

2. Facility purchase or lease agreement(s);

3. Georgia Analyzer System (GAS) purchase or lease agreement(s);

4. Proof of a filed bond or a copy of accepted certificate of liability insurance;

5. Copy of approved business license or application for same showing signature(s) of the business owner(s); and

6. Other documents as deemed necessary by EPD to determine all persons having any ownership, financial and/or operational interest in the inspection station.

(b) A station owner shall obtain all permits and licenses necessary for the establishment of each inspection station. The station shall conform to all applicable federal, state and local code requirements including, but not limited to, planning and building codes, carbon monoxide levels, ventilation, safety, and fire regulations. All permits, licenses, leases, and/or other requirements for the station shall be maintained for the duration of the Certificate of Authorization. An update shall be filed with the Management Contractor, in a format approved by EPD, no later than the next business day for any change in the information in or submitted with the application and/or any change in the permits, licenses and/or other requirements for the station.

(c) Mobile Georgia Analyzer Systems (GAS)

1. EPD may approve a station owner to operate a mobile GAS only at a fleet or car dealer location for the purpose of performing emission inspections only on fleet vehicles subject to the I/M Program that are owned or operated by that fleet or car dealer. A public inspection station owner with an approved mobile test system shall make all invoices submitted to fleet owners and/or car dealers for emission inspections using a mobile test system available to EPD or the Management Contractor.

2. A station owner that has been approved to operate a mobile GAS at a fleet or car dealer location shall comply with all requirements for mobile inspecting as established in these rules. A station owner that has been approved to operate a mobile GAS shall provide the Management Contractor and EPD, if directed to do so by EPD, with advance notice of scheduled emission inspections of fleet or car dealer locations by 2 PM of the previous business day and shall update such notice as the schedule is changed. The station owner may delete locations from the schedule of fleet or car dealer locations after 2 PM of the previous business day, but may not add fleet or car dealer locations to the schedule. EPD may approve an alternate procedure that provides equivalent quality assurance in lieu of a submitted schedule.

3. A public inspection station owner that has received an approval to operate a mobile GAS shall not perform emission inspections on public vehicles at a location other than at the public inspection station location identified on the Certificate of Authorization.

(d) Public inspection station owners shall provide an area adequate to allow four (4) vehicles per inspection lane to wait for an emissions inspection.

(e) A public inspection station owner shall display a sign approved by EPD that indicates that the facility is a State-Certified Emissions Inspection Station and that shows the fee charged for performing the emission inspection. The station owner shall erect the sign in a location visible to the motoring public. All sign locations must meet State and local code requirements. Signs that are illegible, damaged or contain unapproved modifications shall be replaced with an approved sign.

(f) Lanes at each inspection station must be of adequate length, width, and height to accommodate all normal-sized vehicles which are presented for inspection.

(g) A station owner shall provide adequate protection for the GAS to allow it to operate within specifications in all weather conditions. Any component of the GAS, which could affect the emission inspection results, shall not be subjected to temperatures outside the manufacturer's specifications. The station owner shall maintain all GAS in fully operational condition.

(h) A public inspection station owner shall provide to its customers:

1. a public waiting area, which will allow the motorist to observe the emissions inspection of his or her vehicle;

2. a response to inquiries and complaints in person and over the telephone during business hours;

3. EPD public information materials:

(i) The current, quarterly RepairWatch Public Report provided by EPD or the Management Contractor on repair facilities that have a documented history of emission related repairs on vehicles which have failed the emission inspection;

(ii) The program Motorist Rights Poster provided at the time of station certification; and

(iii) The program Q&A brochure.

(iv) The station owner shall maintain such item(s) in legible condition and either posted or made available for motorists' uninhibited viewing.

(i) A station owner shall:

1. be responsible for all emission inspections conducted at the inspection station(s);

2. be responsible for providing adequate oversight to ensure the station and station personnel comply with the requirements of the Act and this Chapter;

3. obtain and maintain in working order a secure static internet connection for each GAS at the station to connect to the VID;

4. transmit all vehicle inspection data and quality assurance data that is collected to the VID;

5. ensure that the GAS is connected to the secure static internet connection at all times, except in the case of a mobile or mobile capable GAS operating offsite at a fleet or car dealer location which shall be connected to the data transmission line within 72 hours of any emission inspection;

(i) Mobile capable GAS shall have the GAS connected at all times to a secure static internet connection while being used as a non-mobile GAS.

6. collect, store and submit to the Management Contractor all Emission Repair Forms for each reinspection performed at the inspection station;

7. obtain and maintain in legible condition any published OBD DLC Location Chart available or copy which is available on the GCAF website- www.cleanairforce.com, at each station;

8. obtain and maintain at all times in legible condition a current copy of the Emissions Inspector Certification Training Program Manual, Version 1.4 or later provided during inspector certification or copy which is available on the GCAF website-www.cleanairforce.com, at each station; and

(j) The station owner shall pay a per-paid-inspection program administration fee. This fee will be collected through the sale of E-Certs or other method determined by the Director. This fee will cover the cost to administer the program, including:

1. the services of the Management Contractor,

2. the cost of EPD administration,

3. the cost to affected county tax offices of monitoring vehicle registrations, and

4. any other costs allowed by the Act.

(k) Liability Insurance

1. Inspection station owners, except fleet inspection station owners, conducting inspections on vehicles as defined in this Chapter shall provide proof of $100,000 bond or liability insurance for the period of the Certificate of Authorization.

2. Inspection station owners shall notify the Management Contractor no later than the next business day upon termination of or any change in insurance coverage.

(l) Hours of Operation

1. Public inspection station owners shall post the inspection station hours of operation, including hours regularly closed for meals if applicable, on the inspection station's State-Certified Emissions Inspection Station sign. Inspection station owners shall provide emissions inspections at all times during the posted hours. Public inspection station owners may provide inspections by appointment only but shall notify the Management Contractor and indicate such on the station's State-Certified Emissions Inspection Station sign.

2. The station owner shall post a "Closed" sign over the station's State-Certified Emissions Inspection Station sign when the inspection station is closed and unstaffed during posted hours.

(m) A public inspection station owner shall display the Certificate of Authorization issued to the inspection station pursuant to this Chapter at said inspection station in a convenient location visible to the public.

(n) Whenever an inspector ceases employment with an inspection station, either through resignation, termination, or by other means, the station owner shall notify the Management Contractor, in a format approved by EPD, within three (3) business days of the inspector ceasing employment.

(o) No station owner, facility owner, station personnel, or facility personnel shall interfere with EPD or the Management Contractor when they are conducting an audit of the inspection station or GAS(s), or when they are conducting an investigation of the emission inspection activities at a station or at any facility claiming or appearing to be an emission inspection station.

(p) During an audit of the inspection station or GAS(s) by EPD or the Management Contractor, or during an investigation of the emission inspection activities at a station, the station owner shall:

1. provide prompt access to the premises, at reasonable times, where inspections are performed and to the GAS(s);

2. provide prompt access to all station related documents and materials necessary to complete the audit or investigation; and

3. provide prompt assistance in operating and calibrating the GAS(s) as necessary to facilitate the audit or investigation, or sign a release of liability that allows EPD or the Management Contractor to operate and calibrate the GAS(s) during the audit or investigation.

(q) The station owner shall maintain a current mailing address, telephone number, email address and other contact information on file with EPD so that EPD may communicate with the owner on all matters regarding the station, including compliance and enforcement issues. The station owner may designate, in the station application or a written update thereto, another person to receive such communication from EPD. In that case, the station owner shall also provide that person's contact information, including email address, will be presumed to have received all communications from EPD through the person he or she has designated, and remains responsible for compliance with the requirements of the Act and this Chapter.

(3) Additional Requirements for Fleet Inspection Stations.

(a) The administrative fee charged to fleet inspection stations shall be at least as much as the fee charged to public inspection stations. This fee may be increased to cover any additional cost of increased monitoring requirements for fleet inspection stations.

(4) Quality Assurance for Fleet Vehicles.

(a) EPD or the Management Contractor may require fleet inspection stations and mobile inspection stations while on-site to re-inspect randomly selected fleet or car dealer vehicles to verify that emissions inspections are being performed properly.

(b) EPD may require fleet inspection stations and mobile inspection stations to install a video camera surveillance system on the GAS to record all emissions inspections.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.09

AUTHORITY: O.C.G.A. § 12-9-40***, et seq.***

HISTORY: Original Rule entitled "Inspection Stations" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: F. May 24, 1994; eff. June 13, 1994.

Amended: Rule re-titled "IM240 Program Inspection Station Requirements." F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule entitled "Inspection Stations Requirements" adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.09 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: ER. 391-3-20-0.36-.09 adopted. F. Oct. 17, 1997; eff. Oct. 15, 1997, the date of adoption.

Amended: ER. 391-3-20-0.38-.09 adopted. F. Dec. 5, 1997; eff. Dec. 3, 1997, the date of adoption.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Aug. 27, 1998; eff. Sept. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 2, 1999; eff. Dec. 22, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.10 Certificates of Authorization

(1) The Director shall issue a Certificate of Authorization to the station owner if the station owner has demonstrated to EPD that the inspection station for which the application has been submitted meets all requirements of the Act and this Chapter.

(2) The Certificate of Authorization shall allow the station owner to operate an inspection station as described in its application.

(3) The Director may suspend or revoke a Certificate of Authorization as authorized by the Act.

(4) Unless suspended, revoked, or the station is closed-out, the Certificate of Authorization shall be valid for two years. For station owners intending to renew their certificate, a station owner must apply for renewal of the Certificate by submitting a complete application at least 30 days prior to the expiration of the existing Certificate.

(5) Upon the sale of an inspection station, or the discontinuation of emission inspections, the station owner named on the Certificate of Authorization shall:

(a) provide not less than five (5) days notice to the Management Contractor prior to the change in ownership or the discontinuation of emissions inspections;

(b) maintain the dedicated data transmission line(s) to the VID and electrical power to the GAS until such time as the Management Contractor performs a close-out audit; and

(c) make arrangements to provide a free reinspection to motorists which are eligible for a free reinspection under this Chapter.

(6) A Certificate of Authorization is only valid for the owner and location for which it is issued. A Certificate of Authorization shall not be assigned, transferred, or used by any other person, business or entity, other than as shown on the Certificate of Authorization. A Certificate of Authorization shall not be assigned, transferred, or used at any location other than the location shown on the Certificate of Authorization. Upon a change in ownership of an inspection station, the new owner(s) must apply for and receive a new Certificate of Authorization prior to operating the station.

(7) The Director may deny issuance or renewal of a Certificate of Authorization for cause including, but not limited to the compliance history of the inspection station, its inspectors, its employees and all persons having any ownership, financial and/or operational interest in the station.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.10

AUTHORITY: O.C.G.A. § 12-9-40***, et seq.***

HISTORY: Original Rule entitled "Inspector Qualifications and Certification" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: Rule retitled "RG240 Program Inspection Station Requirements." F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule entitled "Certificates of Authorization" adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.10 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.11 Inspector Qualifications and Certification

(1) No person shall perform an emission inspection, or any part of an emission inspection, or issue a Certificate of Emission Inspection, unless he or she:

(a) has submitted an Inspector Certification Application to EPD in a format established by EPD. The application shall include all information required by the Director to determine that the applicant meets the requirements of the Act and this Chapter. An update shall be filed with the Management Contractor, in a format approved by EPD, no later than the next business day for any change in the information in or submitted with the application.

(b) has obtained the age of 18 prior to attending the inspector training class;

(c) has completed the appropriate EPD-approved training program for the type of inspection he or she will be performing;

(d) has obtained training on the proper operation of inspection equipment from the manufacturer of the GAS that will be used to perform the emission inspections;

(e) has passed a written and practical test of proficiency, and,

(f) holds a valid Certificate as a certified emission inspector issued by the Director.

(2) The EPD-approved training program will include information on:

(a) air pollution, its causes and effects;

(b) the purpose and functions of the I/M Program;

(c) inspection regulations and procedures, including technical details and the rationale for their design;

(d) emission control devices, their functions, configuration, identification and inspection;

(e) Georgia Analyzer System (GAS) operation, calibration and maintenance;

(f) quality control procedures and their purpose;

(g) public relations; and

(h) safety and health issues related to inspections.

(3) Inspectors must demonstrate knowledge and proficiency in proper inspection procedures. Inspectors must pass (with 80% correct answers) a written test on all aspects of the training. Inspectors must also pass a practical test by demonstrating that they have knowledge about conducting all parts of the inspection correctly.

(4) The Director shall issue a Certificate and one Inspector picture ID badge to inspectors who satisfactorily complete the EPD-approved training program and pass the written and hands-on tests. Certificates may be suspended or revoked at any time, after notice and offer of a hearing, for failure to conduct inspections properly or to otherwise comply with the Act or this Chapter.

(5) Unless suspended, revoked or voluntarily surrendered, a Certificate issued by the Director is valid for two years from the date of issuance.

(a) For inspectors intending to renew their Certificate, a complete application for renewal of an inspector's Certificate must be submitted at least 30 calendar days prior to the expiration of the existing Certificate.

(b) The Director shall renew the Certificate upon timely receipt of a renewal application, determination that there is no cause to deny the renewal in accordance with the Act or Chapter 391-3-20 of the Rules, the inspector successfully completing an EPD approved retraining program, and the inspector passing the written test.

(6) No inspector shall perform an emissions inspection unless he or she is wearing his or her EPD-issued Inspector picture ID badge so the picture is clearly visible on his or her front upper body area. Replacement of a lost, missing, damaged or illegible ID badge is the responsibility of the inspector at a cost of twenty-five dollars ($25.00) paid to the Management Contractor.

(7) No inspector shall hold, or attempt to fraudulently obtain two (2) or more valid Certificates.

(8) Whenever an inspector, after applying for and receiving a Certificate, moves from the address listed in his or her application, the inspector shall notify the Management Contractor of his or her change of address no later than the next business day. The address in the application or as updated by the inspector shall serve as the address for any and all notice required by law.

(9) No unauthorized person shall use a certified emission inspector's personal access code to perform any part of an emission inspection. No certified emission inspector shall use the personal access code of another certified emission inspector to perform any part of an emission inspection.

(10) An inspector shall not divulge or authorize the use of his or her personal access code by any other person(s). An inspector shall be held responsible for all inspections performed by any person using his or her personal access code.

(11) Before an inspector may perform emissions inspections at a station, the Management Contractor must allow the inspector access to the test system(s) at the station. Inspectors must notify the Management Contractor at least three (3) business days before they begin employment at a given station, and no later than the next business day when they cease employment at a station.

(12) The Director may deny issuance or renewal of a Certificate for cause, including, but not limited to, the inspector's compliance history.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.11

AUTHORITY: O.C.G.A. § 12-9-40***, et seq.***

HISTORY: Original Rule entitled "Schedules for Emission Tests" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: Rule retitled "Inspector Qualifications and Certification." F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.11 adopted. F. June 4, 1996; eff. May 29, 1996.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 2, 1999; eff. Dec. 22, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.13 Certificate of Emission Inspection

(1) Inspectors shall provide the motorist or owner of a vehicle which has received an emission inspection a Certificate of Emission Inspection. The Certificate shall be in a form approved by EPD and printed by the GAS such that the information on the Certificate is sharp, clear, legible, and suitable for copying. The Certificate shall include:

(a) the Vehicle Identification Number;

(b) the license plate number and state;

(c) the vehicle make and model year;

(d) the inspection date and time;

(e) the inspection type (initial, after-repairs reinspection);

(f) the inspection fee;

(g) vehicle odometer reading;

(h) fuel type;

(i) the inspection results for the on-board diagnostic check or the exhaust emission test with engine RPM, fuel cap test, and tampering inspection;

(j) the applicable standards;

(k) the pass or fail status for each test, and for the complete emission inspection;

(l) the vehicle engine size and number of cylinders;

(m) the inspection station's name, physical address, public access telephone number, and Certificate of Authorization number;

(n) Certificate of Emission Inspection number:

(o) the inspector's Certificate number, name, and signature; and

(p) any other information required by EPD.

(2) In the case of a vehicle that fails the emission inspection, in addition to the failing Certificate of Emission Inspection, the inspector shall provide to the vehicle owner:

(a) information on the possible availability of warranty emission system repairs and information provided by EPD or the Management Contractor on repairs which may be useful in repairing failed vehicles. Subject to the availability of this information supplied by the EPA, and revised test system software, EPD may modify or waive this requirement;

(b) an Emissions Repair Form. This form, provided by EPD or the Management Contractor (via the GCAF website at www.cleanairforce.com) or the GAS shall include a checklist of common repairs and spaces for the repair technician to insert: his or her name; the business name, address, and telephone number; and the cost of repairs; and

(c) access to the current, quarterly Repair Watch Public Report provided by EPD or the Management Contractor on repair facilities that have a documented history of emission related repairs on vehicles which have failed the emission inspection.

(3) Station owners shall purchase E-Certs from EPD or the Management Contractor at a price established by this Chapter. The method for fee collection and E-Cert distribution shall be as established by EPD.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.13

AUTHORITY: O.C.G.A. § 12-9-40***, et seq.***

HISTORY: Original Rule entitled "Emission Inspection Sticker" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: Rule retitled "Certificate of Emission Inspection." F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule, same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.13 adopted. F. June 4, 1996; eff. May 29, 1996.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Repealed: New Rule entitled "Certificate of Emissions Inspection" adopted. F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Aug. 27, 1998; eff. Sept. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 2, 1999; eff. Dec. 22, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.15 Repairs and Retests

(1) Owners of vehicles which fail any portion of the emission inspection shall have necessary maintenance and repairs performed. Vehicles which are brought to an inspection station operated by the same owner as the station which performed the original inspection within 30 days of an inspection failure, will be given one reinspection at no additional charge. If any additional reinspections are required to pass the inspection requirement, another inspection fee shall be charged. This fee will cover one reinspection and, if required, one additional reinspection.

(2) Owners of vehicles presented for reinspection shall present a completed Emissions Repair Form. No reinspection, whether paid or unpaid, shall be performed unless the repair information form has been completed and submitted to the inspection station. The repair information form should be completed by the repair facility which repaired the vehicle or by the vehicle owner. The information from the form shall be entered into the VID by the inspector performing the reinspection.

(3) Repairs by the owner or other persons who are not recognized repair technicians are permitted; however, the cost of such repairs, except repairs to primary emission control components, shall not be counted toward a waiver for any 1980 or newer model year vehicle.

(4) Except as noted, reinspections shall consist only of the failed portions of the previous inspection, i.e., exhaust, fuel cap, tampering, OBD, provided the previous inspection results are retrieved electronically by the GAS. For an exhaust emission reinspection, the vehicle must pass the inspection for all required pollutants (HC, CO). For an OBD system reinspection, the vehicle must pass the complete OBD system check.

(5) Vehicles which pass the reinspection will receive a passing Certificate of Emission Inspection.

(6) A station owner that is not the owner of the inspection station which performed the previous initial inspection or paid after-repairs reinspection may perform a free after-repairs reinspection provided the free after-repairs reinspection is performed within 30 days of the previous inspection, and the previous inspection was a paid inspection.

(7) When the inspector is presented with a vehicle for a reinspection, the inspector shall verify that the vehicle being submitted for the reinspection matches the vehicle specified on the previous failing Certificate of Emission Inspection and on the Emissions Repair Form.

(8) No station owner or inspector shall charge the motorist or vehicle owner for an after-repairs reinspection, unless a new E-Cert is used and a new Certificate of Emission Inspection is issued containing a new number. The number of any previously issued Certificate of Emission Inspection shall be used only for a reinspection that is free of charge to the motorist or vehicle owner and only in accordance with the requirements of this Chapter.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.15

AUTHORITY: O.C.G.A. § 12-9-40***, et seq.***

HISTORY: Original Rule entitled "Extensions, Reciprocal Tests" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: Rule retitled "Repairs and Retests." F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule, same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391 -3-20-33-.150. adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 2, 1999; eff. Dec. 22, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.17 Waivers

(1) Vehicles which fail a reinspection despite expenditures over a set dollar amount on appropriate repairs and which have met certain other criteria may be granted a waiver from complying with the inspection requirements for that registration period. Expenditures must be reasonable costs as determined by the Director.

(2) In order to obtain a waiver the following criteria must have been met:

(a) Repair Costs:

1. A yearly expenditure, as required by O.C.G.A. 12-9-48(d)(2), must have been made on qualifying repairs after the vehicle fails the initial inspection. The amount will be adjusted each year to reflect the change in the Consumer Price Index after 1989, which was $450. At the start of each inspection term, EPD will determine the new effective amount in accordance with these requirements and will make that information available at the GCAF website, www.cleanairforce.com. For vehicles which otherwise qualify for waivers based on a prior calendar inspection term, the waiver limit shall be that prior year's level of qualifying repairs.

2. No cost for labor performed by a vehicle owner in the repair of his or her own vehicle shall be applied toward the repair waiver amount, except that a fleet owner may apply the actual cost of labor and parts, excluding any and all overhead costs, toward the waiver amount.

(b) Receipts for these expenditures shall be submitted by the vehicle owner. Vehicle owners shall present the vehicle for which the waiver is requested to an authorized waiver inspection facility for verification of waiver eligibility. This verification shall include an inspection of the vehicle to confirm that reported repairs have been performed and to assess possible reasons for the vehicle's failure to meet the emission inspection requirements.

(c) Receipts for parts and labor expenditures being considered for a repair waiver shall be submitted from a licensed business that performs emissions repairs to qualify. Repair forms shall adequately describe the vehicle by indicating, at a minimum, the VIN of the vehicle and shall also indicate date of service.

1. Vehicles must have qualifying repair receipts that are dated not more than 30 days prior to the initial failing inspection for the current registration cycle;

2. Repair receipts shall only be used to obtain a single waiver.

(d) Qualifying repairs do not include:

1. repair or replacement of tampered emissions control equipment;

2. repairs performed by persons other than a recognized repair technician, except for repairs to primary emissions control components;

3. repairs that are unrelated to emissions performance or are inappropriate for the type of test failure.

(e) Motorists must utilize emission performance warranty coverage. If the vehicle is within the age and mileage limitations of the federal Clean Air Act warranty provisions contained in Section 207(b), the owner must present a written denial of warranty coverage from the manufacturer or authorized dealer.

(f) Repairs shall address the OBD system failure or have produced a reduction in tailpipe emission of pollutants which failed during the previous initial inspection. Reinspection exhaust emission levels for pollutants which originally passed shall not exceed the relevant standards.

(g) Waivers shall be issued by EPD, the Management Contractor or an authorized agent of EPD. Before issuing a waiver, the issuer shall verify that receipts for qualifying repairs equaling or exceeding the established waiver amount have been submitted, verify the repairs have been made by presenting the vehicle for a visual inspection and that the vehicle is otherwise qualified to receive a waiver.

(3) Waivers are valid for no more than twelve (12) months and shall be used for no more than one registration.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.17

AUTHORITY: O.C.G.A. § 12-9-40***, et seq.***

HISTORY: Original Rule entitled "Sale of Vehicles" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: Rule retitled "Waivers". F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: Rule reserved. F. Apr. 28, 1995; eff. May 18, 1995.

Amended: New Rule entitled "Waivers" adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.17 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: F. Dec. 5, 1997; eff. Dec. 25, 1997.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Oct. 23, 1998; eff. Nov. 12, 1998.

Amended: F. Dec. 2, 1999; eff. Dec. 22, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 10, 2002; eff. Dec. 30, 2002.

Amended: F. Dec. 5, 2003; eff. Dec. 25, 2003.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. Dec. 21, 2005; eff. Jan. 10, 2006.

Amended: F. Dec. 21, 2006; eff. Jan. 10, 2007.

Amended: F. Dec. 7, 2007; eff. Dec. 27, 2007.

Amended: F. Dec. 8, 2008; eff. Dec. 28, 2008.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

391-3-20-.22 Enforcement

(1) The administration and enforcement of this Chapter shall be as prescribed in the Act and in compliance with the minimum applicable requirements as prescribed by the Georgia Administrative Procedures Act (O.C.G.A. Section 50-13-1, et seq., as amended).

(2) Suspensions and Revocations.

(a) Whenever a Certificate of Authorization has been suspended and that Certificate expires during the suspension period, the inspection station owner may not obtain a Certificate of Authorization until the term of the suspension has expired. Whenever a Certificate of Authorization has been revoked or surrendered as a result of enforcement action, the inspection station owner may not apply for a new Certificate of Authorization for a minimum of two years from the date of the revocation or surrender.

(b) Whenever an inspector's Certificate has been suspended and that Certificate expires during the suspension period, the inspector may not obtain a Certificate until the term of the suspension has expired. Whenever an inspector's Certificate has been revoked or surrendered as a result of enforcement action, the inspector shall surrender his or her Inspector picture ID badge and may not apply for a new Certificate for a minimum of two years from the date of the revocation or surrender.

(3) Any inspection station whose Certificate of Authorization has been revoked or surrendered as a result of enforcement action will not be eligible for listing in the Repair Watch Public Report.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.22

AUTHORITY: O.C.G.A. § 12-9-40***, et seq.***

HISTORY: Original Rule entitled "Inspection Fees" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: F. May 24, 1994; eff. June 13, 1994.

Amended: Rule retitled "Certificates of Authorization; Station Contract." F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule entitled "Enforcement" adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.22 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

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Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

Chapter 391-3. ENVIRONMENTAL PROTECTION

Subject 391-3-24. LEAD-BASED PAINT HAZARD MANAGEMENT

391-3-24-.03 Definitions

(1) "Abatement" means any measures or set of measures designed to permanently eliminate lead-based paint or lead-based paint hazards. Abatement includes, but is not limited to:

(a) The removal of lead-based paint and lead contaminated dust, the permanent enclosure or encapsulation of lead-based paint, the replacement of lead-painted surfaces or fixtures, and the removal or permanent covering of soil, when lead-based paint hazards are present in such paint, dust or soil; and

(b) All preparation, clean-up, disposal, and post-abatement clearance testing activities associated with such measures; and

(c) Specifically, abatement in target housing and child-occupied facilities includes, but is not limited to:

1. Projects for which there are written contracts or other documentation, which provides that an individual or firm certified in accordance with Rule 391-3-24-.05 will be conducting activities in or to a residential dwelling or child-occupied facility that:

(i) Shall result in the permanent elimination of lead-based paint, or lead-based paint hazards; or

(ii) Are designed to permanently eliminate lead-based paint or lead-based paint hazards and are described in paragraphs (a) and (b) of this definition.

2. Projects involving and/or resulting in the permanent elimination of a lead-based paint hazard, or intact lead-based paint equal to or greater than 1.0 milligram(s) per square centimeter (mg/cm2) or equal to or greater than 0.5 percent (0.5%) by weight, conducted by firms or persons certified in accordance with 391-3-24-.05, unless such projects are covered by subsection (d) of this definition;

3. Projects involving and/or resulting in the permanent elimination of a lead-based paint hazard, or intact lead-based paint equal to or greater than 1.0 milligram(s) per square centimeter (mg/cm2) or equal to or greater than 0.5 percent (0.5%) by weight, conducted by firms or persons who, through their company name or promotional literature, or otherwise represent, advertise, or hold themselves to be in the business of performing lead-based paint activities as defined by these Rules, unless such projects are covered by subsection (d) of this definition; or

4. Projects involving and/or resulting in the permanent elimination of lead-based paint hazards or lead-based paint, that are conducted in response to State or local abatement orders.

(d) Abatement does not include renovation, remodeling, landscaping or other activities, when such activities are not designed to permanently eliminate lead-based paint hazards, but instead are designed to repair, restore, or remodel a given structure or dwelling, even though these activities may incidentally result in a reduction or elimination of lead-based paint hazards. Furthermore, abatement does not include interim controls, operations and maintenance activities, or other measures and activities designed to temporarily, but not permanently, reduce lead-based paint hazards.

(2) "Accessible surface" means an interior or exterior surface painted with lead-based paint that is accessible for a child, six (6) years of age or younger, to mouth or chew.

(3) "Accredited training program" means a training program that has been accredited by the Division pursuant to section 391-3-24-.04 to provide training for persons engaged in renovation or lead-based paint activities.

(4) "Adequate quality control" means a plan or design to ensure the authenticity, integrity, and accuracy of samples, including dust, soil, and paint chip or paint film samples. Adequate quality control also includes provisions for representative sampling.

(5) "Agent-in-Charge" means the most responsible person at the location or activity being inspected with the direct responsibility for the property or the activity taking place, e.g., lead supervisor.

(6) "Arithmetic Mean" means the number obtained by dividing the sum of a set of quantities or concentrations (such as wipe sample concentrations) by the number of quantities or concentrations in the set.

(7) "Certificate of mailing" means proof of mailing and proof of delivery.

(8) "Certified Dust Sampling Technician" means an individual who has been trained by an accredited training program, passed the course test, and certified by the Division to conduct dust sampling following renovation activities to meet clearance standards in Rule 391-3-24-.07.

(9) "Certified Lead Firm" means a company, partnership, corporation, sole proprietorship, association, or other business entity that performs lead-based paint activities, to which the Division has issued a certificate of approval pursuant to section 391-3-24-.05.

(10) "Certified Lead Inspector" means an individual who has been trained by an accredited training program and certified by the Division to conduct inspections. A lead inspector also samples for the presence of lead in paint, dust, and soil for the purposes of abatement clearance testing.

(11) "Certified Lead Project Designer" means an individual who has been trained by an accredited training program, passed the course test, and certified by the Division to prepare abatement project designs, occupancy protection plans, and abatement reports.

(12) "Certified Lead Risk Assessor" means an individual who has been trained by an accredited training program and certified by the Division to conduct risk assessments. A lead risk assessor also samples for the presence of lead in paint, dust, and soil for the purposes of abatement clearance testing.

(13) "Certified Lead Supervisor" means an individual who has been trained by an accredited training program and certified by the Division to supervise and conduct abatements in target housing and child-occupied facilities and to prepare occupant protection plans and abatement reports.

(14) "Certified Lead Worker" means an individual who has been trained by an accredited training program, passed the course test, and certified by the Division to perform abatement activities.

(15) "Certified Renovation Firm" means a company, partnership, corporation, sole proprietorship, individual doing business, association, or other business entity; a Federal, State, Tribal, or local government agency; or a nonprofit organization that performs renovation activities to which the Division has issued a certificate of approval pursuant to Section 391-3-24-.09.

(16) "Certified Renovator" means an individual who either performs or directs workers who perform renovations. A certified renovator is a renovator who has successfully completed a renovator course by an accredited training program, passed the course test, and been certified by the Division to perform renovation activities.

(17) "Chewable surface" means an interior or exterior surface painted with lead-based paint that a child six (6) years of age or younger can mouth or chew. A chewable surface is the same as an "accessible surface" as defined in 42

U.S.C. 4851b(2). Hard metal substrates and other materials that cannot be dented by the bite of a young child are not considered chewable.

(18) "Child-occupied facility" means a building, or portion of a building constructed prior to 1978, visited by the same child, six years of age or under, on at least two different days within the same week (Sunday through Saturday period), provided each day's visit lasts at least three hours and the combined weekly visit lasts at least six hours. Child-occupied facilities include, but are not limited to, day-care centers, pre-schools and kindergarten classrooms.

(19) "Cleaning verification card" means a card developed and distributed, or otherwise approved, by EPA for the purpose of determining, through comparison of wet and dry disposable cleaning cloths with the card, whether post-renovation cleaning has been properly completed.

(20) "Clearance levels" means a value that indicates the amount of lead on a surface following completion of an abatement activity. To achieve clearance when dust sampling is required, values below these levels must be achieved.

(21) "Commissioner" means the Commissioner of the Board of Natural Resources, Department of Natural Resources.

(22) "Common area" means a portion of a building that is generally accessible to all occupants. Such an area may include, but is not limited to, hallways, stairways, laundry and recreational rooms, playgrounds, community centers, garages and boundary fences.

(23) "Completion date" means the date on which all activities on a permitted lead-based paint abatement project requiring the use of certified persons are complete, including, but not limited to, the complete disassembly of all removal area barriers, final clearance testing and disposal of all lead-based paint waste.

(24) "Component or building component" means specific design or structural elements or fixtures of a building, residential dwelling, or child-occupied facility that are distinguished from each other by form, function, and location. These include, but are not limited to, interior components such as: ceilings, crown molding, walls, chair rails, doors, door trim, floors, fireplaces, radiators and other heating units, shelves, shelf supports, stair treads, stair risers, stair stringers, newel posts, railing caps, balustrades, windows and trim, including sashes, window heads, jambs, sills, stools and troughs, built-in cabinets, columns, beams, bathroom vanities, counter tops, and air conditioners; and exterior components such as: painted roofing, chimneys, flashing, gutters and downspouts, ceilings, soffits, fascias, rake boards, corner boards, bulkheads, doors and door trim, fences, floors, joists, lattice work, railings and railing caps, siding, handrails, stair risers and treads, stair stringers, columns, balustrades, window sills, casings, sashes, wells and troughs, and air conditioners.

(25) "Concentration" means the relative content of a specific substance contained within a larger mass, such as the amount of lead (micrograms per gram or parts per million by weight) in a sample of dust or soil.

(26) "Containment" means a process to protect the public, occupants, workers and the environment by controlling exposures to the lead-contaminated dust and debris created during an abatement.

(27) "Course agenda" means an outline of the key topics to be covered during a training course, including the time allotted to teach each topic.

(28) "Course test" means an evaluation of the overall effectiveness of the training, which shall test the trainees' knowledge and retention of the topic covered during the course.

(29) "Course test blueprint" means written documentation identifying the proportion of course test questions devoted to each major topic in the course curriculum.

(30) "Deteriorated paint" means any interior or exterior paint or other coating that is peeling, chipping, chalking or cracking or any paint or coating located on an interior or exterior surface or fixture that is otherwise damaged or separating from the substrate.

(31) "Director" means the Director of the Environmental Protection Division of the Department of Natural Resources or his designees.

(32) "Discipline" means one of the specific types or categories of lead-based paint activities identified in these Rules for which persons may receive training from accredited training programs and become certified by the Division. For example, "Lead worker" is a discipline.

(33) "Distinct painting history" means the application history, as indicated by its visual appearance or a record of application, over time, of paint or other surface coatings to a component or room.

(34) "Disturb" means to break up, burn, crush, cut into, dissolve, sand, scrape, abrade, remove, demolish, or otherwise manipulate a painted surface in a manner that generates dust, paint chips, or debris.

(35) "Division" means the Environmental Protection Division of the Department of Natural Resources and shall where applicable include any contractors selected by the Division to carry out any provisions of these Rules.

(36) "Documented methodologies" are current methods or protocols, e.g., ASTM E1728-03, used to sample for the presence of lead in paint, dust, and soil found in the following:

(a) The U.S. Department of Housing and Urban Development (HUD);

(b) The Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing;

(c) The Environmental Protection Agency (EPA) Guidance on Residential Lead-Based Paint, Lead-Contaminated Dust, and Lead-Contaminated Soil and Residential Sampling for Lead: Protocols for Dust and Soil Sampling (EPA Report Number 7474-R-95- 001); and

(d) Regulations, guidance methods or protocols issued by States and Indian Tribes that have been authorized by the EPA; and other equivalent methods and guidelines.

(37) "Dripline" means the area within 3 feet surrounding the perimeter of a building.

(38) "Dry disposable cleaning cloth" means a commercially available dry, electrostatically charged, white disposable cloth designed to be used for cleaning hard surfaces such as uncarpeted floors or counter tops.

(39) "Dust-lead hazard" means surface dust in a residential dwelling or child-occupied facility that contains a mass-per-area concentration of lead equal to or exceeding 10 micrograms per square foot (µg/ft2), on floors or equal to or exceeding 100 micrograms per square foot (µg/ft2), on interior window sills based on wipe samples.

(40) "Elevated blood lead level (EBL)" means an excessive absorption of lead that is a confirmed concentration of lead in whole blood of 20 µg/dl (micrograms of lead per deciliter of whole blood) for a single venous test or of 15-19 µg/dl in two consecutive venous tests taken 3 to 4 months apart.

(41) "Emergency lead-based paint abatement project" means a lead-based paint abatement project that has been determined by a lead risk assessor and the Division to be an imminent lead-based paint hazard to building occupants in a child-occupied facility.

(42) "Emergency renovation project" means a renovation activity that was not planned but resulted from a sudden, unexpected event (such as non-routine failures of equipment) that, if not immediately attended to presents a safety or public health hazard, or threatens equipment and/or property with significant damage.

(43) "Encapsulant" means a substance that forms a barrier between lead-based paint and the environment using a liquid-applied coating (with or without reinforcement materials) or an adhesively bonded covering material.

(44) "Encapsulation" means the application of an encapsulant.

(45) "Enclosure" means the use of rigid, durable construction materials that are mechanically fastened to the substrate in order to act as a barrier between lead-based paint and the environment.

(46) "Floor" means the interior or exterior installed surface on which one stands, walks, crawls or plays. For exterior entrances, the term does not include sidewalks or uncovered porches (e.g. a porch with no roof).

(47) "Friction Surface" means an interior or exterior surface that is subject to abrasion or friction, including, but not limited to, certain windows, floors and stair surfaces.

(48) "Guest Instructor" means a person designated by the training manager or principal instructor to provide instruction specific to the lecture, hands-on activities or work practice components of a course.

(49) "Hands-on skills assessment" means an evaluation, which tests the trainees' ability to satisfactorily perform the work practices and procedures identified in 391-3-24-.04 of these Rules.

(50) "Hazardous waste" means any solid waste which has been defined as hazardous waste in regulations promulgated by Board of Natural Resources, Chapter 391-3-11.

(51) "Health investigation" means the investigation of target housing or a child-occupied facility housing a child, six years of age or under, with an elevated blood lead level. The purpose of a health investigation is to identify a cause or causes for the lead poisoning of a child.

(52) "HEPA vacuum" means a vacuum cleaner, which has been designed with a high-efficiency particulate air (HEPA) filter as the last filtration stage. A HEPA filter is a filter that is capable of capturing particles of 0.3 microns with 99.97 percent (99.97%) efficiency. The vacuum cleaner must be designed, so that all the air drawn into the machine is expelled through the HEPA filter with none of the air leaking past it.

(53) "Impact surface" means an interior or exterior surface that is subject to damage by repeated sudden force, such as certain parts of door frames.

(54) "Inspection" means a surface-by-surface investigation conducted by a lead inspector to determine the presence of lead-based paint and the provision of a report explaining the results of the investigation.

(55) "Interim controls" means a set of measures designed to temporarily reduce human exposure or likely exposure to lead-based paint hazards including, but not limited to specialized cleaning, repairs, maintenance, painting, temporary containment, ongoing monitoring of lead-based paint hazards or potential hazards, standard treatments, and the establishment and operation of management and resident education programs.

(56) "Interior window sill" means the portion of the horizontal window ledge that protrudes into the interior of the room.

(57) "Lead-based paint (LBP)" means paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram(s) per square centimeter (mg/cm2), or 0.5 percent (0.5%) by weight or 5000 parts per million (ppm).

(58) "Lead-based paint abatement project" means the abatement of lead-based paint or lead-based paint hazards from one or more residential dwelling units and/or child-occupied facilities located within the same local government jurisdiction and submitted under a common project notification.

(59) "Lead-based paint activities" means, in the case of target housing and child-occupied facilities, inspection, risk assessment, and abatement, as defined in this Rule. Lead-based paint activities do not include renovation, as defined in this Rule.

(60) "Lead-based paint hazard" means any condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, or lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces,

or impact surfaces that would result in adverse human health effects as identified pursuant to Toxic Substance Control Act (TSCA) section 403.

(61) "Lead-contaminated dust" means surface dust in residential dwellings or in child-occupied facilities that contain an area or mass concentration of lead at or in excess of levels identified pursuant to Rule 391-3-24-.07.

(62) "Lead-contaminated soil" means bare soil on residential real property or on the property of a child-occupied facility that contains lead at or in excess of levels identified pursuant to Rule 391-3-24-.03(85).

(63) "Lead-hazard screen" is a limited risk assessment activity that involves limited paint and dust sampling as described in 391-3-24-.06(3) of these Rules.

(64) "Living Area" means any area of a residential dwelling used by one or more children age six (6) and under, including, but not limited to, living rooms, kitchen areas, dens, play rooms, and children's bedrooms.

(65) "Loading" means the quantity of a specific substance present per unit of surface area, such as the amount of lead in micrograms contained in the dust collected from a certain surface area divided by the surface area in square feet or square meters.

(66) "Mid-yard" means an area of a residential yard approximately midway between the dripline of a residential building and the nearest property boundary or between the driplines of a residential building and another building on the same property.

(67) "Minor repair and maintenance activities" are activities, including minor heating, ventilation or air conditioning work, electrical work, and plumbing, that disrupt 6 square feet or less of painted surface per room for interior activities or 20 square feet or less of painted surface for exterior activities where none of the work practices prohibited or restricted in Rule 391-3-24-.10(3)(c) are used and where the work does not involve window replacement or demolition of painted surface areas. When removing painted components, or portions of painted components, the entire surface area removed is the amount of painted surface disturbed. Jobs, other than emergency renovations, performed in the same room within the same 30 days must be considered the same job for the purpose of determining whether the job is a minor repair and maintenance activity.

(68) "Multi-family dwelling" means a structure that has more than one separate dwelling unit, which is used or occupied, or intended to be used or occupied in whole or in part, as the home or residence of one or more persons.

(69) "Occupant Protection Plan" means a written plan which describes the measure and management procedures that will be taken during abatement to protect building occupants from exposure to lead-based paint hazards. The plan shall be unique to each residential dwelling unit or child-occupied facility. For projects less than five units, the plan shall be prepared by a certified lead supervisor or certified lead project designer. For projects with five or more units, the plan shall be prepared by a lead project designer. The plan shall include the preparer's signature and certification number.

(70) "Paint in poor condition" means more than ten (10) square feet of deteriorated paint on exterior components with large surface areas; or more than two (2) square feet of deteriorated paint on interior components with large surface areas (e.g., walls, ceilings, floors, doors); or more than 10 percent (10%) of the total surface area of the component is deteriorated on interior or exterior components with small surface areas (window sills, baseboards, soffits, trim).

(71) "Paint-lead hazard" means any of the following:

(a) Any lead-based paint on a friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill, or floor) are equal to or greater than the dust-lead hazard levels identified in the definition of dust-lead hazard.

(b) Any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame).

(c) Any chewable lead-based painted surface on which there is evidence of teeth marks.

(d) Any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(72) "Pamphlet" means the EPA pamphlet titled Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools developed under section 406(a) of TSCA for use in complying with section 406(b) of TSCA or any Division pamphlet approved by EPA pursuant to 40 CFR 745.326 that is developed for the same purpose. This includes reproductions of the pamphlet when copied in full and without revision or deletion of material from the pamphlet except for the addition or revision of the Division's sources of information.

(73) "Permanently covered soil" means soil which has been separated from human contact by the placement of a barrier consisting of solid, relatively impermeable materials, such as pavement or concrete. Grass, mulch and other landscaping materials are not considered permanent covering.

(74) "Person" means the State of Georgia or any agency or instrumentality thereof, or any political subdivision, municipality, county, public or private corporation, authority, partnership, individual or association; any interstate body; or department, agency, or instrumentality of the Federal Government.

(75) "Play Area" means an area of frequent soil contact by children six (6) years of age or less as indicated by, but not limited to, such factors including the following: the presence of play equipment (e.g., sandboxes, swing sets, and sliding boards), toys, or other children's possessions, observations of play patterns, or information provided by parents, residents, care givers, or property owners.

(76) "Principal instructor" means the person who has the primary responsibility for organizing and teaching a particular course.

(77) "Recognized laboratory" means an environmental laboratory recognized by EPA pursuant to TSCA 405(b) as being capable of performing an analysis for lead compounds in paint, soil and dust.

(78) "Recognized test kit" means a commercially available kit recognized by EPA under 40 Code of Federal Regulations 745.88 as being capable of allowing a user to determine the presence of lead at levels equal to or in excess of 1.0 milligrams per square centimeter (mg/cm2), or more than 0.5 percent (0.5%) lead by weight, in a paint chip, paint powder, or painted surface.

(79) "Reduction" means measures designed to reduce or eliminate human exposure to lead-based paint hazards through methods including interim controls and abatement.

(80) "Renovation" means the modification of any existing structure, or portion thereof, that results in the disturbance of painted surfaces, unless that activity is performed as part of an abatement as defined by this Rule. The term renovation includes (but is not limited to): the removal, modification or repair of painted surfaces or painted components (e.g., modification of painted doors, surface restoration, window repair, surface preparation activity (such as sanding, scraping, or other such activities that may generate paint dust)); the removal of building components (e.g., walls, ceilings, plumbing, windows); weatherization projects (e.g., cutting holes in painted surfaces to install blown-in insulation or to gain access to attics, planing thresholds to install weather-stripping), and interim controls that disturb painted surfaces. A renovation performed for the purpose of converting a building, or part of a building, into target housing or a child-occupied facility is a renovation. The term renovation does not include minor repair and maintenance activities.

(81) "Renovation activities" mean any activities performed during a renovation including dust sampling following renovation.

(82) "Residential building" means a building containing one or more residential dwellings.

(83) "Residential dwelling" means

(1) a detached single family dwelling unit, including attached structures such as porches and stoops; or

(2) a single family dwelling unit in a structure that contains more than one separate residential dwelling unit, which is used or occupied, or intended to be used or occupied, in whole or in part, as the home or residence of one or more persons.

(84) "Risk assessment" means

(1) an on-site investigation to determine the existence, nature, severity, and location of lead-based paint hazards, and

(2) the provision of a report by the person or the lead firm conducting the risk assessment, explaining the results of the investigation and options for reducing lead-based hazards.

(85) "Room" means a separate part of the inside of a building, such as a bedroom, living room, dining room, kitchen, bathroom, laundry room, or utility room. To be considered a separate room, the room must be separated from adjoining rooms by built-in walls or archways that extend at least six (6) inches from an intersecting wall. Half walls or bookcases count as room separators if built-in. Moveable or collapsible partitions or partitions consisting solely of shelves or cabinets are not considered built-in walls. A screened in porch that is used as a living area is a room.

(86) "Soil-lead hazard" means bare soil on residential real property or on the property of a child-occupied facility that contains total lead equal to or exceeding 400 parts per million in a play area or average of 1,200 parts per million of bare soil in the rest of the yard based on soil samples.

(87) "Soil sample" means a sample collected in a representative location using ASTM E1727, "Standard Practice for Field Collection of Soil Samples for Lead Determination by Atomic Spectrometry Techniques," or equivalent method.

(88) "Start date" means the date on which activities begin on a notified lead-based paint abatement project requiring the use of certified persons, including the abatement area isolation and preparation or any other activity which may disturb lead-based paint. Start date also means the date on which activities begin on a permitted renovation project.

(89) "Target housing" means any housing constructed prior to 1978, except housing for the elderly or persons with disabilities (unless any child/children age six (6) years or under reside or is expected to reside in such housing for the elderly or persons with disabilities) or any zero (0)-bedroom dwelling.

(90) "Third party certification exam" means a third party examination in a particular discipline which is recognized by the Division and administered by a third party certification exam administrator.

(91) "Third party certification exam administrator" means an administrator which is accepted by the Division to conduct third party certification exams.

(92) "Training course curriculum" means an established set of course topics for instruction in an accredited training program for a particular discipline designed to provide specialized knowledge and skills.

(93) "Training hour" means at least 50 minutes of actual teaching, including, but not limited to, time devoted to lecture, learning activities, small group activities, demonstrations, evaluations, and/or hands-on experience.

(94) "Training manager" means the person responsible for administering an accredited training program and monitoring the performance of principal instructors and guest instructors.

(95) "TSCA" means the Toxic Substances Control Act, 15 U.S.C. 2601.

(96) "Visual inspection for clearance testing" means the visual examination of a residential dwelling or a child-occupied facility following an abatement to determine whether or not the abatement has been successfully completed.

(97) "Visual inspection for risk assessment" means the visual examination of a residential dwelling or a child-occupied facility to determine the existence of deteriorated lead-based paint or other potential sources of lead-based paint hazards.

(98) "Weighted Arithmetic Mean" means an arithmetic mean determined by assigning a multiplier to each quantity or concentration (such as a wipe sample concentration) to be averaged to indicate the relative importance of each quantity's contribution to the average. For example, multiplying each wipe sample concentration by the size of the area wiped, adding the resulting mathematical products, adding the size of the areas wiped, and dividing the sum of the mathematical products by the sum of the areas wiped.

(99) "Wet disposable cleaning cloth" means a commercially available, pre-moistened white disposable cloth designed to be used for cleaning hard surfaces such as uncarpeted floors or counter tops.

(100) "Wet mopping system" means a device with the following characteristics: A long handle, a mop head designed to be used with disposable absorbent cleaning pads, a reservoir for cleaning solution, and a built-in mechanism for distributing or spraying the cleaning solution onto a floor, or a method of equivalent efficacy.

(101) "Window trough" means, for the typical double-hung window, the portion of the exterior windowsill between the interior windowsill (or stool) and the frame of the storm window. If there is no storm window, the window trough is the area that receives both the upper and lower window sashes when they are both lowered. The window trough is sometimes referred to as the window "well".

(102) "Wipe sample" means the sample collected by wiping a representative surface of known area, as determined by ASTM E1728, "Standard Practice for Field Collection of Settled Dust Samples Using Wipe Sampling Methods for Lead Determination by Atomic Spectrometry Techniques," or equivalent method, with an acceptable wipe material as defined in ASTM E1792, "Standard Specification for Wipe Sampling Materials for Lead in Surface Dust."

(103) "Work area" means the area that the certified renovator establishes to contain the dust and debris generated by a renovation.

(104) "Working day" means any day Monday through Friday. Holidays falling on any of these days are included in this definition.

(105) "Zero (0)-bedroom dwelling" means any residential dwelling in which the living area is not separated from the sleeping area. The term includes efficiencies, studio apartments, dormitory housing, military barracks, and rentals of individual rooms in residential dwellings.

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391-3-24-.06 Standards for Conducting Lead-Based Paint Activities

(1) Scope.

(a) When performing any lead-based paint activities, a certified person must perform that activity in compliance with the requirements specified in this section.

(b) Persons performing lead-based paint activities shall work for a certified lead firm.

(c) No person or firm shall engage in a lead-based paint abatement project prior to notifying the Division and receiving a notice to proceed from the Division.

(d) For each inspection, risk assessment, or lead hazard screen conducted, the lead inspector or lead risk assessor shall submit an inspection report or risk assessment report to the party for which services are rendered, and the Division, if requested. The report shall be submitted within thirty (30) days of the activity.

(2) Inspection.

(a) An inspection shall be conducted only by a person certified by the Division as a lead inspector and/or a combined inspector/risk assessor. The inspection must be conducted according to the procedures in this section.

(b) When conducting an inspection, the following locations shall be selected according to documented methodologies and tested for the presence of lead-based paint:

1. In a residential dwelling and child-occupied facility, each interior component with a distinct painting history and each exterior component with a distinct painting history shall be tested for lead-based paint, except those components that the lead inspector or lead risk assessor determines to have been replaced after 1978, or to not contain lead-based paint; and

2. In a multi-family dwelling or child-occupied facility, each component with a distinct painting history in every common area, except those components that the lead inspector or lead risk assessor determines to have been replaced after 1978, or to not contain lead-based paint.

(c) Paint shall be sampled in the following manner:

1. The analysis of paint to determine the presence of lead shall be conducted using documented methodologies, which incorporate adequate quality control procedures; and/or

2. All collected paint chip samples shall be analyzed according to paragraph (6) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(d) The certified lead inspector or lead risk assessor shall prepare an inspection report, which shall include the following information:

1. Date of each inspection.

2. Address of building.

3. Date of construction.

4. Apartment numbers (if applicable).

5. Name, address, and telephone number of the owner or owners of each residential dwelling or child-occupied facility.

6. Name, signature, and certification number of each certified inspector and/or risk assessor conducting testing.

7. Name, address, and telephone number of the certified lead firm employing each inspector and/or risk assessor, if applicable.

8. Each testing method and device and/or sampling procedure employed for paint analysis, including quality control data and, if used, the serial number of any x-ray fluorescence (XRF) device.

9. Specific locations of each painted component tested for the presence of lead-based paint.

10. The results of the inspection expressed in terms appropriate to the sampling method used.

(3) Lead Hazard Screen.

(a) A lead hazard screen shall be conducted only by a person certified by the Division as lead risk assessor.

(b) If conducted, a lead hazard screen shall be conducted as follows:

1. Background information regarding the physical characteristics of the residential dwelling or child-occupied facility and occupant use patterns that may cause lead-based paint exposure to one or more children age six (6) years and under shall be collected.

2. A visual inspection of the residential dwelling or child-occupied facility shall be conducted to:

(i) Determine if any deteriorated paint is present, and

(ii) Locate at least two dust sampling locations.

3. If deteriorated paint is present, each surface with deteriorated paint, which is determined, using documented methodologies, to be in poor condition and to have a distinct painting history, shall be tested for the presence of lead.

4. In residential dwellings, at least two dust samples shall be collected, one from a floor and the other from a window, in rooms, hallways or stairwells where one or more children, age six (6) and under, are most likely to come in contact with dust.

5. In multi-family dwellings and child-occupied facilities, in addition to the floor and window samples required in paragraph (3)(b)4. of this section, the lead risk assessor shall collect dust samples from common areas where one or more children, age six (6) and under, are most likely to come into contact with dust.

(c) Dust samples shall be collected and analyzed in the following manner:

1. All dust samples shall be taken using documented methodologies that incorporate adequate quality control procedures.

2. All collected dust samples shall be analyzed according to paragraph (6) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(d) Paint shall be sampled in the following manner:

1. The analysis of paint to determine the presence of lead shall be conducted using documented methodologies which incorporate adequate quality control procedures; and/or

2. All collected paint chip samples shall be analyzed according to paragraph (6) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(e) The lead risk assessor shall prepare a lead hazard screen report, which shall include, but not be limited to, the following information.

1. The information required in a risk assessment report as specified in paragraph (4) of this section, including any background information collected pursuant to paragraph (b)1 of this section shall be included in the risk assessment report; and

2. Recommendations, if warranted, for a follow-up risk assessment and, as appropriate, any further actions.

(4) Risk Assessment.

(a) A risk assessment shall be conducted only by a person certified by the Division as a lead risk assessor and, if conducted, must be conducted according to the procedures in this section:

(b) A visual inspection for risk assessment of the residential dwelling or child-occupied facility shall be undertaken to locate the existence of deteriorated paint, assess the extent and causes of the deterioration, and other potential sources of lead-based paint hazards.

(c) Background information regarding the physical characteristics of the residential dwelling or child-occupied facility and occupant use patterns that may cause a lead-based paint exposure to one or more children age six (6) years and under shall be collected.

(d) The following surfaces, which are determined, using documented methodologies, to have a distinct painting history, shall be tested for the presence of lead.

1. Each friction surface or impact surface with visibly deteriorated paint; and

2. All other surfaces with visibly deteriorated paint.

(e) In residential dwellings, dust samples (single-surface samples) from the interior window sill(s) and floor shall be collected in all living areas where one or more children age six (6) and under are most likely to come into contact with dust.

(f) For multi-family dwellings and child-occupied facilities, the samples required in paragraph (4)(d) of this section shall be taken. In addition, interior window sill and floor dust samples (single-surface samples) shall be collected in the following locations:

1. Common areas adjacent to the sampled residential dwelling or child-occupied facility, and

2. Other common areas in the building where the lead risk assessor determines that one or more children age six (6) years and under, are likely to come into contact with dust.

(g) For child-occupied facilities, window and floor dust samples (single-surface samples) shall be collected in each room, hallway or stairwell utilized by one or more children, age six (6) and under, and in other common areas in the child-occupied facility where the lead risk assessor determines one or more children, age six (6) and under, are likely to come into contact with dust.

(h) Soil samples shall be collected and analyzed for lead concentrations in the following locations:

1. Exterior play areas where bare soil is present.

2. Dripline/ foundation areas where bare soil is present.

3. The rest of the yard (i.e., non-play areas) where bare soil is present.

(i) Any paint, dust or soil samples shall be taken using documented methodologies that incorporate adequate quality control procedures.

(j) Any collected paint chip, dust, or soil samples shall be analyzed according to paragraph (6) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(k) The lead risk assessor shall prepare a risk assessment report which shall include the following information:

1. Date of assessment.

2. Address of each building.

3. Date of construction of buildings.

4. Apartment number (if applicable).

5. Name, address, and telephone number of each owner of each building.

6. Name, signature, and certification of the lead risk assessor conducting the assessment.

7. Name, address, and telephone number of the lead firm employing each lead risk assessor.

8. Name, address, and telephone number of each recognized laboratory conducting analysis of collected samples.

9. Results of the visual inspection.

10. Testing method and sampling procedure for paint analysis employed.

11. Specific locations of each painted component tested for the presence of lead.

12. All data collected from on-site testing, including quality control data and, if used, the serial number of any XRF device.

13. All results of laboratory analysis on collected paint, soil, and dust samples.

14. Any other sampling results.

15. Any background information collected pursuant to paragraph (4)(c) of this section.

16. To the extent that they are used as part of the lead-based paint hazard determination, the results of any previous inspections or analyses for the presence of lead-based paint, or other assessments of lead-based paint-related hazards.

17. A description of the location, type, and severity of identified lead-based paint hazards and any other potential lead hazards.

18. A description of interim controls and/or abatement options for each identified lead-based paint hazard and a suggested prioritization for addressing each hazard. If the use of an encapsulant or enclosure is recommended, the report shall recommend a maintenance and monitoring schedule for the encapsulant or enclosure.

(5) Abatement.

(a) An abatement shall be conducted only by a person certified by the Division and shall be conducted in accordance with the procedures and requirements specified in this section.

(b) A lead supervisor is required for each abatement project and shall be on-site at all times when abatement is being conducted. This would include preparation, cleanup, disposal and testing activities associated with such measures.

(c) All abatement shall be conducted in accordance with the requirements of this section.

(d) Notification for a lead-based paint abatement project in a residential dwelling, child-occupied facility, or multi-family dwelling shall be made on forms supplied by the Division and submitted to the Division fifteen (15) calendar days prior to the start date of the lead-based paint abatement project.

(e) Abatement shall not commence until the Division has provided a notice to proceed in accordance with paragraph (11) of this section.

(f) A written occupant protection plan shall be developed for all abatement projects and shall be prepared according to the following procedures:

1. The occupant protection plan shall be unique to each residential dwelling, multi-family dwelling or child-occupied facility and developed prior to the abatement. The occupant protection plan shall describe the measures and management procedures that will be taken during the abatement to protect the building occupants from exposure to any lead-based paint hazards.

2. A certified lead supervisor or certified lead project designer shall prepare the occupant protection plan.

(g) The work practices listed below shall be restricted during an abatement as follows:

1. Open-flame burning or torching of lead-based paint is prohibited;

2. Machine sanding or grinding or abrasive blasting or sandblasting of lead-based paint is prohibited unless used with High Efficiency Particulate Air (HEPA) exhaust control capable of removing particles of 0.3 microns or larger from air at 99.97 percent or greater efficiency;

3. Operating a heat gun on lead-based paint is permitted only at a temperature below 1100 degrees Fahrenheit; and

4. Dry scraping of lead-based paint is permitted only in conjunction with heat guns or around electrical outlets or when treating defective painting spots no more than two (2) square feet in any one room, hallway or stairwell or totaling no more than twenty (20) square feet on exterior surfaces.

(h) If conducted, soil abatement shall be conducted in one of the following ways:

1. If soil is removed, the lead-contaminated soil shall be replaced with soil with a lead concentration less than 400 parts per million or background concentration of lead, whichever is lower; or

2. If soil is not removed, the lead-contaminated soil shall be permanently covered as defined in TSCA § 745.223.

3. If soil is removed, it shall not be used as top soil at another site.

(i) The following post-abatement clearance procedures shall be performed only by a lead inspector or lead risk assessor:

1. Following an abatement, a visual inspection shall be performed to determine if deteriorated painted surfaces and/or visible amounts of dust, debris or residue are still present. If deteriorated painted surfaces or visible amounts of dust, debris or residue are present, these conditions must be eliminated prior to the continuation of the clearance procedures.

2. Following the visual inspection and any post-abatement cleanup required by paragraph (5)(i)1. of this section, clearance sampling for lead-contaminated dust shall be conducted. Clearance sampling may be conducted by employing single-surface sampling techniques.

3. Dust samples for clearance purposes shall be taken using documented methodologies that incorporate adequate quality control procedures. Dust samples for clearance purposes shall be taken a minimum of one (1) hour after completion of final post-abatement cleanup activities.

4. The following post-abatement clearance activities shall be conducted based upon the extent or manner of abatement activities conducted in or to the residential dwelling or child-occupied facility:

(i) After conducting an interior abatement with containment between abated and unabated areas, one (1) dust sample shall be taken from one (1) interior window sill and from one (1) window trough (if available) and one dust sample shall be taken from the floors of each of no less than four (4) rooms, hallways or stairwells within the containment area. In addition, one (1) dust sample shall be taken from the floor outside the containment area. If there are less than four (4) rooms, hallways or stairwells within the containment area, then all rooms, hallways or stairwells shall be sampled.

(ii) After conducting an interior abatement with no containment, two (2) dust samples shall be taken from no less than four (4) rooms, hallways or stairwells in the residential dwelling or child-occupied facility. One (1) dust sample shall be taken from one (1) window (if available) and one (1) dust sample shall be taken from one (1) interior window sill and window trough (if present) and one (1) dust sample shall be taken from the floor of each room, hallway or stairwell selected. If there are less than four (4) rooms, hallways or stairwells within the residential dwelling or child-occupied facility, then all rooms, hallways or stairwells shall be sampled.

(iii) Following an exterior paint abatement, a visible inspection shall be conducted. All horizontal surfaces in the outdoor living area closest to the abated surface shall be found to be cleaned of visible dust and debris. In addition, a visual inspection shall be conducted to determine the presence of paint chips on the dripline or next to the foundation below any exterior surface abated. If paint chips are present, they must be removed from the site and properly disposed of in accordance with applicable standards set forth by the Division, and in compliance with all federal, state and local requirements. Clearance wipe samples must be collected from the exterior floors and concrete involved with the abatement project.

5. The rooms, hallways or stairwells selected for sampling shall be selected according to documented methodologies.

6. The lead inspector or risk assessor shall compare the residual lead dust level (as determined by the laboratory analysis) from each dust sample with applicable clearance levels for lead in dust on floors, concrete, windowsills, and window troughs as found in 391-3-24-.07. If the residual dust levels in a dust sample exceed the clearance levels, all the components represented by the failed sample shall be re-cleaned and retested until clearance levels are met.

(j) In a multi-family dwelling with similarly constructed and maintained residential dwellings, random sampling for the purposes of clearance may be conducted provided:

1. The certified persons who abate or clean the residential dwelling do not know which residential dwellings will be selected for the random sample.

2. A sufficient number of residential dwellings are selected for dust sampling to provide a ninety-five percent (95%) level of confidence that no more than 5 percent (5%) or 50 of the residential dwellings (whichever is smaller) in the randomly sampled population exceed the appropriate clearance levels.

3. The randomly selected residential dwellings shall be sampled and evaluated for clearance according to the procedures found in paragraph (5)(i) of this section.

(k) An abatement project completion notification shall be prepared by a lead supervisor or lead project designer. The notification shall be prepared on forms supplied by the Division and shall include, but not be limited to, the following information:

1. Start and completion dates of abatement.

2. The name and address of each lead firm conducting the abatement and the name of each lead supervisor assigned to the abatement project.

3. The name and title of the lead supervisor or lead project designer who prepared the occupant protection plan pursuant to paragraph (5)(f) of this section.

4. The name, address, signature, and lead firm of each lead risk assessor or lead inspector conducting clearance sampling and the date of clearance testing.

5. The results of clearance testing and all soil analyses (if applicable) and the name of each recognized laboratory that conducted the analyses.

6. A detailed written description of the abatement, including abatement methods used, locations of rooms and/or components where abatement occurred, reason for selecting particular abatement methods for each component, and any monitoring of encapsulants or enclosures.

(l) Abatement project completion notifications shall be submitted to the Division no later than thirty (30) working days after the completion date of lead-based paint abatement project.

(6) Collection and Laboratory Analysis of Samples.

(a) Any paint chip, dust, or soil samples collected pursuant to the work practice standards contained in this section shall be:

1. Collected by persons certified by the Division as a lead inspector or lead risk assessor; and

2. Analyzed by a laboratory recognized by the EPA pursuant to section 405(b) of TSCA as being capable of performing analyses for lead compounds in paint chip, dust, and soil samples.

(7) A paint-lead hazard is present:

(a) On any friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill or floor) are equal to or greater than the dust hazard levels identified in 391-3-24-.07;

(b) On any chewable lead-based paint surface on which there is evidence of teeth marks;

(c) Where there is any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame); and

(d) If there is any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(8) A dust-lead hazard is present in a residential dwelling or child-occupied facility:

(a) On floors and interior window sills when the weighted arithmetic mean lead loading for all single surface of floors and interior window sills are equal to or greater than 10 micrograms per square foot (µg/ft2) for floors and equal to or greater than 100 micrograms per square foot (µg/ft2) for interior window sills respectively;

(b) On floors or interior window sills in an un-sampled residential dwelling in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled residential unit on the property; and

(c) On floors or interior window sills in an unsampled common area in a multi-family dwelling or child-occupied facility, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled common area in the same common area group on the property.

(9) A soil-lead hazard is present:

(a) In a play area when the soil-lead concentration from a composite play area sample of bare soil is equal to or greater than 400 parts per million; or

(b) In the rest of the yard when the arithmetic mean lead concentration from a composite sample (or arithmetic mean of composite samples) of bare soil from the rest of the yard (i.e., non-play areas) for each residential building on a property is equal to or greater than 1,200 parts per million.

(10) Project Fees.

(a) A lead firm or lead supervisor shall submit to the Division a project fee for each lead-based paint abatement project at least fifteen (15) calendar days prior to the start date of each abatement project. Project fees shall be submitted electronically or in the form of a check or money order and made payable to the Environmental Protection Division - Lead Abatement Fees. Project fees shall be based upon the following formula:

1. $50 per residential dwelling unit or child-occupied facility plus 2% (.02) of the total value of lead-based paint abatement work covered by the notification. Notifications submitted less than fifteen (15) calendar days prior to the state date, and with Division approval to commencement of lead-based paint abatement activities, are Emergency Notifications and must include an additional $50 fee.

(11) Lead-Based Paint Abatement Project Notification.

(a) No person shall conduct abatement without a notice to proceed from the Division, except as provided for in paragraph (c)(2) of this section. All abatement activities shall be conducted by certified persons and certified lead firms.

(b) All notifications shall be made on forms provided by the Division. The notification shall include, but not be limited to, the following applicable information:

1. Name, address, contact name, and phone number of the owner and operator of the target housing or child-occupied facility;

2. Name, certification number, address, contact name and phone number of the lead firm;

3. Name, certification number, address, firm, and phone number of the lead inspector and lead risk assessor;

4. Name, certification number, address, firm, and phone number of the lead project designer;

5. Location and street address, including building number or name and floor or room number, city, county, and state of the building where the abatement is taking place;

6. Scheduled start and completion dates of active lead-based paint abatement work including preparation work and cleanup work;

7. Work schedule, including days of the week and hours to be worked;

8. Amount and locations of material to be abated;

9. Method(s) of abatement;

10. Waste transporter, address, contact name, and phone number;

11. Waste disposal site, address, contact name, and phone number;

12. For ordered abatements, the name, title, and authority of the State or local government representative who has ordered the abatement, the date that the order was issued, and the date the abatement was ordered to begin;

13. For emergency abatements, a description of the nature of the emergency and an explanation of how failure to correct the situation would cause a lead-based paint hazard;

14. Total value of the lead-based paint abatement work covered by the notification;

15. Total number of residential dwelling units and/or child occupied facilities abated; and

16. The original signature and date of the lead firm representative.

17. The person who developed the Occupant Protection Plan for the project.

(c) Notifications for lead-based paint abatement projects shall adhere to the following schedule:

1. Notifications for a lead-based paint abatement project shall be postmarked or delivered to the Division at least fifteen (15) calendar days prior to the scheduled start date;

2. The fifteen (15) calendar day notice may be waived if the abatement project is deemed an emergency lead-based paint abatement project by a lead risk assessor and approved by the Division prior to commencement of lead-based paint abatement activities. A notification involving an emergency lead-based paint abatement project shall be postmarked or hand delivered to the Division by the workday following the request for the emergency abatement project. Notifications for emergency abatement projects shall be submitted along with a letter from the owner or the lead risk assessor explaining the nature of the emergency.

(d) All notifications, both regular and emergency, for lead-based paint abatement shall be accompanied by a project fee in accordance with paragraph (10) of this section. Project fees shall be submitted electronically or in the form of check or money order and made payable to the Environmental Protection Division - Lead Abatement Fees.

(e) Revisions to lead-based paint abatement project notifications shall be made in writing on a form provided by the Division and shall be submitted to the Division for the following:

1. Revision to a start date for a project that will begin after the start date stated in the previous notification shall be received on or before the previously stated start date or previously revised start date;

2. Revision to a start date for a project that will begin before the start date stated in the previous notification or subsequent revisions shall be received at least fifteen (15) calendar days before the new start date;

3. Revision to a completion date that will be extended beyond the completion date stated in the previous notification shall be received by the original completion date or previously revised completion date;

4. Revision to a completion date that will be earlier than the completion date stated in the previous notification or subsequent revision shall be received by the new completion date; and

5. Revisions to notifications other than start or completion dates shall be submitted to the Division prior to initiating the activity which the revision addresses.

(f) The following shall be maintained on site during abatement activities and be immediately made available for review by the Division:

1. A copy of the project notification, notice to proceed and all revisions;

2. The occupant protection plan;

3. A copy of the applicable lead-based paint abatement design, risk assessment and inspection reports; and

4. Certifications issued by the Director for all certified persons and firms performing lead-based paint activities.

(g) All abatement shall be conducted in accordance with Rule 391-3-24-.06.

(h) All abatement shall be conducted under the direct supervision of a certified lead supervisor who shall be on-site at all times when abatement activities are being conducted.

(12) Recordkeeping.

(a) All reports or plans required in this section shall be maintained by the certified lead firm or person who prepared the report for no fewer than three (3) years. The certified lead firm or person shall also provide copies of these reports to the building owner who contracted for its services.

Cite as Ga. Comp. R. & Regs. R. 391-3-24-.06

AUTHORITY: O.C.G.A. § 31-41-1**, *et seq*.**

HISTORY: Original Rule entitled "Accreditation and Certification Fees" adopted. F. June 28, 1996; eff. July 18, 1996.

Repealed: New Rule entitled "Standards for Conducting Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities" adopted. F. June 26, 1998; eff. July 16, 1998.

Amended: F. June 27, 2002; eff. July 17, 2002.

Repealed: New Rule entitled "Standards for Conducting Lead-Based Paint Activities" adopted. F.Nov. 19, 2010; eff. Dec. 9, 2010.

Amended: F. Mar. 18, 2022; eff. Apr. 7, 2022.

391-3-24-.07 Lead Clearance Levels

Clearance procedures shall be conducted on all abatement projects by a certified inspector or lead risk assessor after appropriate cleaning has been completed. The following lead clearance levels must be met.

CLEARANCE DUST STANDARDS (Wipe Sampling Only)

Surface/ Medium	Level (µg/ft2) (Equal to or less than)
Bare and carpeted floors	10 µg/ft2
Interior Window Sills	100 µg/ft2
Window Troughs	400 µg/ft2
Exterior Concrete	800 µg/ft2

Cite as Ga. Comp. R. & Regs. R. 391-3-24-.07

AUTHORITY: O.C.G.A. § 31-41-1**, *et seq*.**

HISTORY: Original Rule entitled "Standards for Conducting Lead-Based Paint Activities for Target Housing and Child-Occupied Facilities" adopted. F. June 28, 1996; eff. July 18, 1996.

Repealed: New Rule entitled "Lead Clearance Levels" adopted. F. June 26, 1998; eff. July 16, 1998.

Amended: F. June 27, 2002; eff. July 17, 2002.

Repealed: New Rule of the same title adopted. F. Nov. 19, 2010; eff. Dec. 9, 2010.

Amended: F. Mar. 18, 2022; eff. Apr. 7, 2022.

Department 478. RULES OF THE STATE PERSONNEL BOARD

Chapter 478-1. RULES OF THE STATE PERSONNEL BOARD

478-1-.08 Political Activity

(1) **Introduction**:

(a) Employees engaging in political activity are responsible for complying with the provisions within this Rule, applicable laws, and their agency policy. Employees who are uncertain whether political activity is permissible are expected to seek guidance from their agency ethics officer or other designated official.

(b) Typically, employees may engage in political activity as private citizens that does not:

1. Conflict with their employment or take place during work time or on work premises;

2. Disrupt their work environment or otherwise negatively affect business operations;

3. Coerce or appear to coerce the political action of other employees, contractors, vendors, or customers; or,

4. Create the perception that the employee's personal political views or actions are representative of the State.

(2) **Applicability**:

The policies and procedures within this Rule apply to all agencies of the executive branch, local departments of public health, and community service boards, but do not apply to authorities, public corporations, and the Board of Regents of the University System of Georgia.

(3) **Definitions**:

(a) "Political activity" means activity directed toward the success or failure of a political party, candidate for partisan political office, or partisan political group.

(b) "Recall application or petition" means an application or petition to remove a public official from elective office.

(c) "Work time" means time an employee is scheduled to work, but does not include time during which an employee is using leave or compensatory time.

(4) **Candidacy and Holding Office**:

(a) Candidacy for Office:

1. An employee wishing to campaign for any elective office must consult with the employing agency and notify the agency ethics officer before announcing and/or qualifying for the office.

2. An employee may campaign for elective office if doing so does not conflict with the performance of the employee's official duties and is not otherwise prohibited by law.

3. An agency, by written policy, may require an employee campaigning for office to be placed on a leave of absence without pay upon determination that candidacy conflicts with current employment.

4. Candidacy for federal, state, county, or municipal office will be established when an employee files a notice of candidacy with the Georgia Secretary of State's Office. Candidacy for office in a political party or organization will be established upon official public announcement of candidacy.

5. Any employee whose salary is entirely federally funded is covered by the Hatch Act and is prohibited from being a candidate for public elective office in a partisan election.

i. This prohibition applies to candidacy for both part-time and full-time offices.

ii. This prohibition does not apply to the Governor, Lieutenant Governor, duly elected agency heads, or other elected officials.

(b) Holding Office:

1. Any employee who is elected or is appointed to full-time office or other office that conflicts with current employment must resign or forfeit employment upon assuming office.

2. Executive branch employees are not permitted to simultaneously hold office or employment in the legislative or judicial branches of state government except that an employee may be temporarily employed with the legislative branch during the legislative session provided that the employee is on an authorized leave of absence without pay.

(5) **Prohibited Political Activities**:

Employees are prohibited from engaging in the following political activities:

(a) Conducting political activities of any nature during work time or on work premises and/or using state property or resources to do so;

(b) Soliciting other employees for any political purpose, whether or not during work hours or on work premises;

(c) Coercing other employees, contractors, vendors, or customers to pay, lend, or contribute items of value for political purposes;

(d) Soliciting or knowingly accepting any campaign contributions in a state building or office except when the space is rented for the specific purpose of holding a campaign fundraiser;

(e) Holding or being a candidate for political office that conflicts with current employment (see Section (4) of this Rule);

(f) Seeking, using, or attempting to use any coercive political pressure to secure for themselves or any other person an appointment, promotion, salary increase, or any other employment advantage;

(g) Using or promising to use any official authority to influence or coerce the political action of any other person (including other employees, contractors, vendors, or customers), or to affect the results of a nomination, campaign, or election for office;

(h) Representing that a personal endorsement of or opposition to a political candidate is the official position of the State or a state agency;

(i) Circulating a recall application or petition by any means, including email or social media; or,

(j) Receiving state-paid transportation mileage while transporting any political campaign literature or matter, soliciting votes, or transporting any person soliciting votes in any election.

(6) **Consequences for Prohibited or Conflicting Political Activity**:

(a) Any applicant or employee who seeks, uses, or attempts to use any coercive political pressure to secure an advantage in employment will be subject to appropriate action up to and including denial or termination of employment.

(b) Any employee who is elected or appointed to full-time office or other office that conflicts with current employment must resign or forfeit employment upon assuming office.

(c) Any employee whose employment is entirely federally funded must resign from or forfeit such employment upon becoming a candidate for any elective office.

(d) Any employee who engages in prohibited political activity will be subject to appropriate action, up to and including termination of employment. Such termination of employment will be considered a voluntary forfeiture of employment under Rule 478-1-.15, Changes to Employment Status and Rule 478-1-.28, Voluntary Separation for Classified Employees.

(7) **Non-discrimination and Anti-Retaliation**:

(a) The State will not discriminate for or against any person or employee in any employment matter because of political affiliation.

(b) Retaliating against any employee, contractor, vendor, or customer for engaging in permissible political activity is prohibited.

Cite as Ga. Comp. R. & Regs. R. 478-1-.08

AUTHORITY: O.C.G.A. §§ 45-20-3**,** 45-20-3.1**,** 45-20-4**.**

HISTORY: Original Rule entitled "Vacancies" adopted. F. July 31, 1985; eff. July 1, 1985, as specified by the Board.

Amended: F. Aug. 2, 1988; eff. July 8, 1988, as specified by the Board.

Amended: F. Dec. 31, 1996; eff. Sept. 20, 1996, as specified by the Board.

Amended: F. Oct. 8, 1997; eff. Sept. 25, 1997, as specified by the Board.

Repealed: New Rule entitled "Political Activity" adopted. F. Dec. 23, 2008; eff. Dec. 17, 2008, as specified by the Agency.

Amended: F. Mar. 24, 2022; eff. Mar. 10, 2022, as specified by the Board.

Department 505. PROFESSIONAL STANDARDS COMMISSION

Chapter 505-3. EDUCATOR PREPARATION RULES

505-3-.29 Science Education Program

(1) **Purpose.** This rule states field-specific content standards for approving programs that prepare individuals to teach broad field science and/or the science specialties of life sciences, chemistry, earth space science, and physics in grades 6-12 and supplements requirements in Rule 505-3-.01, REQUIREMENTS AND STANDARDS FOR APPROVING PROFESSIONAL EDUCATION UNITS AND EDUCATOR PREPARATION PROGRAMS. The standards are based on National Science Teaching Association/Association for Science Teacher Education standards (2020) and A Framework for K-12 Science Education - Practices, Crosscutting Concepts, and Core Ideas (2012).

(2) **Requirements.**

(a) A GaPSC-approved educator preparation provider shall offer an educator preparation program described in program planning forms, catalogs, and syllabi addressing the following standards.

1. Content Knowledge. Effective teachers of science understand and articulate the knowledge and practices of contemporary science and engineering. They connect important disciplinary core ideas, crosscutting concepts, and science and engineering practices for their fields of certification. Preservice teachers will:

(i) Use and apply the major concepts, principles, theories, laws, and interrelationships of their fields of licensure and supporting fields. Explain the nature of science and the cultural norms and values inherent to the current and historical development of scientific knowledge; and

(ii) Demonstrate knowledge of how to implement science standards, learning progressions, and sequencing of science content for teaching their certification level to 6-12 students.

2. Content Pedagogy. Effective teachers of science plan learning units of study and equitable, culturally responsive opportunities for all students based upon their understandings of how students learn and develop science knowledge, skills, and habits of mind. Effective teachers engage students in the use of science and engineering practices and crosscutting concepts to develop deep understandings of the core disciplinary ideas in their instructional planning. Preservice teachers will:

(i) Use science standards and a variety of appropriate, student-centered, and culturally-relevant science disciplinary-based instructional approaches that follow safety procedures and incorporate science and engineering practices, disciplinary core ideas, and crosscutting concepts;

(ii) Incorporate appropriate differentiation strategies, wherein all students develop conceptual knowledge and an understanding of the nature of science. Lessons should engage students in applying science practices, clarifying relationships, and identifying natural patterns from phenomena and empirical experiences;

(iii) Use engineering practices in support of science learning wherein all students design, construct, test and optimize possible solutions to a problem;

(iv) Align instruction and assessment strategies to support instructional decision making that identifies and addresses student misunderstandings, prior knowledge, and naïve conceptions; and

(v) Integrate science-specific technologies to support all students' conceptual understanding and application of science and engineering.

3. Learning Environments. Effective teachers of science are able to plan for engaging all students in science learning by identifying appropriate learning goals that are consistent with knowledge of how students learn science and are aligned with standards. Plans reflect the selection of phenomena appropriate to the social context of the classroom and community, and safety considerations, to engage students in the nature of science and science and engineering practices. Effective teachers create an anti-bias, multicultural, and social justice-learning environment to achieve these goals. Preservice teachers will:

(i) Plan a variety of lessons based on science standards that employ strategies that demonstrate their knowledge and understanding of how to select appropriate teaching and motivating learning activities that foster an inclusive, equitable, and anti-bias learning environment;

(ii) Plan learning experiences for all students in a variety of environments (e.g., the laboratory, field, virtual, and community) within their fields of certification;

(iii) Plan lessons in which all students have a variety of opportunities to obtain information, evaluate, communicate, investigate, collaborate, learn from mistakes, and defend their own explanations of phenomena, observations, and data. This includes the proposal and defense of potential solutions to real-world, authentic, scientific and engineering problems; and

(iv) Plan and implement instruction incorporating universal technologies that support and enhance virtual learning either in person or digitally to include all students in investigation and application of science content, engineering practices, and crosscutting concepts.

4. Safety. Effective teachers of science demonstrate biological, chemical, and physical safety protocols in their classrooms and workspace. They also implement ethical treatment of living organisms and maintain equipment and chemicals as relevant to their fields of certification. Preservice teachers will:

(i) Implement activities appropriate for the abilities of all students that demonstrate safe techniques for the procurement, preparation, use, storage, dispensing, supervision, and disposal of all chemicals/materials/equipment used within their fields of certification;

(ii) Demonstrate an ability to: recognize hazardous situations including overcrowding; implement emergency procedures; maintain safety equipment; provide adequate student instruction and supervision; and follow policies and procedures that comply with established state and national guidelines, appropriate legal state and national safety standards (e.g., Occupational Safety and Health Administration, National Fire Protection Association, Environmental Protection Agency), and best professional practices (e.g., National Science Teaching Association, Georgia Science Teachers Association, National Science Education Leadership Association). This includes awareness of personal liability, duty of care as it relates to students (face-to-face and remote), fellow staff, and visitors to the classroom;

(iii) Demonstrate ethical decision-making with respect to safe and humane treatment of all living organisms in and out of the classroom, and comply with the legal restrictions and best professional practices on the collection, care, and use of living organisms as relevant to their fields of certification; and

(iv) Demonstrate an awareness of safety implications associated with remote learning. This includes awareness of personal responsibility for instructing students on safety precautions for remote learning.

5. Impact on Student Learning. Effective teachers of science provide evidence that students have learned and can apply disciplinary core ideas, crosscutting concepts and science and engineering practices as a result of instruction. Effective teachers analyze learning gains for individual students, the class as a whole, and subgroups of students disaggregated by demographic categories, and use these to inform planning and teaching. Preservice teachers will:

(i) Design and implement diverse and balanced assessments that allow all students to demonstrate their knowledge and ability to apply, synthesize, evaluate, and communicate their understanding of disciplinary knowledge, nature of science, science and engineering practices, and crosscutting concepts in practical, authentic, and real-world situations;

(ii) Collect, organize, analyze, evaluate and reflect on a variety of formative and summative evidence and use those data to inform future planning and teaching; and

(iii) Analyze science-specific assessment data based upon student demographics, categorizing the levels of learner knowledge, and reflect on results for subsequent lesson plans.

6. Professional Knowledge and Skills. Effective teachers of science strive to continuously improve their knowledge of both science content and pedagogy, including approaches for addressing inequities and inclusion for all students in science. Teachers will also possess a deeper understanding of how to apply science and engineering practices for their discipline. They identify with and conduct themselves as part of the science education community. Preservice teachers will:

(i) Engage in critical reflection on their own science teaching to continually improve their instructional effectiveness;

(ii) Participate in professional learning opportunities to deepen their science content knowledge, and knowledge of science and engineering practices; and

(iii) Participate in professional learning opportunities to expand their science-specific pedagogical knowledge.

7. Commitment to Three-dimensional Learning. Effective teachers of 6-12 science and engineering should focus on a limited number of disciplinary core ideas and crosscutting concepts that are designed so that students continually build on and revise their knowledge and abilities over multiple years while supporting the integration of such knowledge and abilities with the practices needed to engage in scientific inquiry and engineering design. There are three major dimensions, Scientific and Engineering Practices, Disciplinary Core Ideas, and Crosscutting Concepts. All three dimensions need to be integrated into standards, curriculum, instruction, and assessment. Preservice teachers will:

(i) Emphasize science and engineering practices in their planning and implementation of lessons and units for all science students.

(I) Asking questions (for science) and defining problems (for engineering);

(II) Developing and using models;

(III) Planning and carrying out investigations;

(IV) Analyzing and interpreting data;

(V) Using mathematics and computational thinking;

(VI) Constructing explanations (for science) and designing solutions (for engineering);

(VII) Engaging in argument from evidence; and

(VIII) Obtaining, evaluating, and communicating information.

(ii) Focus deeply on a limited number of Disciplinary Core Ideas within each major category of science disciplines.

(I) Life Sciences

I. From Molecules to Organisms: Structures and processes

A. Cell structure and function

B. Growth and development of organisms

C. Organization for matter and energy flow in organisms

D. Information processing

II. Ecosystems: Interactions, Energy, and Dynamics

A. Interdependent relationships in ecosystems

B. Cycles of matter and energy transfer in ecosystems

C. Ecosystem dynamics, functioning, and resilience

D. Social interactions and group behavior

III. Heredity: Inheritance and Variation of Traits

A. Inheritance of traits

B. Variation of traits

IV. Biological Evolution: Unity and Diversity

A. Evidence of common ancestry and diversity

B. Natural selection

C. Adaptation

D. Biodiversity and humans

(II) Chemistry

I. Matter and Its Interaction

A. Structure and properties of matter

B. Chemical reactions

C. Nuclear processes

D. Atomic bonding

E. Solutions

II. Energy

A. Kinetic molecular theory

B. Conservation of energy and energy transfer

C. Electromagnetic radiation

(III) Earth Space Science

I. Earth's Place in the Universe

A. The universe and its stars

B. Earth and the solar system

C. History of planet Earth

II. Earth's Systems

A. Earth materials and systems

B. Plate tectonics and large system interactions

C. The roles of water in Earth's surface processes

D. Weather and climate

E. Bio-geology

III. Earth and Human Activity

A. Natural resources

B. Natural hazards

C. Human impacts on Earth systems

D. Global climate change

(IV) Physics

I. Matter and Its Interactions

A. Nuclear processes

II. Motion and Stability: Forces and Interactions

A. Forces and motion

B. Types of interactions

C. Stability and instability in physical systems

III. Energy

A. Work-energy theorem

B. Conservation of energy and energy transfer

C. Relationship between energy and forces

D. Energy in chemical processes and everyday life

IV. Waves and their applications in technologies for information transfer

A. Wave properties

B. Electromagnetic and mechanical waves

C. Information technologies and instrumentation

(iii) Consistently bear in mind crosscutting concepts as a means to provide linkages between science disciplines across multiple grades.

(I) Patterns

(II) Cause and effect: Mechanism and explanation

(III) Scale, proportion, and quantity

(IV) Systems and system models

(V) Energy and matter: Flows, cycles, and conservation

(VI) Structure and function

(VII) Stability and change

(b) Single-field Program Requirements. The program shall require a major or equivalent in one of the science areas listed in paragraph 7(ii). A major or equivalent shall be defined as a minimum of twenty-one semester hours of upper division content coursework that addresses the appropriate content area standards.

(c) Dual-field Program Requirements. The program shall require a major or equivalent in two of the content areas listed in paragraph 7 (ii). A major or equivalent shall be defined as a minimum of twenty-one semester hours of upper division content coursework that addresses the appropriate content area standards.

(d) Broad Field Program Requirements. The program shall require a major or equivalent in one of the science content areas listed in paragraph 7 (ii) and at least two additional areas of concentration listed in (ii). A major or equivalent shall be defined as a minimum of twenty-one semester hours of upper division content coursework that addresses the appropriate content area standards. An area of concentration shall be defined as a minimum of fifteen semester hours of content that address the appropriate content area standards listed in 7 (ii).

Cite as Ga. Comp. R. & Regs. R. 505-3-.29

AUTHORITY: O.C.G.A. § 20-2-200**.**

HISTORY: Original Rule entitled "English Education Program" adopted. F. Dec. 18, 1991; eff. Jan. 7, 1992.

Repealed: New Rule entitled "Middle Grades Education Program" adopted. F. Dec. 16, 1992; eff. July 1, 1993, as specified by the Agency.

Amended: F. June 29, 1994; eff. July 19, 1994.

Amended: F. June 8, 1999; eff. July 1, 1999, as specified by the Agency.

Repealed: New Rule, same title adopted. F. Nov. 9, 2001; eff. Dec. 1, 2001, as specified by the Agency.

Amended: F. May 9, 2002; eff. June 1, 2002, as specified by the Agency.

Amended: F. Aug. 20, 2004; eff. Sept. 15, 2004, as specified by the Agency.

Repealed: New Rule entitled "Social Science Education Program" adopted. F. Oct. 24, 2005; eff. Nov. 15, 2005, as specified by the Agency.

Repealed: F. Feb. 10, 2006; eff. Mar. 15, 2006, as specified by the Agency.

Adopted: New Rule entitled "Science Education Program." F. Apr. 24, 2014; eff. May 15, 2014, as specified by the Agency.

Amended: F. Mar. 25, 2022; eff. Apr. 15, 2022, as specified by the Agency.

Department 560. RULES OF DEPARTMENT OF REVENUE

Chapter 560-11. LOCAL GOVERNMENT SERVICES DIVISION

Subject 560-11-14. STATE AND LOCAL TITLE AD VALOREM TAX FEE

560-11-14-.01 Definitions

(1) As used in O.C.G.A. § 48-5C-1 and in these regulations, the term:

(a) "Commercial motor vehicle" shall have the same meaning as provided for in O.C.G.A. § 40-1-8.3.

(b) "Commissioner" means the State Revenue Commissioner.

(c) "County tag agent" or "tag agent" means those persons that have been designated as tag agents of the commissioner as provided for in O.C.G.A. § 40-2-23.

(d) "Date of purchase" means the date so provided on the application for certificate of title.

(e) "Dealer" or "dealership" shall have the same meaning as a dealer of new or used motor vehicles as provided for in O.C.G.A. § 40-3-2(3).

(f) "Department" means the Department of Revenue.

(g) "Electronic Title and Registration" means an electronic process by which a dealer, through a vendor authorized by the commissioner, initiates the motor vehicle titling and registration process and by which the application for certificate of title is considered received by the county tag agent.

(h) "Fair market value" means:

1. For a new motor vehicle the retail selling, less any reduction for the trade-in value of another motor vehicle and any rebate. The retail selling price shall include any charges for labor, freight, delivery, dealer fees, and similar charges, tangible accessories, dealer add-ons, and mark-ups, but shall not include any federal retailers' excise tax or extended warranty, service contract, maintenance agreement, or similar products itemized on the dealer's invoice to the customer or any finance, insurance, and interest charges for deferred payments billed separately. No reduction for the trade-in value of another motor vehicle shall be taken unless the name of the owner and the vehicle identification number of such trade-in motor vehicle are shown on the bill of sale;

2. For a motor vehicle that is leased:

(A) In the case of a motor vehicle that is leased to a lessee for use primarily in the lessee's trade or business and for which the lease agreement contains a provision for the adjustment of the rental price as described in Code Section 40-3-60, the agreed upon value of the motor vehicle less any reduction for the trade-in value of another motor vehicle, including any vehicle(s) owned by the lessor, and any rebate; or

(B) In the case of a motor vehicle that is leased other than described in part (1)(h)2.(A) of this regulation, the total of the depreciation plus any amortized amounts pursuant to the lease agreement plus any down payments. The term "any down payments" as used in this subparagraph means cash collected from the lessee at the inception of the lease which shall include cash supplied as a capital cost reduction; shall not include rebates, noncash credits, or net trade allowances; and shall include any upfront payments collected from the lessee at the inception of the lease except for taxes or fees imposed by law and monthly lease payments made in advance.

3. For a used motor vehicle purchased from a new or used car dealer other than under a seller financed sale arrangement, the retail selling price of the motor vehicle, less any reduction for the trade-in value of another motor vehicle. The retail selling price shall include any charges for labor, freight, delivery, dealer fees and similar charges, tangible accessories, dealer add-ons, and mark-ups, but shall not include any federal retailers' excise tax or extended warranty, service contract, maintenance agreement, or similar products itemized on the dealer's invoice to the customer or any finance, insurance, and interest charges for deferred payments billed separately. No reduction for the trade-in value of another motor vehicle shall be taken unless the name of the owner and the vehicle identification number of such trade-in motor vehicle are shown on the bill of sale.

4. For a used motor vehicle purchased from a person other than a new or used car dealer or purchased under a seller financed sale arrangement, the average of the current fair market value and the current wholesale value of a motor vehicle for a vehicle listed in the current motor vehicle ad valorem assessment manual utilized by the state revenue commissioner and based upon a nationally recognized motor vehicle industry pricing guide for fair market and wholesale market values in determining the taxable value of a motor vehicle under Code Section 48-5-442; provided, however, that, if the motor vehicle is not listed in such current motor vehicle ad valorem assessment manual, the fair market value shall be the value from a reputable used car market guide designated by the commissioner and, in the case of a motor vehicle purchased from a new or used car dealer under a seller financed sale arrangement, less any reduction for the trade-in value of another motor vehicle.

(i) "Immediate family member" means a spouse, parent, child, sibling, grandparent, or grandchild and includes those who have attained such immediate family member status through a legal determination recognized in this state.

(j) "International Registration Plan" means the international reciprocal registration agreement for commercial motor vehicles and all amendments thereto as provided for in O.C.G.A. § 40-2-88.

(k) "Loaner vehicle" means a motor vehicle owned by a dealer which is withdrawn temporarily from dealer inventory for exclusive use as a courtesy vehicle loaned at no charge for a period not to exceed thirty (30) days within a 366-day period to any one customer whose motor vehicle is being serviced by such dealer.

(l) "Motor vehicle" shall have the same meaning as provided for in O.C.G.A. § 40-1-1(33).

(m) "New motor vehicle" shall have the same meaning as provided for in O.C.G.A. § 40-1-1(34).

(n) "Month" means a period of thirty (30) consecutive calendar days.

(o) "Owner" shall have the same meaning as provided for in O.C.G.A. § 40-1-1(39).

(p) "Person" means any individual, firm, partnership, cooperative, nonprofit membership corporation, joint venture, association, company, corporation, agency, syndicate, estate, trust, business trust, receiver, fiduciary, or other group or combination acting as a unit, body politic, or political subdivision, whether public, private, or quasi-public.

(q) "Proceeds" means the combined state ad valorem title tax fee, local ad valorem title tax fee, administrative fee, penalties, and interest.

(r) "Rebuilt title" shall have the same meaning as provided for in O.C.G.A. § 40-3-37.

(s) "Rental charge" means the title value received by a rental motor vehicle concern for the rental or lease for thirty-one (31) or fewer consecutive days of a rental motor vehicle, including the total cash and nonmonetary consideration for the rental or lease, including, but not limited to, charges based on time or mileage and charges for insurance coverage or collision damage waiver but excluding all charges for motor fuel taxes or sales and use taxes.

(t) "Rental motor vehicle" means a motor vehicle designed to carry fifteen (15) or fewer passengers and used primarily for the transportation of persons that is rented or leased without a driver.

(u) "Rental motor vehicle concern" means a person or legal entity which owns or leases five (5) or more rental motor vehicles and which regularly rents or leases such vehicles to the public for value.

(v) "Salvage motor vehicle" shall have the same meaning as provided for in O.C.G.A. § 40-3-2(11).

(w) "Salvage title" shall have the same meaning as provided for in O.C.G.A. § 40-3-36.

(x) "Sales and use tax" means combined state and local sales and use tax as imposed by Chapter 8 of Title 48, unless otherwise specifically provided for in O.C.G.A. § 48-5C-1 or these regulations to refer only to state sales and use tax, or local sales and use tax, respectively.

(y) "Tax collector" or "tax commissioner" means those persons that have been designated as tag agents of the commissioner as provided for in O.C.G.A. § 40-2-23.

(z) "Used motor vehicle" shall have the same meaning as provided for in O.C.G.A. § 40-1-1(74).

Cite as Ga. Comp. R. & Regs. R. 560-11-14-.01

AUTHORITY: O.C.G.A. §§ 40-3-3**,** 48-5C-1**.**

HISTORY: Original rule entitled "Definitions" approved. F. Jan. 4, 2013; eff. Jan. 24, 2013.

Repealed: New Rule of same title adopted. F. Nov. 30, 2017; eff. Dec. 20, 2017.

Amended: F. Dec. 14, 2018; eff. Jan. 3, 2019.

Amended: F. Jan. 29, 2020; eff. Feb. 18, 2020.

Amended: F. Mar. 31, 2022; eff. Apr. 20, 2022.

Department 560. RULES OF DEPARTMENT OF REVENUE

Chapter 560-11. LOCAL GOVERNMENT SERVICES DIVISION

Subject 560-11-16. TABLE OF FOREST LAND PROTECTION ACT LAND USE VALUES

560-11-16-.02 Definitions

As used in this Article, the term:

(a) "Bona Fide Production of Trees" means the good faith, real, actual, and genuine production of trees for commercial uses.

(b) "Contiguous" means real property within a county that abuts, joins, or touches and has the same undivided common ownership. If an applicant's tract is divided by a county boundary, public roadway, public easement, public right of way, natural boundary, land lot line, or railroad track, then the applicant may make an election at the time of application to declare the tract as contiguous irrespective of a county boundary, public roadway, public easement, public right of way, natural boundary, land lot line, or railroad track.

(c) "Department" means the Georgia Department of Revenue.

(d) "Forest Management Plan" means a plan written by a registered forester to manage a forest stand in accordance with accepted commercial forestry practices. Forest Management Plans may include, but are not limited to, information about soils, logging methods, disease or insect problems, road conditions, growth and age data, environmental concerns, and recommended silvicultural treatments and their timing.

(e) "Qualified Owner" means an individual or entity that meets the conditions of Code Section 48-5-603.

(f) "Qualified Timberland Property" (QTP) means timberland property that meets the conditions of Code Section 48-5-604. Such property shall be classified as a separate and distinct class of tangible property for ad valorem tax purposes.

(g) "Timberland Property" means tangible real property that has as its primary use the Bona Fide Production of Trees for commercial uses.

Cite as Ga. Comp. R. & Regs. R. 560-11-16-.02

AUTHORITY: O.C.G.A. §§ 48-2-12**,** 48-5-600**,** 48-5-607**.**

HISTORY: Original Rule entitled "Definitions" adopted. F. Feb. 5, 2021; eff. Feb. 25, 2021.

Amended: F. Mar. 31, 2022; eff. Apr. 20, 2022.

560-11-16-.03 Applications

(1) All applications for certification as a Qualified Owner and for QTP certification shall be submitted electronically through the Georgia Tax Center (GTC). No other filing method shall be permitted.

(2) Applications for certification as a Qualified Owner and for QTP certification must be filed annually with the Revenue Commissioner between January 1 and March 1 of the applicable tax year.

(3) The applicant shall submit the following documentation to the Revenue Commissioner through GTC:

(a) Application for QTP certification;

(b) Recorded deed evidencing legal ownership of the property;

(c) An affidavit in which the qualified owner attests that the timberland property is used for the bona fide production of trees and is consistently managed with generally accepted commercial forestry practices; and

(d) A list of all parcels that contain timberland property and that identifies the specific portions of such parcels that such owner certifies are timberland property, which requirement may be satisfied by

(i) A parcel map drawn by the county cartographer or GIS technician and signed by the county board of assessors and qualified owner;

(ii) A legal description of the property;

(iii) A plat of the property prepared by a licensed land surveyor, showing the location and measured area of the parcel;

(iv) A written legal description of the property delineating the metes and bounds and measured area; or

(v) Such other alternative property boundary description as is mutually agreed upon by the taxpayer and the Department that may accurately represent the parcel which is the subject of the QTP application.

(4) The applicant may, but is not required to, include a Forest Management Plan demonstrating the use of accepted commercial forestry practices. The Department considers a Forest Management Plan to be prima facie evidence of bona fide commercial production of timber.

(5) The applicant may also submit an individual soil map delineating the soil types on the property.

(6) An application for QTP certification may be amended or withdrawn at any time prior to the initial certification or non-certification by the Department by giving written notification of such amendment or withdrawal.

Cite as Ga. Comp. R. & Regs. R. 560-11-16-.03

AUTHORITY: O.C.G.A. §§ 48-2-12**,** 48-5-603**,** 48-5-604**,** 48-5-607**.**

HISTORY: Original Rule entitled "Applications" adopted. F. Feb. 5, 2021; eff. Feb. 25, 2021.

Amended: F. Mar. 31, 2022; eff. Apr. 20, 2022.

560-11-16-.05 Table of Commercial Timberland Per Acre Values by Ecological Region and Soil Productivity Classification

(1) For the purpose of prescribing the 2020 table of values for use in the appraisal of Qualified Timberland Property, the state shall be divided into four ecological regional valuation areas, and per acre values shall be assigned to qualified land according to soil productivity classifications 1 - 9 (W1-W9).

(a) **Ecological region #1** includes the following counties: Appling, Atkinson, Bacon, Brantley, Bryan, Camden, Charlton, Chatham, Clinch, Echols, Effingham, Glynn, Jeff Davis, Lanier, Liberty, Long, McIntosh, Pierce, Ware, and Wayne. The following per acre values shall be applied to each qualified acre according to soil productivity classifications W1 - W9:

W1-1,152, W2-1,043, W3-839, W4-770, W5-713, W6-653, W7-529, W8-449, W9-388.

(b) **Ecological region #2** includes the following counties: Baker, Ben Hill, Berrien, Bibb, Bleckley, Brooks, Bulloch, Burke, Calhoun, Candler, Chattahoochee, Clay, Coffee, Colquitt, Cook, Crawford, Crisp, Decatur, Dodge, Dooly, Dougherty, Early, Emanuel, Evans, Glascock, Grady, Houston, Irwin, Jefferson, Jenkins, Johnson, Laurens, Lee, Lowndes, Macon, Marion, Miller, Mitchell, Montgomery, Muscogee, Peach, Pulaski, Quitman, Randolph, Richmond, Schley, Screven, Seminole, Stewart, Sumter, Tattnall, Taylor, Telfair, Terrell, Thomas, Tift, Toombs, Treutlen, Turner, Twiggs, Washington, Webster, Wheeler, Wilcox, and Wilkinson. The following per acre values shall be applied to each qualified acre according to soil productivity classifications W1 - W9:

W1-953, W2-852, W3-680, W4-613, W5-558, W6-520, W7-425, W8-360, W9-338.

(c) **Ecological region #3** includes the following counties: Baldwin, Banks, Barrow, Bartow, Butts, Carroll, Catoosa, Chattooga, Cherokee, Clarke, Clayton, Cobb, Columbia, Coweta, Dade, Dawson, Dekalb, Douglas, Elbert, Fayette, Floyd, Forsyth, Franklin, Fulton, Gordon, Greene, Gwinnett, Habersham, Hall, Hancock, Haralson, Harris, Hart, Heard, Henry, Jackson, Jasper, Jones, Lamar, Lincoln, Madison, McDuffie, Meriwether, Monroe, Morgan, Murray, Newton, Oconee, Oglethorpe, Paulding, Pickens, Pike, Polk, Putnam, Rockdale, Spalding, Stephens, Talbot, Taliaferro, Troup, Upson, Walker, Walton, Warren, White, Whitfield, and Wilkes. The following per acre values shall be applied to each qualified acre according to soil productivity classifications 1 - 9:

W1-870, W2-801, W3-734, W4-671, W5-616, W6-583, W7-523, W8-485, W9-396.

(d) **Ecological region #4** includes the following counties: Fannin, Gilmer, Lumpkin, Rabun, Towns, and Union. The following per acre values shall be applied to each qualified acre according to soil productivity classifications 1 - 9:

W1-962, W2-904, W3-853, W4-801, W5-743, W6-686, W7-616, W8-580, W9-551.

(2) The appraised value produced using the table of values in paragraph (1) of this Rule shall be determined and, if needed, adjusted so that the final value is at least 175% of such property's forest land conservation use value.

Cite as Ga. Comp. R. & Regs. R. 560-11-16-.05

AUTHORITY: O.C.G.A. §§ 48-2-12**,** 48-5-7**,** 48-5-602**,** 48-5-607**.**

HISTORY: Original Rule entitled "Table of Commercial Timberland Per Acre Values by Ecological Region and Soil Productivity Classification" adopted. F. Feb. 5, 2021; eff. Feb. 25, 2021.

Amended: F. Mar. 31, 2022; eff. Apr. 20, 2022.

560-11-16 Appendix: Qualified Timberland Property Appraisal Manual

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Department 560. RULES OF DEPARTMENT OF REVENUE

Chapter 560-13. FEES AND EXCISE TAXES

Subject 560-13-3. TRANSPORTATION SERVICES TAX

560-13-3-.01 Transportation Services Tax

(1) **Purpose.** This Rule addresses the transportation services tax imposed pursuant to Title 48, Chapter 13, Article 8 of the Official Code of Georgia.

(2) **Definitions.** For purposes of this Rule only:

(a) "Fare" means a fee by a For-Hire Ground Transport Service Provider for a Journey.

(b) "For-Hire Ground Transport Service Provider" means a Limousine Carrier, Ride Share Network Service, Taxi Service, or Transportation Referral Service.

(c) "For-Hire Ground Transport Trip" means any request for a Journey by passenger vehicle provided for by a For-Hire Ground Transport Service Provider for which a person is charged a fee, whether such Journey was completed or not.

(d) "Journey" means a transport of a person from one location to another, as requested by such person.

(e) "Limousine Carrier" means any person licensed with Georgia pursuant to O.C.G.A. § 40-1-151(5) who owns or operates a prearranged service regularly rendered to the public by furnishing transportation as a motor carrier for hire, not over fixed routes, by means of one or more unmetered:

1. Limousines;

2. Extended limousines;

3. Sedans;

4. Extended sedans;

5. Sport utility vehicles;

6. Extended sport utility vehicles;

7. Other vehicles with a capacity for seating and transporting no more than 15 persons for hire including the driver; or

8. Any combination of subparagraphs (2)(e)1. through (2)(e)7. on the basis of telephone contract or written contract.

(f) "Ride-Share Network Service" means any person or entity that uses a digital network or internet network to connect passengers to ride-share drivers for the purpose of prearranged transportation for hire or for donation. The term excludes any "corporate sponsored vanpool" or "exempt rideshare" as such terms are defined in O.C.G.A. § 40-1-100, provided that such corporate sponsored vanpool or exempt ride-share is not operated for the purpose of generating a profit.

(g) "Shared For-Hire Ground Transport Trip."

1. "Shared For-Hire Ground Transport Trip" means

(i) any For-Hire Ground Transport Trip in which a person has been matched with another person (other than the driver) by a For-Hire Ground Transport Service Provider for purposes of such Journey; and

(ii) any For-Hire Ground Transport Trip in which a person makes a request to be matched with another person (other than the driver) for purposes of such Journey by a For-Hire Ground Transport Service Provider, even if the For-Hire Ground Transport Service Provider does not match the person with another person, but only if the For-Hire Ground Transport Service Provider, in its regular course of business, matches passengers with other passengers in exchange for a reduced Fare.

2. The number of passengers in a passenger group at a single location allowed to request a Shared For-Hire Ground Transport Trip may be limited by the For-Hire Ground Transport Service Provider. Notwithstanding subparagraph (2)(g)1., a Journey provided by a For-Hire Ground Transport Service Provider to a passenger group that exceeds the service provider's Shared For-Hire Ground Transport Trip passenger group limit constitutes a For-Hire Ground Transport Trip and does not constitute a Shared For-Hire Ground Transport Trip, even if the passenger group requests a Shared For-Hire Ground Transport Trip.

(h) "Taxi Service" means any taxicab company or provider that utilizes a motor vehicle or similar vehicle, device, machine, or conveyance to transport passengers; uses a taximeter; and is authorized to provide taxicab services pursuant to an ordinance of a local government in Georgia.

(i) "Transportation Referral Service" means any person or entity that books, refers clients to, collects money for, or advertises transportation services provided by a Limousine Carrier or Taxi Service by means of a telephone, through cellular telephone software, through the internet, in person, by written instrument, by any person, or by any other means, and does not own or lease any motor vehicle required to be registered with the Department of Public Safety as a Limousine Carrier or a Taxi Service. A Transportation Referral Service shall not include emergency or nonemergency medical transports.

(3) **Imposition.**

(a) Beginning August 5, 2020, an excise tax known as the transportation services tax is levied on For-Hire Ground Transport Trips and Shared For-Hire Ground Transport Trips.

1. Example: Using Ride, Inc.'s mobile application, a person requests Ride, Inc., a For-Hire Ground Transport Service Provider and a Ride Share Network Service, to transport the person from point A to point B. Ride, Inc. must collect and remit the transportation services tax.

2. Example: A passenger telephones Great Cabs, a For-Hire Ground Transport Service Provider and Taxi Service, to send a taxi to transport the passenger from point A to point B. Great Cabs dispatches a taxi to point A where it picks up and transports the passenger to point B. The driver charges a Fare to the passenger. The driver is not a For-Hire Ground Transport Service Provider; therefore, Great Cabs must remit the tax to the Department.

(b) The transportation services tax shall be collected and remitted by the For-Hire Ground Transport Service Provider itself and not the vehicle driver. Notwithstanding the foregoing, to the extent a Transportation Referral Service books or refers clients for a For-Hire Ground Transport Trip to a Taxi Service or a Limousine Carrier which is also a For-Hire Ground Transport Service Provider, then the Taxi Service or Limousine Carrier, and not the Transportation Referral Service, shall be responsible for the collection and remittance of such excise tax.

(c) A For-Hire Ground Transport Service Provider is relieved from the duty to collect the transportation services tax if the For-Hire Ground Transport Service Provider takes, in good faith, as such term is more fully described in O.C.G.A. § 48-8-38, a certificate of exemption from a purchaser of a For-Hire Ground Transport Trip.

(d) In lieu of collecting the tax, a For-Hire Ground Transport Service Provider is permitted to absorb the tax in accordance with O.C.G.A. § 48-8-36 and Rule 560-12-2-.21.

(e) The transportation services tax is a debt from the passenger to the For-Hire Ground Transport Service Provider until it is paid and is recoverable at law in the same manner as authorized for the recovery of other debts.

(f) Any For-Hire Ground Transport Service Provider who neglects, fails, or refuses to collect the transportation services tax as required by this Rule is liable for the fee.

(g) The transportation services tax shall be administered, collected, and due and payable in the same manner as would otherwise be required by the tax imposed under Title 48, Chapter 8, Article 1 of the Official Code of Georgia.

(4) **Rate.**

(a) Beginning August 5, 2020 through and including March 31, 2022, the rate of the tax is 50¢ for For-Hire Ground Transport Trips and 25¢ for Shared For-Hire Ground Transport Trips.

(b) In calendar year 2022 and annually thereafter, the Department will adjust the rate effective April 1 to reflect the effect of annual inflation or deflation for the cost of living that consumers in this state experienced on average during the immediately preceding calendar year. For such purpose, the Department will use the Consumer Price Index for All Urban Consumers rate published by the Bureau of Labor Statistics of the United States Department of Labor. The Department will publish the rate to its website on or before March 1st of each year.

(c) The examples in this Rule assume rates of 50¢ for For-Hire Ground Transport Trips and 25¢ for Shared For-Hire Ground Transport Trips. The rates in the examples may not be current. For-Hire Ground Transport Service Providers are responsible for collecting the tax at the current rate as published on the Department's website.

(d) The rate applies to each Fare charged by the For-Hire Transportation Service Provider, documented by the For-Hire Transportation Service Provider's records and passenger receipts.

1. Example: A group of passengers at a single location calls a Taxi Service to transport the group from point A to point B. The Taxi Service dispatches a taxicab to point A, which then transports the group to point B. The Taxi Service charges one Fare as shown on the Taxi Service's records and the passenger receipt. The Taxi Service must collect the transportation services tax in the amount of 50¢ (the 50¢ tax on For-Hire Ground Transport Trips X 1 Fare = 50¢) and remit the tax to the Department, regardless of whether the passengers split the Fare or one passenger pays the entire Fare.

2. Example: A group of four passengers at a single location requests a ride through a mobile application provided by Ride, Inc., a Ride Share Network Service. The group requests Ride, Inc. to pick them up at point A. The group has not been matched with another person by Ride, Inc., nor has the group of passengers made a request to Ride, Inc. to be matched with another person by Ride, Inc. The driver picks up the group at point A and drops each passenger off at different destination points. Ride, Inc. charges each passenger a separate Fare, as indicated by Ride, Inc.'s records and the passengers' receipts. Ride, Inc. must collect the transportation services tax in the amount of $2.00 (the 50¢ tax on For-Hire Ground Transport Trips X 4 Fares = $2.00) and remit the tax to the Department, regardless of whether the passengers pay separately or one passenger pays for all the Fares.

3. Example: Assume the same facts as in subparagraph (4)(d)2., except that Ride, Inc. charges only one Fare, as indicated by the Ride Inc.'s records and the passengers' receipts. Ride, Inc. must collect the transportation services tax in the amount of 50¢ (the 50¢ tax on For-Hire Ground Transport Trips X 1 Fare = 50¢) and remit the tax to the Department, regardless of whether the passengers split the Fare or one passenger pays the entire Fare.

4. Example: Using a mobile application, a passenger requests a ride from Ride, Inc., a Ride Share Network Service. The passenger requests to share the ride with passengers that Ride, Inc. chooses to pick up along the way. After picking up the first passenger, the driver then picks up one lone passenger and one 2-passenger group. Ride, Inc. charges each lone passenger a separate Fare and charges one Fare to the 2-passenger group, as indicated by Ride, Inc.'s records and the passengers' receipts. Ride, Inc. must collect the transportation services tax in the amount of $1.00 (the 25¢ tax on Shared For-Hire Ground Transport Trips X 4 Fares = $1.00) and remit the tax to the Department.

5. Example: A passenger requests a ride through the mobile application of Ride, Inc., a Ride Share Network Service. The passenger has not been matched with another person by Ride, Inc., nor has the passenger made a request to Ride, Inc. to be matched with another person by Ride, Inc. The driver picks up the passenger at point A and, at the passenger's request, drives the passenger to point B to pick up a passenger chosen by the passenger. The driver then transports both passengers to point C. As indicated by Ride Inc's records and the passengers' receipts, Ride, Inc. charges one Fare for the Journey from point A to point B and one Fare for the Journey from point B to point C. Ride, Inc. must collect the transportation services tax in the amount of $1.00 (the 50¢ tax on For-Hire Ground Transport Trips X 2 Fares = $1.00) and remit it to the Department, regardless of whether the passengers split the Fares or one passenger pays for both Fares.

6. Example: Assume the same facts as in subparagraph (4)(d)5, except that Ride, Inc. charges one Fare for the Journey from point A to point B to point C, as indicated by Ride, Inc.'s records and the passengers' receipts. Ride, Inc. must collect the transportation services tax in the amount of 50¢ (the 50¢ tax on For-Hire Ground Transport Trips X 1 Fare = 50¢) and remit the tax to the Department, regardless of whether the passengers split the Fare or one passenger pays the entire Fare.

(5) **Itemized charges.**

(a) Separate or itemized charges for either (i) a waiting period; (ii) a cancellation or no-show; or (iii) travel time by the For-Hire Ground Transportation Service Provider without transporting one or more persons by the For-Hire Ground Transportation Service Provider do not constitute Fares and, as such, are not subject to the transportation services tax.

(b) In the event a For-Hire Ground Transportation Service Provider charges a flat fee that includes at least one Journey provided by the For-Hire Ground Transportation Service Provider, then such flat fee constitutes a single Fare that is subject to the transportation services tax.

1. Example: A group of people hires a Limousine Carrier to pick up the group at point A, transport the group to point B, wait at point B for several hours, and then transport the group back to point A. The Limousine Carrier charges a fee for the Journey from point A to point B, another fee for the Journey from point B back to point A, and another fee for the waiting period. Each fee for a Journey constitutes one Fare. Thus, the Limousine Carrier must collect the transportation services tax in the amount of $1.00 (the 50¢ tax on For-Hire Ground Transport Trips X 2 Fares = $1.00) and remit the tax to the Department, regardless of whether the passengers split the Fare or one passenger pays the entire Fare. The transportation services tax does not apply to the charge for the waiting period because the charge is not a Fare.

2. Example: A group of people hires a Limousine Carrier for the evening to pick up the group at point A, transport the group to point B, wait at point B for several hours, and then transport the group back to point A. The Limousine Carrier charges a flat fee for the entire evening. The flat fee constitutes a Fare. The Limousine Carrier must collect the transportation services tax in the amount of 50¢ (the 50¢ tax on For-Hire Ground Transport Trips X 1 Fare = 50¢) and remit the tax to the Department, regardless of whether the passengers split the Fare or one passenger pays the entire Fare.

(6) **Exemptions and exclusions.**

(a) Persons that are exempt from sales tax on purchases of services under Chapter 8 of Title 48 of the Official Code of Georgia are exempt from the transportation services tax. To make a purchase that is exempt from transportation services tax, persons qualifying for exemption must present to the dealer the same documentation that they would otherwise present to make a purchase exempt from sales tax.

(b) Foreign missions, their members, and dependents and Taipei Economic and Cultural Representative Office (TECRO), Taipei Economic and Cultural Offices (TECOs), their employees and dependents are exempt from the transportation services tax to the same extent they are exempt from sales and use tax.

(c) The transportation services tax does not apply to charges for delivery of tangible personal property.

(d) Trips that originate in another state and end in Georgia or originate in Georgia and end in another state are not subject to the transportation services tax.

(7) **Application of sales and use tax.**

(a) Beginning on August 5, 2020, For-Hire Ground Transport Trips and Shared For-Hire Ground Transport Trips are exempt from state and local sales and use taxes.

(b) Tangible personal property used and consumed in the performance of a For-Hire Ground Transport Trip, including, but not limited to, gasoline, automobile accessories, and automobile parts are subject to sales and use taxes.

(8) **Returns.**

(a) For-Hire Ground Transport Service Providers must report and remit the tax electronically to the Department.

(b) Returns and taxes are due on the 20th day of each month following the month of collection in accordance with O.C.G.A. § 48-2-39**.**

(c) For-Hire Ground Transport Service Providers are required to report tax exempt trips.

(d) For-Hire Ground Transport Service Providers are required to file returns for months in which no trips were provided.

(9) **Quarterly reporting.**

(a) Every quarter, For-Hire Ground Transport Service Providers must report the total number of trip originations per county and the total number of trip destinations per county on the transportation services tax quarterly report. The transportation services tax quarterly report will appear on the returns for the September, December, March, and June periods. Service providers who have provided trips during the quarter must complete the quarterly report to submit their September, December, March, and June returns.

(b) For-Hire Ground Transport Service Providers must report one origination and one destination for each For-Hire Ground Transport Trip and each Shared For-Hire Ground Transport Trip.

1. **Example**: Rideshare, Inc. in one quarter provides 1,000 For-Hire Ground Transport Trips that begin and end in Fulton County, 10 Shared For-Hire Ground Transport Trips that begin in Fulton County and end in DeKalb County, 15 For-Hire Ground Transport Trips that begin in DeKalb County and end in Fulton County, and 300 Shared For-Hire Ground Transport Trips that begin in Cherokee County and end in Clayton County. Rideshare, Inc. must report 300 originations and zero destinations for Cherokee County, zero originations and 300 destinations for Clayton County, 15 originations and 10 destinations for DeKalb County, and 1,010 originations and 1,015 destinations for Fulton County.

(10) **Penalties and interest.**

(a) The penalty provisions applicable to sales and use tax in Title 48 of the Official Code of Georgia are applicable to the transportation services tax. In addition to those penalties, any For-Hire Ground Transport Service Provider that knowingly and willfully violates the requirements of Title 48, Chapter 13, Article 8 of the Official Code of Georgia may be assessed a civil penalty of not more than $10,000.00 in addition to the amount of tax due.

(b) The transportation services tax bears interest in accordance with O.C.G.A. § 48-2-40.

(11) **Vendors' compensation.** When reporting and paying the tax, each For-Hire Ground Transport Service Provider is allowed the following deduction, but only if the return was timely filed and the amount due was not delinquent at the time of payment:

(a) A deduction of three percent of the first $3,000.00 of the total tax reported due on such return; and

(b) A deduction of one-half of one percent of that portion exceeding $3,000.00 of the total tax reported due on such return.

(12) **Periods of limitation for assessment of fees.** Except as otherwise provided in O.C.G.A. § 48-2-49 and Title 48 of the Official Code of Georgia, the transportation services tax may be assessed at any time.

(13) **Refunds.** Tax erroneously or illegally assessed and collected and interest on the tax will be refunded in accordance with O.C.G.A. § 48-2-35 and O.C.G.A. § 48-2-35.1.

(a) For-Hire Ground Transport Service Providers seeking a refund must file a claim electronically.

(b) Purchasers (i.e., passengers) seeking a refund must file the paper Claim for Refund (Form ST-12) and either the Waiver of Vendor's Rights (Form ST-12A) or the Affidavit for Purchaser's Claim for Tax Refund (Form ST-12B).

(c) A refund claim may be filed at any time within three years after the date of the payment of the tax to the Department.

Cite as Ga. Comp. R. & Regs. R. 560-13-3-.01

AUTHORITY: O.C.G.A. Title 48, Chapter 13, Article 8; O.C.G.A. §§ 40-1-100**,** 40-1-151**,** 48-2-12**,** 48-2-35**,** 48-2-35.1**,** 48-2-39**,** 48-2-49**,** 48-8-36**,** 48-2-35.1**,** 48-8-3**,** 48-8-38**.**

HISTORY: Original Rule entitled "Transportation Services Tax" adopted. F. Mar. 25, 2022; eff. Apr. 14, 2022.