Rules and Regulations of the State of Georgia

Department 351 GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Current through Rules and Regulations filed through May 10, 2024

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ADMINISTRATIVE HISTORY

The **Administrative History** following each Rule gives the date on which the Rule was originally filed and its effective date, as well as the date on which any amendment or repeal was filed and its effective date. Principal abbreviations used in the Administrative History are as follows:

f. - filed

eff. - effective

R. - Rule (Abbreviated only at the beginning of the control number)

Ch. - Chapter (Abbreviated only at the beginning of the control number)

ER. - Emergency Rule

Rev. - Revised

Note: Emergency Rules are listed in each Rule's Administrative History by Emergency Rule number, date filed and effective date. The Emergency Rule will be in effect for 120 days or until the effective date of a permanent Rule covering the same subject matter superseding this Emergency Rule is adopted, as specified by the Agency.

Chapters 351-1 entitled "Organization," 351-2 entitled "Definitions," 351-3 entitled "Applications," 351-4 entitled "Class 1 and Class 2 Productions Licensees," 351-5 entitled "Seed-to-Sale Tracking," 351-6 entitled "Dispensing Licensees," 351-7 entitled "Independent Laboratories," 351-8 entitled "Enforcement" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rules 351-2-.01, 351-3-.02, 351-4-.02, .06, .07, .08, .09, .12, 351-6-.01, .02, .05, .09, 351-7-.01, .05, .07, .08, .09 amended. F. Nov. 9, 2023; eff. Nov. 29, 2023.

Chapter 351-1. ORGANIZATION.

Rule 351-1-.01. Organization of the Commission.

(1) The Georgia's Hope Act provides that the Georgia Access to Medical Cannabis Commission ("GMCC" or the "Commission"), a State of Georgia executive branch agency, is created to protect public health, safety, and welfare, and to provide for the regulated production, growing, manufacturing, and dispensing of products in Georgia for the lawful access to medical cannabis by patients on the Georgia Low-THC Oil Patient Registry.

(2) The Georgia's Hope Act further dictates the Commission's composition, methods of appointment, and terms of office. The Act specifies Commission functions and duties thus providing for the implementation of the Georgia's Hope Act through the adoption of rules and regulations.

(3) The Commission receives, reviews, and adjudicates complaints with regard to its licensees, licensee conduct, cannabis, and products regulated by the Commission.

(4) The public may obtain information from and submit requests to the Executive Director. The contact information for the GMCC Executive Director may be obtained from the Commission's website at www.gmcc.ga.gov.

Cite as Ga. Comp. R. & Regs. R. 351-1-.01
Authority: O.C.G.A. §§ 16-12-202, 16-12-203, 16-12-210, 50-13-3.
History. Original Rule entitled "Organization of the Commission" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-1-.02. Meetings, Officers, Duties.

(1) The Commission shall meet as set forth in Code Section 16-12-202.

(2) A majority of the seven (7) Commission Members shall constitute a quorum.

(3) Annually, the Commission shall elect from its Members a Vice Chair, and may elect additional officers from among its Members as it deems appropriate.

(4) The Chair shall preside at meetings, perform all duties of that office, and appoint Commission Members to serve on committees as created. The Vice Chair shall preside in the absence of the Chair and shall assume the duties of the Chair when necessary.

(5) Meetings of the Commission shall be conducted, to the extent practicable and permissible, in accordance with Robert's Rules of Order, Newly Revised. The Chair of the Commission, or the Member of the Commission acting in such capacity, shall have authority to make rulings regarding procedural matters and issues coming before the Commission.

Cite as Ga. Comp. R. & Regs. R. 351-1-.02
Authority: O.C.G.A. §§ 16-12-202, 16-12-203, 16-12-210, 16-12-224.
History. Original Rule entitled "Meetings, Officers, Duties" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-1-.03. Declaratory Rulings.

(1) A person whose legal rights are affected by the application of any statutory provision or any rule or order of the Commission may petition the Commission to request a declaratory ruling thereon.

(a) The petition shall be sent by certified mail, return receipt requested, addressed to the Executive Director at the Georgia Access to Medical Cannabis Commission with the attention line referencing a petition for declaratory ruling. The contact information for the Executive Director may be obtained from the Commission's website at www.gmcc.ga.gov.

(b) Declaratory rulings shall not be made upon untrue, moot, contingent, or hypothetical facts or situations, but only upon actual facts set forth in the petition requesting a declaratory ruling.

(2) The petition shall be made in writing and include the following:

(a) Name and contact information of the petitioner;

(b) The notarized signature of the petitioner;

(c) The full text of the statute, rule, or order of the Commission upon which a ruling is requested;

(d) All pertinent facts and evidence necessary to make a ruling;

(e) The petitioner's contention, if any, as to the applicability of the aforesaid statute, rule, or order with citations of legal authorities, if any, that authorize, support, or require a ruling in accordance therewith;

(f) A statement, setting forth in detail, the petitioner's interest in the requested ruling, including how and why the petitioner is uncertain with respect to his or her rights in the matter; and

(g) Any legal authorities relevant to the requested ruling not provided pursuant to any of the other paragraphs of this subsection.

(3) Within thirty (30) days of the date of filing such petition, the Commission shall issue such declaratory ruling, provided, however, that:

(a) The Chair of the Commission may issue an order to extend such thirty (30) day period stating the reason for such extension.

(b) If it is determined that the requisites for a declaratory ruling are not present, then the Commission shall issue a written explanation for such determination.

(4) The date of filing shall be the date received by the Commission office.

(5) The Commission shall not be required to render a declaratory ruling if it relates to an investigation pending before the Commission.

(6) If the petition requests a declaration as to the applicability of an order of the Commission, then the petitioner shall serve a copy of the petition on all parties to the case.

Cite as Ga. Comp. R. & Regs. R. 351-1-.03
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 50-13-11.
History. Original Rule entitled "Declaratory Rulings" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-1-.04. Petition for Promulgation, Amendment, or Repeal of Rules.

(1) Each petition for promulgation, amendment, or repeal of rules shall be submitted in writing to the Commission. The petition shall be verified under oath by the petitioner and shall include:

(a) The name, address, and contact information of the petitioner;

(b) The full text of the rule requested to be amended with the petitioner's proposed changes or desired language, the citation and full text of the rule desired to be repealed, or the full text of the rule desired to be promulgated;

(c) A statement of the reason such rule should be amended, repealed, or promulgated, including a statement of all pertinent existing facts which relate to petitioner's interest in the matter; and

(d) Citations of legal authority, if any, which authorize, support, or require the action requested by the petition.

(2) Within thirty (30) days after receipt of the petition, the Commission shall either deny the petition in writing or initiate rule-making proceedings in accordance with Code Section 50-13-4.

Cite as Ga. Comp. R. & Regs. R. 351-1-.04
Authority: O.C.G.A. §§ 16-12-203, 50-13-9.
History. Original Rule entitled "Petition for Promulgation, Amendment, or Repeal of Rules" adopted. F. Mar. 16,

2023; eff. Apr. 5, 2023.

Rule 351-1-.05. Fees.

(1) All fee payments submitted to the Commission are non-refundable.

(2) Fees shall be paid in U.S. funds; the Commission may require certified funds at its discretion.

(3) The fee schedule shall be made available at the Commission office and on the Commission's website.

(4) Checks returned for insufficient funds will be addressed, as set forth in Code Section 16-9-20, and the Commission shall assess a processing fee, as outlined on the fee schedule, for any returned check, money order, or payment.

(5) Notices for fees due are sent only as a courtesy.

Cite as Ga. Comp. R. & Regs. R. 351-1-.05
Authority: O.C.G.A. §§ 16-9-20, 16-12-203, 16-12-206, 16-12-211, 16-12-212, 16-12-222.
History. Original Rule entitled "Fees" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Chapter 351-2. DEFINITIONS.

Rule 351-2-.01. Definitions.

(1) "Accreditation" means the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks and verifies that the appropriate quality management system is in place.

(2) "Act" means O.C.G.A. Sections 16-12-200 through 16-12-236, as amended, and referred to as "Georgia's Hope Act."

(3) "Action level" means the threshold at or above which the testing of a product sample would result in a failed certificate of analysis for a given analyte.

(4) "Adverse event" means an undesirable experience associated with the lawful use of product in final packaged form where the outcome was death, life-threatening complications, hospitalization, disability or permanent damage, congenital anomaly or birth defect, required intervention to prevent permanent impairment or damage, or any other medical event that required medical treatment.

(5) "Advertise" means, but is not limited to, the act of publicizing, disseminating, soliciting, or circulating visual, oral, or written communication to induce or persuade any person to purchase or consume any specific regulated cannabis. This definition does not include education and consultation provided directly to patients and caregivers regarding product safety information.

(6) "Agent" means a person who is authorized to serve as a representative of an entity and whose signature has binding legal authority of such an entity.

(7) "Analyte" means a chemical, compound, element, bacteria, yeast, fungus, microbial, or toxin for which a product sample is tested by an independent laboratory.

(8) "Applicant" means an entity applying for a license as set forth in Code Section 16-12-200(1).

(9) "Batch" means a quantity of regulated cannabis harvested or produced together at the same time by the same production licensee, the meaning of which shall include the following:

(a) "Harvest batch" means a specific quantity of regulated cannabis grown under the same conditions, and harvested during a specified period of time from specified cultivation space(s) using the same standards.

(b) "Manufactured batch" means a quantity of regulated cannabis produced and manufactured together at the same time, using the same standards.

(10) "Batch number" means the number assigned to each batch of regulated cannabis by a production licensee.

(11) "Cannabinoid profile" means a list of the chemical compounds that are the active constituents of cannabis, which are present in the product.

(12) "Cannabis" means marijuana, hashish, and other substances which are identified as including any parts of the plant family Cannabaceae and including any and all genera, strains, and subspecies, such as cannabis sativa, indica, ruderalis, and any and all derivatives thereof, whether growing or not, the seeds thereof, the resin extracted from any part of such plant, and any compound, salt, derivative, mixture, or preparation of such plant, its seeds, or resin, including tetrahydrocannabinol (THC), cannabidiol, and all other cannabinol derivatives, including its naturally occurring ingredients, whether produced directly or indirectly by extraction.

(13) "Canopy" means the designated area(s) of a production licensee's cultivation space that contains mature, flowering plants at any point in time.

(14) "Caregiver" shall have the same meaning as set forth in Code Section 31-2A-18.

(15) "Certificate of analysis" means the report of analytical testing of product in final packaged form performed and the results obtained by an independent laboratory.

(16) "Child-resistant package" means the special packaging of a product in final package form in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. Section 1471*et seq.*, as amended, and with the rules of the Commission.

(17) "Clone" means regulated cannabis that is produced by asexual reproduction and is a genetic match to the mother plant.

(18) "Commission" or "GMCC" means the Georgia Access to Medical Cannabis Commission created as set forth in Code Section 16-12-202.

(19) "Complainant" means the person who submitted a written complaint to the Commission alleging violations of state laws, rules, and/or regulations by an entity or person.

(20) "Concentrate" means a condensed accumulation of cannabis, having a greater proportion of cannabinoids and terpenes than those that are naturally occurring in cannabis.

(21) "Contaminant" means any pollutant, physical, chemical, biological, or radiological substance or matter found in the production of regulated cannabis.

(22) "Contractor" means a third-party person or entity performing work for a licensee or registrant under contractual agreement directly associated with the operations and activities regulated by the Commission.

(23) "Corrective action plan" means the plan created by a licensee or registrant detailing how they will correct any deficiencies or violations found during an inspection.

(24) "Cultivation space" means the measured canopy for the indoor production of regulated cannabis and equipped with locks or other security devices that allow access only by an authorized person, but which does not include propagation or vegetative spaces, ancillary spaces, and aisles between grow spaces, as set forth in Code Sections 16-12-211 and 16-12-212.

(25) "Day" means a calendar day.

(26) "Dispensary" means the retail location of a dispensing licensee. As used throughout the rules of the Commission, the related terms "dispensing licensee" and "dispensing license" refer to such terms as set forth in Code Section 16-12-206(a)(2).

(27) "Duress alarm" means a silent security alarm signal generated by the entry of a designated code into an arming station that signals duress.

(28) "Employee" means, but is not limited to, a person whose duties involve any aspect of the production, research, testing, transportation, or dispensing of regulated cannabis, whether or not compensated for the performance of such duties. This definition does not

apply to the term "employee" as used in these rules when referring to the employees of the Commission.

(29) "Enclosed" means a structure with a floor that is covered securely, or able to be covered securely on all vertical sides and an ultimate horizontal covering affixed on top of said vertical sides.

(30) "Entity" means, but is not limited to, a corporation and foreign corporation, nonprofit corporation and foreign nonprofit corporation, professional corporation and foreign professional corporation, limited partnership and foreign limited partnership, foreign limited liability partnership, and limited liability company and foreign limited liability company as set forth in Code Section 14-2-203.

(31) "Extract" means a preparation that contains the active ingredient(s) of a substance in concentrated form.

(32) "Fence" or "fencing" means a locking barrier, railing, or other upright structure fully enclosing an area of ground to mark a boundary, and to effectively prevent or control access.

(33) "Final packaged form" means product in properly labeled, tamper-evident, child-resistant packaging, including the unique batch number for the purposes of identifying and tracking, ready for dispensing. This definition does not include exit packaging or a shipping container or an outer wrapping used solely for the transport of products in bulk quantity.

(34) "Floor" means the lower inside surface of a structure that serves as a barrier between the native soil and regulated cannabis that is nonporous, impermeable, impervious, waterproof, or otherwise sealed from, covered over, and permanently restrictive to the earth's terranean shell.

(35) "Formulation" means the ingredients, recipe, method of processing in order to be shelf stable, certificates of analysis for any ingredient used, and description of the process in which all ingredients are combined to produce a final form.

(36) "Fully operational" means:

(a) A Class 1 or Class 2 production licensee is active and operational such that its production facility is capable of producing adequate amounts of product in final packaged form to ensure uninterrupted availability at its dispensaries, for a period of thirty (30) days for patients; or

(b) A dispensing licensee is active and operational such that it maintains an adequate on-site inventory of product in final package form to ensure uninterrupted availability of inventory for a period of thirty (30) days for patients.

(37) "Holdup alarm" means a silent alarm signal generated by the manual activation of a device for the purpose of signaling that a robbery is in progress.

(38) "Immature plant" means a non-flowering cannabis plant that is no taller than 8 inches (203.2 mm) from the growing or cultivating medium and no wider than 8 inches (203.2 mm), produced from a cutting, clipping, tissue culture, or seedling that is in a growing or cultivating medium or in a growing or cultivating container.

(39) "Independent laboratory" means a laboratory approved and authorized by the Commission, pursuant to the rules of the Commission, to test product for purposes specified in the Act and the rules of the Commission.

(40) "Indoor" means of or relating to the interior of a building or enclosed structure.

(41) "Ingredient" means a component of regulated cannabis that is:

(a) An inactive ingredient approved by the U.S. Food and Drug Administration ("FDA") cataloged in its current database; the published FDA database is accessible at https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm; or

(b) An active ingredient, substance, or group of substances, which includes, but is not limited to, purified compounds, oils, therapeutic chemicals, oleoresins, essences or extracts, protein hydrolysates, distillates, or isolates.

(42) "Inspection" means an evaluation of facilities, laboratory, testing, records, employees, equipment, operations, methodology, and quality assurance practices conducted by the Commission or its employees for the purpose of ensuring compliance with the requirements of the Act and these rules.

(43) "Labeling" means any display of written, printed, or graphic matter printed on or affixed to any container, wrapper, liner, or insert accompanying the product. This shall include any material or image printed on or attached to the final retail package and bulk package unit.

(44) "Licensee" means any entity with an active license issued by the Commission.

(45) "Low-THC oil" shall have the same meaning as set forth in Code Section 16-12-190.

(46) "Low-THC Oil Patient Registry" means the registration of individuals who have been issued registration cards by the Georgia Department of Public Health.

(47) "Manufacture" shall have the same meaning as set forth in Code Section 16-12-200(13).

(48) "Manufacturing space" means the indoor area utilized to manufacture and package products, including extraction and other related practices applied to harvested plant material.

(49) "Market" or "marketing" means any act or process of promoting or selling products, including, but not limited to, sponsorship of sporting events, point-of-sale advertising, and development of products specifically designed to appeal to certain demographics.

(50) "Minor" shall have the same meaning as set forth in Code Section 39-1-1.

(51) "Minority Business Enterprise" shall have the same meaning as set forth in Code Section 50-5-131.

(52) "Mother plant" means a plant grown for the purpose of being a source of propagative material.

(53) "Package" or "packaging" means any container or wrapper that may be used for enclosing or containing any product. This definition does not include a shipping container or an outer wrapping used solely for the transport of products in bulk quantity to the premises of a licensee, pharmacy, or registrant.

(54) "Panic alarm" means an audible system signal to indicate an emergency situation.

(55) "Patient" means the same as set forth in Code Section 16-12-200(16).

(56) "Perimeter alarm" means a security alarm signal generated by a breach or crossing of, or entry to, the outermost parts or boundary of a premises.

(57) "Pest" means an undesired insect, rodent, nematode, fungus, bird, vector, vertebrate, invertebrate, undesired herbaceous plant, virus, bacteria, or other microorganism (except for microorganisms on or in living humans or other living animals) that is, or is likely to become, injurious, dangerous, or detrimental to health, the environment, or the agricultural environment of the state; provided however, nothing in this definition shall apply to industry recognized beneficial biological control agents.

(58) "Pesticide" means any substance or mixture of substances intended for preventing, destroying, eradicating, repelling, or mitigating any pest.

(59) "Pharmacy" means a pharmacy licensed by the Georgia Board of Pharmacy to dispense low-THC oil and products that have been purchased or received from a licensee.

(60) "Physician" means a person licensed to practice medicine by and in good standing with the Georgia Composite Medical Board as set forth in Code Section 43-34-2.

(61) "Plant waste" means all plant parts including roots, stalks, leaves, stems, flower, trim, or solid plant material and any plant material rendered from the extraction process not used directly for production that have been pruned, trimmed, shucked, or otherwise removed during cultivation, harvest, or manufacturing.

(62) "Premises" means a licensee's or registrant's building(s), together with its real property.

(63) "Produce" means to grow and harvest regulated cannabis to manufacture and create low-THC oil and products in accordance with the Act and these rules.

(64) "Product" shall have the same meaning as set forth in Code Section 16-12-200(15).

(65) "Proficiency testing" means the evaluation, relative to a given set of criteria, of the performance, under controlled conditions, of an independent laboratory in analyzing unknown samples provided by an external source.

(66) "Program participant" means the same as set forth in Code Section 16-12-191(b)(1)(A)(i).

(67) "Propagation space" means an indoor area or facility used for the growing of immature or nonflowering plants including but not limited to: seeds, seedlings, clones or cuttings, tissue culture, and any other propagative means. This definition does not include space used for mother plants which will be used for harvest.

(68) "Quality control" means the set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control for which errors have been reduced to acceptable levels.

(69) "Recall" means the return of product in final packaged form, whether Commission-ordered or licensee-initiated, due to the potential for, or actual occurrence of, adverse events from the use of such product by patients.

(70) "Registrant" means an entity that is approved by the Commission, pursuant to the rules of the Commission, as an independent laboratory for purposes of testing low-THC oil and products and is on the Commission's approved and current list of such approved independent laboratories.

(71) "Regulated cannabis" means all cannabis regulated by the Commission, including, but not limited to, plants and plant material, plant waste, extracts, concentrates, and products.

(72) "Regulated cannabis waste" means the waste related to or directly produced by regulated cannabis.

(73) "Remediation" means the neutralization or removal of any substances or contaminants from product.

(74) "Restricted access area" means a building, room, or other area in a licensee's or registrant's premises where regulated cannabis is grown, cultivated, harvested, weighed, packaged, tested, researched, processed, or stored.

(75) "Sample" means a single or representative part of a batch which is composed of several sample increments.

(a) "Controlled sample" means the official sample of product in final packaged form collected by a sample collector from an independent laboratory, which is used to determine, among other things, official compliance with THC limits.

(b) "Reserve sample" means an internal sample of regulated cannabis taken for purposes of ensuring product quality and making determinations about whether to dispense the product.

(76) "Standard operating procedures" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, process, task, or action.

(77) "Tag" means an approved unique identifier for the purpose of tracking regulated cannabis in the tracking system provided or operated by a Commission-approved vendor.

(a) "Plant tag" means an approved tag attached to each individual plant.

(b) "Product tag" means an approved tag printed on, or attached to, the individual product in final packaged form.

(c) "Bulk package tag" means an approved tag printed on, or attached to, the product batch package for the purpose of storage and transport.

(78) "Tamper-evident" means having one (1) or more indicators of modification which, if breached, missing, or altered, can reasonably be expected to provide visible evidence that tampering has occurred.

(79) "Total THC" means the sum of the percentage by weight of delta-9-tetrahydrocannabinolic acid (D9-THCA) multiplied by 0.877, plus the percentage by weight of delta-8-tetrahydrocannabinol (D8-THC), plus the percentage by weight of delta-9-tetrahydrocannabinol (D9-THC), plus the percentage by weight of exo-tetrahydrocannabinol (Exo-THC), plus the percentage by weight of delta-10-tetrahydrocannabinol (D10-THC). I.e., Total THC = (% D9-THCA * 0.877) + % D8-THC + % D9-THC + % Exo-THC + % D10-THC.

(80) "Tracking system" or "Commission-approved tracking system" means a seed-to-sale tracking system provided or operated by a vendor approved by the Commission to track regulated cannabis that is grown, processed, manufactured, transferred, transported, stored, dispensed, recalled, or disposed of.

(81) "Transport" and "transportation" means to move or transfer product from one location to another.

(82) "Universal symbol" means the universal cannabis product symbol authorized by the Commission for use on product containers, packaging, and labeling.

(83) "Visitor" means a non-employee or contractor, present on a licensee's or registrant's premises for a specific purpose or task not directly related to the production of regulated cannabis, dispensing of product in final packaged form, or testing of regulated cannabis and product in final packaged form.

(84) "Visitor identification badge" means a physical badge issued to a visitor used to easily verify the status of a person while on a licensee's or registrant's premises.

Cite as Ga. Comp. R. & Regs. R. 351-2-.01
Authority: O.C.G.A. §§ 16-12-200, 16-12-203, 16-12-206, 16-12-210.
History. Original Rule entitled "Definitions" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Chapter 351-3. APPLICATIONS.

Rule 351-3-.01. Class 1 and Class 2 Production License Applications.

(1) An application for a Class 1 or Class 2 production license shall only be accepted during an open application period announced by the Commission.

(2) An applicant for a Class 1 or Class 2 production license shall submit the following to the Commission:

(a) A complete application as required by the Commission; and

(b) The required non-refundable application fee, as listed on the fee schedule, payable in certified funds.

(3) Applications for a Class 1 or Class 2 production license shall meet the requirements outlined in the Commission's Competitive Application Request for Proposals and all requirements in the Commission's application instructions, mandatory requirements, addenda, and exhibits.

(4) The applicant for a Class 1 or Class 2 production license shall submit with their application sufficient documentation to prove that the applicant possesses one (1) of the following:

(a) A $1.5 million bond;

(b) An irrevocable letter of credit; or

(c) Other comparable surety approved by the Commission.

(5) An application for a Class 1 or Class 2 production license will not be accepted from any owner or entity holding a Class 1 or Class 2 production license who is seeking to gain ownership interest in a second production license.

(6) If an initial application contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

Cite as Ga. Comp. R. & Regs. R. 351-3-.01
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-211, 16-12-212, 16-12-219, 16-12-221.
History. Original Rule entitled "Class 1 and Class 2 Production License Applications" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-3-.02. Dispensing License Applications.

(1) Only Class 1 or Class 2 production licensees are eligible to apply for a dispensing license as set forth in Code Section 16-12-206.

(2) Applications for dispensing licenses and other required information as set forth in this rule shall only be submitted during an open application period announced by the Commission.

(3) If an applicant wishes to apply for more than one dispensing license during the same application period, then such applicant shall submit a separate application for each proposed dispensary.

(4) To apply for a dispensing license, an applicant shall submit all of the following to the Commission:

(a) A complete dispensing license application as required by the Commission.

(b) The required non-refundable application fee, as listed on the fee schedule.

(c) The Class 1 or Class 2 production license name and number associated with the application.

(d) The business information about the dispensing license applicant, including:

1. The legal business name, any trade name(s), telephone number, and electronic mail address for such applicant;

2. The type of business entity;

3. Copies of the articles of incorporation, articles of organization, or other organizational documents as filed with the Georgia Secretary of State; and

4. The name, telephone number, and electronic mail address of the applicant's agent, and if different than the agent, a point of contact for day-to-day operational matters.

(e) Location information about the proposed dispensary, including:

1. The physical address, any suite number(s), city, and county;

2. The executed lease agreement, purchase agreement, or other written agreement for the applicant's use of the location for such dispensary;

3. An attestation that such dispensary complies with Code Section 16-12-215(a), and if applicable, documentation from the local government for any variance or other local approval as to location of such dispensary;

4. The proximity to all dispensaries and to all proposed dispensaries identified in other pending applications submitted by such applicant; and

5. A description explaining how the proposed dispensary is needed to serve patients in and around the geographic area of such dispensary.

(f) Information about the dispensing license applicant's agent, owner(s), and officer(s), including:

1. Current title(s) of such persons;

2. Whether any such is an owner, as defined in Georgia's Hope Act, in any other entity licensed by the Commission or in any cannabis-related license issued by another state; and

3. An attestation that such persons can either demonstrate a lack of a felony conviction within the previous ten years or that a felony conviction within the previous ten years has been expunged, the person has been pardoned, or the person had his or her civil rights restored.

(g) Information about the applicant's employees for the proposed dispensary, including:

1. The description of job titles and duties of employees;

2. The reporting and management structure of employees; and

3. An attestation that such employees can either demonstrate a lack of a felony conviction within the previous ten years or that a felony conviction within the previous ten years has been expunged, the person has been pardoned, or the person had his or her civil rights restored.

(h) A copy of floor- and site-specific plans and renderings showing the interior and exterior of the proposed dispensary, drawn to scale with square footage clearly illustrated. The site-specific plans shall include and identify all of the following:

1. The area of the retail point of dispensing;
2. Restricted access areas;
3. Patient consultation room(s);
4. Other areas and rooms; and
5. An enclosed receiving bay or other secured delivery area where product in final packaged form will be received.

(i) Information about the involvement of any of the following:

1. Minority business enterprises as defined in Code Section 50-5-131, either as co-owners of the business or as significant suppliers of goods and services for the business;
2. Minority or women owned businesses;
3. Georgia agricultural businesses; and
4. Military veterans.

(j) An affidavit for lawful presence signed and sworn to by the applicant's agent, along with a copy of such agent's secure and verifiable document, as required by Code Section 50-26-1 and Code Section 50-36-2.

(k) An attestation that the application for a dispensing license is true and current at the time of submission.

(l) Any other documentation requested by the Commission or its employees to determine the dispensing license applicant's suitability for licensure or to ensure public health and safety.

(5) If an application for a dispensing license contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

(6) An application for a dispensing licensee may be denied or not processed for failure to meet requirements set forth in the Act and these rules.

(7) If an application for a dispensing license is approved, then the applicant shall submit the required dispensing license fee, as listed on the fee schedule, to the Commission within thirty (30) days from the issuance of the respective dispensing license.

Cite as Ga. Comp. R. & Regs. R. 351-3-.02
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-215, 16-12-223.
History. Original Rule entitled "Dispensing License Applications" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-3-.03. Renewals.

(1) The responsibility to renew a license on or before the expiration date remains with the respective licensee.

(2) A license expires upon the expiration date if a licensee has not filed a renewal application and remitted all of the required application, where applicable, and payment of the license fees prior to the expiration date.

(3) To apply for renewal, a licensee shall submit a complete application and the required non-refundable annual renewal fee, as listed on the fee schedule.

(a) A licensee shall apply for the renewal prior to the expiration date.

(b) The licensee may submit a renewal application, once the renewal period opens, prior to the expiration of its respective license.

(c) When applying for a renewal, licensees shall update, as needed, all information submitted in the initial application or the last renewal application, whichever was last approved by the Commission. Licensees shall include all approved changes and modifications to such application, if applicable to the respective licensee.

(d) Once the licensee submits a complete and timely application for renewal, the license remains in active or valid status pending renewal until the Commission renews the license. The Commission hereby delegates the authority and responsibility to determine whether applications for renewal are approved, or denied, to the GMCC Executive Director.

(4) If a renewal application contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

(5) A licensee who does not submit a complete and timely renewal application shall:

(a) Cease all licensed operations at all premises upon expiration of the respective license; and

(b) Dispose of any regulated cannabis by the date specified by the Commission.

(6) The licensee is responsible for payment of all unpaid and undisputed fines by the time of renewal. A license shall not be renewed if the licensee has any unpaid and undisputed fines.

(7) Class 1 and Class 2 production licensees are required to renew annually during the renewal period established by the Commission and follow any additional terms of renewal as stated in their license contracts. In addition to such contract terms, Class 1 and Class 2 production licensees shall also submit the following with their renewal applications:

(a) Proof that one (1) of the following has been maintained as an operational requirement for the year:

1. A $1.5 million bond;

2. An irrevocable letter of credit; or

3. Other comparable surety approved by the Commission.

(b) Detailed records documenting the involvement of minorities and women in:

1. Ownership;

2. Leadership or management positions;

3. Employment; and

4. Contracts:

(i) With contractors; and

(ii) With suppliers.

(8) A dispensing license may renew on the condition that the requisite Class 1 or Class 2 production license has an active status with no unpaid and undisputed fines with the Commission. Unless otherwise provided by law, the expiration of a Class 1 or Class 2 production license shall automatically result in the expiration of all dependent dispensing licenses.

Cite as Ga. Comp. R. & Regs. R. 351-3-.03
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212, 16-12-221.
History. Original Rule entitled "Renewals" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Chapter 351-4. CLASS 1 AND CLASS 2 PRODUCTION LICENSEES.

Rule 351-4-.01. Production Pre-operational Inspections.

(1) A production licensee shall submit to pre-operational progress inspections conducted by the Commission or its employees to ensure and confirm that the production licensee is fully operational as required by Code Section 16-12-223(a)(5).

(2) Prior to the inspection to be deemed fully operational, a production licensee shall submit the following to the Commission:

(a) A satisfactory report of full compliance with, and completion of, all applicable public safety inspections required by local, state, and federal jurisdictions, including, without limitation, fire, building, health, and air quality inspections; and

(b) A list of all plant strains and cultivars which will be propagated and/or cultivated at the premises, which shall be maintained at the premises during the term of the production license contract and provided to the Commission or its employees upon request.

(3) Failure of a production licensee to be fully operational within twelve (12) months of the date the license is awarded will result in the revocation of the license and any associated dispensing licenses.

Cite as Ga. Comp. R. & Regs. R. 351-4-.01
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212, 16-12-217, 16-12-223.
History. Original Rule entitled "Production Pre-operational Inspections" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-4-.02. General Production License Rules.

(1) A production licensee shall conduct activities and operations as represented in the respective license contract awarded by the Commission. Such license contract includes compliance with the following:

(a) Exhibits to the license contract;

(b) License contract amendments agreed to in writing between the licensee and the Commission;

(c) The Act, as amended;

(d) The Commission's rules and regulations, as promulgated and amended; and

(e) The Commission's policies and procedures, as approved.

(2) A production licensee shall be fully operational within twelve (12) months from the date of which the respective Notice of Award is issued. Failure to remain fully operational during licensure shall result in citations and fines up to and including revocation.

(3) A production licensee shall grow cannabis and produce and manufacture products only at the physical location as listed on the respective license contract. The licensee shall prominently display the following to be viewed by individuals entering the premises:

(a) The production license issued by the Commission;

(b) Any signage required by the Act and these rules; and

(c) The laws and these rules; provided, however, that signage approved by the Commission may be displayed in lieu of a complete copy of the laws and rules.

(4) A production licensee may sell its products in final packaged form to a dispensing licensee or pharmacy so that such dispensing licensee or pharmacy may dispense such products to patients and caregivers in accordance with Georgia's Hope Act and applicable state rules and regulations.

(5) A production licensee shall not:

(a) Dispense products in final packaged form at the premises;

(b) Give away or receive free or complimentary regulated cannabis;

(c) Use the Commission's name or logo on any sign at the premises, on the business' website, or in any advertising or social media, except to the extent that information is contained on the proof of licensure or is contained in part of warnings, signage, or other documents required by these rules;

(d) Sublet any portion of a premises; or

(e) Use pesticides other than those certified organic by the Organic Materials Review Institute or another similar standards organization.

(6) All rooms on the premises shall be identified on the respective doors or the exterior of such rooms so as to indicate the purposes of such rooms.

(7) A production licensee shall continue to provide the Commission and its employees with current contact information and notify the Commission and its employees, in writing, of any changes to the mailing addresses, phone numbers, or electronic mail addresses.

(8) A production licensee shall notify the Commission and its employees within ten (10) days of the initiation and/or conclusion of any new citations, fines, judgments, lawsuits, legal

proceedings, charges, or government investigations, involving cannabis-related operations, whether initiated, pending, or concluded, against the licensee and its owners in Georgia and in any other state.

(9) A production licensee shall create and maintain employee policies and procedures, including, at a minimum, the following:

(a) Code of ethics;

(b) Whistle-blower policy;

(c) A policy which notifies persons with disabilities of their rights, which includes provisions prohibiting discrimination and providing reasonable accommodations; and

(d) All applicable state and federal Department of Labor procedures and posting of appropriate placards.

(10) A production licensee shall have a continuing responsibility to ensure that persons employed by such licensee or who otherwise participate in the business activities of such licensee are not prohibited by Georgia's Hope Act from such employment or participation.

(11) A production licensee shall take reasonable measures and precautions to ensure all employees working with direct access to regulated cannabis use hygienic practices while on duty for the prevention of contamination, including:

(a) Ensuring handwashing facilities are located within all production spaces, equipped with effective hand-cleaning and sanitizing preparations and sanitary towel service or electronic drying devices;

(b) Requiring employees wash hands thoroughly with soap before starting work and at any other time when hands have become soiled or contaminated; and

(c) Responding reasonably and promptly to reports or concerns of any employee who has been diagnosed with, or has displayed, or experienced symptoms of, a contagious illness or a communicable disease.

(12) Common areas on the production licensee premises, including but not limited to, a designated area for the consumption of food and beverages for employees, toilet and lavatory facilities, office or meeting space, or a lobby shall conform to the following requirements:

(a) The common areas shall be separated from the restricted access areas by floor-to-ceiling-high walls to prevent the spread of hair, skin, dirt, dust, and debris and to reduce the spread of moisture, mold, bacteria, and other contaminants;

(b) The door separating the common areas from the restricted access areas shall have secure electronic controls to restrict access; and

(c) Toilet and lavatory facilities shall be equipped with toilet tissue, soap dispenser with soap or other hand cleaning material, sanitary towels or drying device and at least one (1) waste receptacle.

Cite as Ga. Comp. R. & Regs. R. 351-4-.02
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212, 16-12-219, 16-12-223.
History. Original Rule entitled "General Production License Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-4-.03. Security.

(1) A production licensee is responsible for the security of all regulated cannabis on the premises, including providing adequate safeguards against theft or diversion of regulated cannabis.

(2) A production licensee shall have a comprehensive security system to prevent and detect diversion, theft, or loss of regulated cannabis utilizing commercial grade equipment, which shall, at a minimum, include:

(a) An alarm system which provides:

1. A perimeter alarm;

2. A duress alarm;

3. A panic alarm;

4. A holdup alarm; and

5. Sensors at all possible points of entry into the facility to include all doors, windows, roof hatches, and skylights.

(b) A surveillance system that includes:

1. Motion detectors;

2. Video cameras in all areas that contain regulated cannabis and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

(i) A production licensee shall direct video cameras at:

(I) All safes and vaults;

(II) All areas where regulated cannabis is being propagated, cultivated, harvested, manufactured, stored, or handled;

(III) Regulated cannabis waste processing and storage areas;

(IV) All restricted access areas;

(V) The entrance to the video surveillance room;

(VI) Shipping and receiving area;

(VII) All parking lots; and

(VIII) Entry and exit points to ensure that cameras are angled to capture a clear and certain identification of all persons entering or exiting the facility and at all perimeter controlled access points.

(ii) Video cameras shall operate twenty-four (24) hours a day, seven (7) days a week, recording interior and exterior, which the production licensee shall make available for viewing upon request by the Commission or its employees and shall retain all recordings for at least forty-five (45) days.

(I) Editing or altering the recordings at any point is strictly prohibited.

(II) The physical media or storage device on which surveillance recordings are stored shall be secured in a manner to protect the recording from decay, tampering, or theft.

(III) Any failed component of the video surveillance recording system shall be repaired within twenty-four (24) hours unless notice is provided to the Commission and its employees. The GMCC Executive Director may issue an extension to allow additional time for repair(s).

(iii) All video cameras shall:

(I) Have the ability to produce a clear, color, still photo either live or from a recording;

(II) Have a minimum digital resolution of 2560 x 1440 pixels or pixel equivalent for analog;

(III) Record continuously twenty-four (24) hours per day, at a minimum of thirty (30) frames per second;

(IV) Utilize a failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the production licensee within five (5) minutes of the failure, either by telephone, electronic mail address, or text message;

(V) Have a date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

(VI) Remain operational during a power outage.

3. Surveillance recording and monitoring equipment shall be housed in a designated, locked, and secured room or other enclosure with restricted access.

(c) Sufficiently lit outside perimeter to facilitate surveillance by employees, security, or law enforcement.

1. External lighting shall be equipped to automatically activate and remain operational in the event of a power outage.

2. External lighting shall be equipped with protective devices to prevent breakage.

(d) The use of non-residential door locks and secure electronic access by each person at all restricted access points and all entry and exit points.

(3) A production licensee shall utilize perimeter fencing in order to establish a boundary and provide security of the premises. The fencing shall, at a minimum, meet the following requirements:

(a) Have a height of at least seven (7) feet;

(b) Utilize wood or metal posts securely anchored in the ground;

(c) The bottom of the fence shall be no more than three (3) inches from the ground;

(d) There may be a maximum of three (3) inches between any location at which fencing abuts, or is adjacent to, a permanent structure;

(e) Only utilize gated, locking, and controlled entry and exit points;

(f) Incorporate secure access measures as a part of the production facility's security system;

(g) All gates through which vehicles and/or personnel enter or exit shall be monitored at all times by cameras that meet the requirements as set forth in this rule; and

(h) Fencing systems shall be regularly inspected for integrity, functionality, and signs of damage, and repaired within twenty-four (24) hours.

(4) Fences shall be constructed of high quality, durable materials. Acceptable materials include:

(a) Chain-link;

(b) Wood;

(c) Brick;

(d) Masonry block;

(e) Stone;

(f) Tubular steel;

(g) Wrought iron;

(h) Vinyl, composite, or recycled materials;

(i) Other manufactured material or combination of materials commonly used for fencing; and

(j) Other materials of similar quality and durability, but not listed herein, may be used upon approval by the Commission and as set forth in these Rules.

(5) A production licensee shall utilize security personnel who are licensed under the Georgia Private Detective and Security Agencies Act, O.C.G.A. Sections 43-38-1 through 43-38-16, as amended, for the licensee's premises.

(6) A production licensee shall establish an adequate facility maintenance system to ensure both the interior and exterior of the licensee's building structures are maintained to ensure security, safety, and sanitation.

(7) A production licensee shall ensure the surrounding premises are adequately maintained and manicured in order to prevent the introduction and spread of pests and contaminants into the facility and to deter possible criminal activity.

(8) A production licensee shall keep all security system components and equipment in good-working order and shall test such system quarterly.

(a) A production licensee shall keep a log of all security systems tests completed, which shall include:

1. Date(s) the security systems tests were completed;

2. Name(s) of the individual(s) who completed the testing;

3. Details regarding tests completed; and

4. Any issues found during the testing.

(b) The security system testing log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system testing log shall be provided upon request to the Commission or its employees.

(9) A production licensee shall notify the Commission and its employees, within twenty-four (24) hours, of any security system failure.

(a) The production licensee shall keep a log of any security system failure.

(b) The security system failure log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system failure log shall be provided upon request to the Commission or its employees.

(10) While on the premises, all production licensee employees shall wear a form of identification that clearly identifies them, including their position on the premises. An employee identification shall contain:

(a) The name of the employee;

(b) Job title;

(c) The date of issuance;

(d) The expiration date, which shall not exceed the quinquennial expiration date of the production license;

(e) The name of the production licensee;

(f) The license number of the production license;

(g) An alphanumeric identification number that is unique to the employee;

(h) A photographic image of the employee; and

(i) Security measures to prevent unauthorized duplication of the identification.

(11) Upon termination of an employee, a production licensee shall:

(a) Obtain and destroy the terminated employee's identification within twenty-four (24) hours of termination of employment;

(b) Immediately disable the employee's electronic access; and

(c) Immediately disable the employee's access to the Commission-approved tracking system and all other security access systems.

(12) A production licensee employee shall escort and monitor visitors at all times.

(a) A visitor shall visibly display the visitor identification badge at all times the visitor is on the premises.

(b) A visitor shall return the visitor identification badge to a production licensee employee upon exiting the premises.

(c) A production licensee shall maintain a current and accurate inventory of all visitor identification badges.

(d) Any loss of a visitor identification badge shall be documented separately and maintained with the visitor log.

(e) A production licensee shall log all visitors, contractors, and local, state, and federal government officials, and shall maintain a log that includes the date, time in and out, and purpose of the visit. The log shall:

1. Retain a photocopy of the government-issued photo identification for each individual in a secure location with controlled access;

2. Include the name and identification number of the employee escorting the individual;

3. Be maintained for at least three (3) years; and

4. Be made available to the Commission or its employees upon request.

(f) A visitor shall not handle any regulated cannabis.

(13) A production licensee shall ensure that only authorized individuals access the restricted access areas of the premises.

(a) Prior to entering a restricted access area, all authorized individuals shall obtain and wear an identification badge from management employees of the licensee which shall remain visible while in the restricted access area.

(b) A production licensee shall maintain a record of all authorized individuals, who are not employees of the licensee, who enter the restricted access areas. The record shall include:

1. The name of the individual;

2. The individual's employer;

3. The reason the individual entered the restricted access area; and

4. The date and times the individual entered and exited the restricted access area.

5. The restricted access areas log shall be maintained for at least three (3) years.

6. These records shall be made available to the Commission or its employees upon request.

(c) A production licensee shall not prohibit the Commission or its employees, or local, state, or federal law enforcement from entering a restricted access area upon presentation of official credentials identifying them as such.

(d) All restricted access areas shall have a sign posted on or near the door indicating that access to the area is restricted to authorized individuals or employees only.

(14) A production licensee shall keep a surveillance equipment maintenance activity log on the premises to record all service activity and equipment updates.

(a) The log shall include, at a minimum, the following:

1. The date of the service and maintenance activity;

2. A summary of the service and maintenance activity performed; and

3. The name, signature, and title of the individual(s) who performed the service and maintenance activity.

(b) The surveillance equipment maintenance activity log shall be maintained for a period of at least three (3) years.

(c) The surveillance equipment maintenance activity log shall be provided upon request by the Commission or its employees.

(15) A production licensee shall maintain documentation in an auditable form for a period of at least three (3) years:

(a) Any alarm activation or other event which requires a response by public safety employees; and

(b) Any unauthorized breach of security.

(16) A production licensee shall notify the Commission and its employees as well as local law enforcement within twenty-four (24) hours any time there is a suspected loss of regulated cannabis and shall cooperate fully with any investigation into any of the following:

(a) Diversion, theft, loss, or any other criminal activity by an agent or employee of the licensee pertaining to the operations of the licensee;

(b) Suspected diversion, theft, loss, or any other criminal activity by an individual not employed by the licensee; or

(c) Loss or unauthorized alteration of records related to regulated cannabis.

(17) A production licensee shall establish, maintain, and follow standard operating procedures, for the security of all regulated cannabis on the premises and during all transport, including providing adequate safeguards against theft or diversion of regulated cannabis.

Cite as Ga. Comp. R. & Regs. R. 351-4-.03
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-211, 16-12-212, 16-12-217.
History. Original Rule entitled "Security" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-4-.04. Propagation and Cultivation Operations.

(1) Propagation space shall be used for growing immature and non-flowering plants only.

(a) Mother plants in this space shall not be utilized for harvest but for propagation only.

(b) Immature or nonflowering plants in this space shall not be calculated in cultivation space.

(c) Plant material located in the propagation space intended for harvest and production shall be entered in the Commission-approved tracking system.

(2) All cultivation space shall be contained within the canopy as set forth in Code Sections 16-12-211(a)(1) and 16-12-212(a)(1).

(a) Square footage of canopy shall be measured using clearly identifiable boundaries of all space(s) that will contain mature flowering plants at any point in time, including all space(s) within the boundaries;

(b) The canopy may be noncontiguous, including vertical space, but each unique space included in the total canopy calculation shall be separated by an identifiable boundary that includes, but is not limited to, tables, benches, shelves, or interior walls;

(c) If mature flowering plants are being cultivated using a shelving system, the surface area of each level shall be included in the total calculation of the canopy;

(d) Canopy is measured starting from the outermost point of a plant on the perimeter of a dedicated growing space and continuing around the outside of all plants located within the dedicated growing space; and

(e) This space shall be separate from the manufacturing space.

(3) A production licensee shall submit to the Commission and its employees a list of any new plant strains and cultivars which will be propagated and/or cultivated at the premises at least ten (10) days prior to entry into the Commission-approved tracking system. The list shall be maintained at the premises during the term of the license contract and shall be provided upon request to the Commission or its employees.

(4) All pesticides applied to plants shall be:

(a) Certified organic as set forth in Code Sections 16-12-211(b)(6) and 16-12-212(b)(6);

(b) Documented in a pesticide application log, which shall be maintained for a minimum of twelve (12) months, with the following information:

1. Date;

2. Time;

3. Location, bench, or growing chamber;

4. Batch number;

5. Chemical name and active ingredient(s); and

6. Name and employee identification number of pesticide applicator(s).

(c) Stored separately from regulated cannabis, in a designated storage area, which shall have a door separating the secured area with locked access to provide authorized access only; and

(d) Used in a manner consistent with the manufacturer's label.

(5) All pesticides and other chemicals present on the premises not directly related to cultivation or propagation shall be securely stored in a designated area, separate from all regulated cannabis and all pesticides used for production.

(6) A production licensee shall establish, maintain, and follow standard operating procedures for cultivation and propagation operations, which shall include:

(a) Adherence to all recommended personal protective equipment guidelines utilized on the premises.

(b) Sanitation procedures for:

1. The handling of infested or infected plant material prior to disposal;

2. Growing space(s) between harvests; and

3. Tools involved in the growth of plant material in all dedicated and/or separate cultivation or propagation spaces.

(c) Storage procedures for:

1. Growing media;

2. Growing containers;

3. Growing media inputs; and

4. Harvested regulated cannabis prior to being manufactured into products, which shall be:

(i) Separated according to batch and appropriately labeled;

(ii) Stored in a secure enclosed container;

(iii) Located in designated, secure areas of the facility with secure electronic access required; and

(iv) Maintained with adequate ventilation, climate, and humidity control.

(d) A water management plan that includes:

1. Disposal of wastewater generated during the cultivation of regulated cannabis in a manner that complies with applicable local, state, and federal laws and regulations;

2. Water storage;

3. Water recycling and re-treatment;

4. Stormwater collection and greywater reclamation; and

5. Runoff and discharge.

(e) An odor and air pollution reduction plan that may include the use and regular maintenance of:

1. Air filtration systems, both internal and exhaust, such as a high efficiency particulate air or carbon;

2. Air scrubbers;

3. Air purification systems;

4. Ozone generators;

5. Internal air quality practices such as plastic door curtains or negative pressure;

6. Odor neutralizers; and

7. High intensity ultraviolet light.

(f) A sensor system which detects when any gas, utilized in or emitted as a result of the production process, reaches an unsafe level and can signal an alert, if applicable.

(g) The preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases;

2. Quarantined pests;

3. Invasive alien species;

4. Harmful biological agents; and

5. Living modified organisms.

(h) A plan for cultivation and propagation spaces to be routinely inspected by employees for pests and documented in a scouting log with the following information:

1. Date;

2. Location, bench, or growing chamber;

3. Findings; and

4. Name and employee identification number of the scout(s).

(7) The cultivation and propagation standard operating procedures shall be:

(a) Maintained on the premises;

(b) Provided to every owner and employee who performs a task, or set of tasks, that are referenced in the standard operating procedures and documentation of training;

(c) Provided to the Commission or its employees upon request; and

(d) Made available during an inspection by the Commission or its employees.

Cite as Ga. Comp. R. & Regs. R. 351-4-.04
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-211, 16-12-212, 16-12-213.
History. Original Rule entitled "Propagation and Cultivation Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-4-.05. Production Operations.

(1) A production licensee shall ensure all phases of production take place in designated, restricted access areas only.

(2) A production licensee shall document the formulation and size for each batch produced.

(3) All ingredients, other than those naturally occurring in or otherwise derived from cannabis, shall be approved by the U.S. Food and Drug Administration.

(4) Each batch shall meet the following requirements:

(a) Plant tags and plant strains shall be easily identifiable and legible.

(b) Each immature plant batch shall consist of no more than one hundred (100) immature plants.

(c) After a tagged plant is harvested, it is part of a harvest batch.

(d) A harvest batch shall be easily distinguishable from other harvest batches until the batch is manufactured into products.

(e) Once the harvest batch is manufactured into products, it is part of a manufactured batch.

(5) A production licensee shall submit a list of all products and their formulations, which will be manufactured on the premises, to the Commission and its employees within thirty (30) days of licensure. The list shall be maintained on the premises during the term of the license contract and provided to the Commission or its employees upon request.

(6) A production licensee shall ensure that all regulated cannabis is stored in a designated, locked, and secured room or enclosure with restricted access.

(7) A production licensee shall ensure that all recalled products for remediation are stored in a designated, locked, and secured room or enclosure with restricted access and are segregated from other products.

(8) A production licensee shall ensure that regulated cannabis waste is:

(a) Stored in a securely locked and enclosed container that is securely fastened to a permanent structure so that the receptacles cannot be moved;

(b) Located in a restricted access area designated for regulated cannabis waste; and

(c) Disposed, documented, and managed in accordance with all local, state, and federal regulations.

(9) Regulated cannabis waste shall be disposed of by:

(a) Rendering all regulated cannabis waste unusable and unrecognizable or irretrievable prior to the waste leaving the premises;

(b) Transferring the regulated cannabis waste securely to a processor for recycling, reuse, or composting; or

(c) A Commission approved plan for onsite composting, burial or other means of disposing of regulated cannabis waste.

(10) A production licensee shall establish, maintain, and follow standard operating procedures for production operations, which shall include processes for the following:

(a) Monitoring, recording, and regulating:

1. Temperature;

2. Humidity;

3. Ventilation; and

4. Lighting.

(b) Storage and handling requirements of all fuel, chemicals, pesticides, solvents, and any other hazardous materials utilized on the premises.

(c) Extraction including, but not limited to, one (1) or more of the following extraction methods:

1. Using hydrocarbons N-butane, isobutane, propane, heptane, or other solvents or gasses exhibiting low to minimal potential human health related toxicity approved by the Commission. These solvents shall be of at least ninety-nine percent (99%) purity and a production licensee shall:

   (i) Use the solvents in a professional grade, closed-loop extraction system designed to recover the solvents;

   (ii) Work in a spark-free environment with proper ventilation;

   (iii) The hydrocarbon extraction system or room shall have sensors which detect when hydrocarbon levels reach unsafe levels and signal an alert; and

   (iv) Follow all applicable state and local fire, safety, and building codes in the processing, storage, and disposal of the solvents.

2. A professional grade, closed-loop CO2 gas extraction system where every cylinder is rated to a minimum of nine hundred (900) pounds per square inch and it follows all applicable state and local fire, safety, and building codes in the processing and the storage of the solvents.

   (i) The CO2 shall be of at least ninety-nine percent (99%) purity.

   (ii) The CO2 gas extraction system shall have sensors which detect when CO2 levels reach unsafe levels and signal an alert.

3. Ethanol extraction, provided a system to recover the ethanol to be properly disposed of exists.

4. Mechanical extraction using potable water, ice, dry screening or sieving, cryonic extraction, pressure, or temperature provided a detailed description of the processes shall be on the premises.

(d) Verification of compliance of any vessel, cylinder, or tank that is used in the extraction process containing pressures greater than fifteen (15) pounds per square inch with the American Society of Mechanical Engineers (ASME);

(e) Refinement practices and procedures; and

(f) Proper disposal of any:

1. Wastewater;

2. Spent solvents;

3. Any other by-product resulting from the manufacturing of regulated cannabis; and

4. Outdated, damaged, deteriorated, misbranded, or adulterated regulated cannabis.

(11) A production licensee shall establish and implement a product waste management plan that describes, at a minimum:

(a) Procedures for retrieving or receiving product waste from the dispensing licensees; and

(b) Record maintenance and retention procedures for product waste records.

(12) The production standard operating procedures shall be:

(a) Maintained on the premises;

(b) Provided to every owner and employee who performs a task, or set of tasks, that are referenced in the standard operating procedures; and

(c) Made available upon request by the Commission or its employees.

(13) If a production licensee makes a change to their standard operating procedures, then the licensee shall:

(a) Document the change and revise the standard operating procedures accordingly;

(b) Maintain records detailing the change on the premises and submit them to the Commission or its employees upon request; and

(c) Record any change from the standard operating procedure:

1. The change log shall be maintained on the premises for a period of at least three (3) years.

2. The change log shall be made available to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-4-.05
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-211, 16-12-212.
History. Original Rule entitled "Production Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-4-.06. Quality Control Procedures.

(1) Prior to distributing or transporting product in final packaged form to a dispensary or pharmacy, a production licensee shall ensure the following:

(a) The production licensee contracts with and uses an independent laboratory listed on the Commission's list of approved independent laboratories as set forth in Code Section 16-12-217(b)for sample collection and testing;

(b) The manufactured batch has passed all required testing and has been issued a passing certificate of analysis; and

(c) Retest product in final packaged form, prior to or upon expiration of an existing and passing certificate of analysis, to ensure such product continues to pass all required testing.

(2) For the collection of controlled samples on the production licensee's premises, a production licensee shall ensure the following:

(a) Such samples are collected by a sample collector from an independent laboratory on the premises, in the presence of an employee of the licensee and in full view of security cameras; and

(b) During such collection, the sample collector has the ability to randomly collect such samples from the entire manufactured batch so that each unit from such batch has the same probability of being selected.

(3) For the selection and retention of reserve samples on the production licensee's premises, a production licensee shall ensure that such samples are:

(a) Selected by a sample collector from an independent laboratory in the presence of an employee of the licensee and in full view of security cameras;

(b) Selected by such collector at the same time, place, and manner as the collection of controlled samples from the same manufactured batch; and

(c) Retained, labeled, stored, and secured by such licensee on the premises for a minimum of twelve (12) months after a certificate of analysis is issued.

(4) If a sample of product in final packaged form is tested by an independent laboratory, and such sample passes the required testing, then the sample results shall be valid for twelve (12) months from the date on the certificate of analysis.

(5) If a sample of product in final packaged form is tested by an independent laboratory, and such sample fails the required testing, then upon notice or knowledge of such results, the production licensee shall physically quarantine the entire respective, manufactured batch in a sealed package that prevents cross-contamination and is labeled in a manner that indicates the batch failed required testing. In such circumstances, the production licensee may proceed in any and all of the following manner:

(a) Refute the testing results and request no more than two (2) reanalyses for the same manufactured batch. Such two (2) reanalyses may be conducted using the failed controlled sample or another controlled sample from the same manufactured batch, the latter of which shall meet the requirements set forth in this rule.

(b) Remediate the manufactured batch and ensure that:

1. The collection of controlled samples and the selection and retention of reserve samples for the remediated batch follow the corresponding requirements set forth in this rule;

2. Prior to being removed from such quarantine, the controlled samples of the remediated batch undergo and pass two (2) separate tests, with the second of such two (2) tests to be conducted within twenty-four (24) hours of receipt of a passing certificate of analysis for the first of such two (2) tests; and

3. The batch remediation process is documented and such records include the relevant manufactured batch number, the date of remediation, the process of remediation, and the persons involved in the remediation process.

(c) Dispose of the manufactured batch as set forth in Rule 351-4-.05.

(6) A production licensee shall ensure all samples submitted for testing are entered into the Commission-approved tracking system and properly reflected in inventory totals.

(7) A production licensee shall ensure all product in quarantine are entered into the Commission-approved tracking system and properly reflected in inventory totals.

(8) A production licensee shall establish, maintain, and follow standard operating procedures to ensure quality control and quality assurance in producing and manufacturing products in final packaged form. Such procedures, and changes to such procedures, shall be maintained on the premises and made available to the employees of such licensee.

Cite as Ga. Comp. R. & Regs. R. 351-4-.06
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-211, 16-12-212, 16-12-213, 16-12-217.
History. Original Rule entitled "Quality Control Procedures" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-4-.07. Packaging and Labeling.

(1) A production licensee shall submit drafts of the packaging and labeling designs to the Commission for approval prior to using such designs for the product. The Commission hereby delegates the authority and responsibility to review packaging and labeling designs as set forth in Code Section 16-12-203(6), and determine whether such designs shall be approved to the GMCC Executive Director. The licensee shall not use such designs unless they have been approved by the GMCC Executive Director.

(2) A production licensee shall package product in final packaged form on such licensee's premises. Packaging used to contain product shall:

(a) Protect the product from contamination and shall not expose the product to any toxic or harmful substance;

(b) Be tamper-evident or have tamper-evident features applied to such packaging;

(c) Be opaque;

(d) Not imitate any packaging used for goods that are publicly known to be marketed to minors;

(e) Not include the following so as to attract or market to minors:

1. Any cartoon, comic drawing, a series of drawings, or animation;

2. Words such as "candy" or "candies" or any alternative spelling of such words; and

3. Depictions of people or animals.

(f) Use only Commission-approved trademarks, logos, or imagery;

(g) Be a child-resistant package; and

(h) Be resealable if the product has more than one (1) dose.

(3) A production licensee shall label product in final packaged form on such licensee's premises. Labeling used shall be weather resistant, unobstructed, and legible, and include the following:

(a) The name and license number of the production licensee;

(b) The brand name of the product;

(c) The unique identifying manufactured batch number of the product;

(d) The registration number of the independent laboratory who completed the required testing;

(e) The expiration date;

(f) The quantity contained therein;

(g) The weight of the product in grams;

(h) A list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THCA);

3. Cannabidiol (CBD);

4. Cannabidiolic acid (CBDA); and

5. Any other active ingredient that constitutes at least one percent (1%) of the cannabis used in the product.

(i) The American Society for Testing and Materials International Intoxicating Cannabinoid Product Symbol standard (D8441/D8441M) universal symbol, or other symbol requirements for labeling, if designated by the Commission, indicating that products contain intoxicating cannabinoids; and

(j) A statement that the product, in final packaged form, has been tested by an independent laboratory.

(4) Before any product is transported to a dispensary or pharmacy, a production licensee shall package and label such product in accordance with this rule.

Cite as Ga. Comp. R. & Regs. R. 351-4-.07
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212.
History. Original Rule entitled "Packaging and Labeling" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-4-.08. Inventory.

(1) Upon the issuance of a production license, a production licensee shall conduct an initial inventory, and thereafter a monthly inventory, of regulated cannabis, which shall indicate the date on which the inventory was conducted and the information on the persons who conducted such inventory.

(2) A production licensee shall ensure the on-site inventory and the inventory reflected in the Commission-approved tracking system reflect the same information.

(3) If a production licensee identifies or becomes aware of a discrepancy between the on-site inventory and inventory reflected in the Commission-approved tracking system, then such licensee shall conduct an audit within twenty-four (24) hours of such finding and notify the Commission or its employees of any discrepancies of the following:

(a) Any plant designated for cultivation;

(b) Any plant designated for propagation;

(c) More than three percent (3%) of any harvest batch;

(d) More than three percent (3%) of any manufactured batch; or

(e) Any remediated or quarantined product.

Cite as Ga. Comp. R. & Regs. R. 351-4-.08
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-211, 16-12-212, 16-12-213.
History. Original Rule entitled "Inventory" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-4-.09. Transportation.

(1) A production licensee shall ensure security and oversight throughout any transport of product, including, but not limited to, compliance with the following:

(a) Transport of product to or from a licensee, pharmacy, or independent laboratory shall be:

1. Transported only by an authorized employee of a licensee or by an employee of an independent laboratory;

2. Entered into the Commission-approved tracking system and properly reflected in inventory totals; and

3. Contained in a sealed package that prevents cross-contamination and labeled as such.

(b) Personal vehicles shall not be utilized to transport products.

(c) A licensee is prohibited from transporting products outside the state of Georgia.

(d) Vehicles and trailers transporting products are subject to inspection by the Commission or its employees at any time.

(e) A licensee shall notify the Commission and its employees immediately when:

1. A vehicle transporting products is involved in any accident or other situation involving product loss;

2. There is a stop at a location that exceeds one (1) hour in duration and is not already listed in the shipping manifest; or

3. A mechanical issue involving the transport vehicle necessitates the transfer of product to an alternate vehicle to complete the transport. The licensee shall enter the information into the Commission-approved tracking system immediately to reflect the change.

(2) A production licensee shall establish, maintain, and follow standard operating procedures for the transport of product. Such procedures, and changes to such procedures, shall be maintained on the premises and made available to employees of such licensee.

(3) A production licensee shall maintain a current list, updated monthly, of such licensee's drivers, including the following information of each employee:

(a) First, middle, and last name;

(b) Date of birth;

(c) Photograph; and

(d) Contact information including telephone number.

(4) A production licensee shall register each vehicle or vehicle-trailer combination used for the transportation of product by submitting the following to the Commission:

(a) A copy of the vehicle registration or lease which shall include the Vehicle Identification Number ("VIN") assigned by the vehicle manufacturer;

(b) A copy of the vehicle's annual safety inspection;

(c) A copy of the vehicle's unique vehicle number assigned by the production licensee; and

(d) Photos of the vehicle:

1. Left front corner;

2. Right front corner;

3. Right rear corner;

4. Rear, including the affixed, government-issued license plate;

5. Left rear corner; and

6. VIN plate.

(5) All vehicles utilized for transporting product shall contain a global positioning system ("GPS") device for identifying the geographic location of the transport vehicle.

(a) The device shall be permanently affixed to the transport vehicle.

(b) The device shall remain active at all times during transportation of products.

(c) At all times, the production licensee shall be able to identify the geographic location of all vehicles and employees transporting product.

(d) The production licensee shall provide the GPS information to the Commission or its employees upon request.

(e) The use of cellular telephones as a device for GPS tracking does not meet the requirements of this rule.

(6) All vehicles shall be equipped with the following:

(a) Climate control capabilities to ensure the integrity of the product transported;

(b) A vehicle alarm system designed to discourage theft and unauthorized entry or access to the vehicle; and

(c) Permanently installed video cameras that shall:

1. Record during the transport of product;

2. Provide constant coverage of the driver and product being transported; and

3. Maintain recorded material available for no less than forty-five (45) days and be made available for review by the Commission or its employees upon request.

(7) A production licensee shall ensure that the following transportation security requirements are followed:

(a) All transport vehicles shall be staffed with a minimum of two (2) employees who are at least twenty-one (21) years of age. At least one (1) transport team member shall remain with the vehicle at all times that the vehicle contains products;

(b) Employees shall carry their employee identification and valid state-issued driver license at all times when transporting or delivering products;

(c) Employees shall produce their identification to the Commission or its employees or to a law enforcement officer acting in the course of official duties upon request;

(d) Products shall only be transported inside of a registered vehicle or trailer and shall not be visible or identifiable from outside of the vehicle or trailer;

(e) Products shall be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle or trailer, shielded from view from the exterior of the vehicle. No portion of the enclosed box, container, or cage shall be comprised of any part of the body of the vehicle or trailer. For the purposes of this section, the inside of the vehicle also includes, but is not limited to, the trunk and cargo areas;

(f) The vehicle transporting the products shall not contain any marks, logos, brands, or other illustrations on the exterior of the vehicle, other than those affixed to the vehicle by the vehicle manufacturer or dealership, or required placards and signage; and

(g) All transport times and routes are randomized and within the borders of the state of Georgia.

(8) A production licensee shall ensure all shipments comply with the following requirements:

(a) Prior to transporting product off of the premises, the licensee originating the shipment shall prepare a shipping manifest that contains the following information:

1. The name, license number, and premises address of the originating licensee;

2. The name, license number, and premises address of the licensee or pharmacy receiving the product into inventory or storage;

3. The batch number(s) for all product being transported;

4. The item name, description, count, and weight of product associated with each batch;

5. The estimated date and time of departure from the premises;

6. The estimated date and time of arrival at each premises;

7. The valid driver's license number of each employee transporting product, and the make, model, and license plate number of the vehicle used for transport; and

8. Name and signature of the employees accompanying the transport.

(b) During transportation, the licensee transporting the product shall maintain a physical or digital copy of the shipping manifest.

(c) When a shipment is complete, the licensee shall:

1. Enter a record verifying the receiving licensee's, pharmacy's, or independent laboratory's receipt of the shipment in the Commission-approved tracking system with the details of the shipment;

2. Ensure that the shipment has been received by the receiving licensee, pharmacy, or independent laboratory is as described on the shipping manifest; and

3. Immediately adjust its inventory records to reflect such receipt.

(d) A licensee shall not alter the information of the receiving licensee, pharmacy, or independent laboratory after the information has been entered on the shipping manifest. However, if any product on the shipping manifest is damaged or otherwise undeliverable, then the licensee shall:

1. Off-load damaged product only when it can be properly quarantined in the receiving licensee's, pharmacy's, or independent laboratory's inventory and storage;

2. Document the receipt of any damaged product and the quantities received in the Commission-approved tracking system;

3. Update the shipping manifest accordingly; and

4. Maintain a log of any damaged and any returned product as set forth in Rule 351-4-.11.

Cite as Ga. Comp. R. & Regs. R. 351-4-.09
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212, 16-12-213, 16-12-217.
History. Original Rule entitled "Transportation" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-4-.10. Advertising and Marketing.

(1) A production licensee shall ensure that information regarding its products shall be accurate, truthful, and appropriately substantiated and as permissible by the Act and these rules.

(2) A production licensee may provide information regarding its products directly to physicians as set forth in Code Section 16-12-215, via:

(a) Electronic communication;

(b) Printed mail pieces; or

(c) In-person communication.

(3) No production licensee shall advertise or market products to patients, caregivers, or the public as set forth in Code Section 16-12-215.

Cite as Ga. Comp. R. & Regs. R. 351-4-.10
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-215.
History. Original Rule entitled "Advertising and Marketing" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-4-.11. Records.

(1) A production licensee shall keep records identified by these rules on the premises.

(2) All records shall be provided to the Commission or its employees upon request.

(3) A production licensee shall keep and maintain records in connection with the production license for at least five (5) years from the date the record was created, unless a shorter time is specified in these rules or otherwise specific by law.

(4) Records shall be kept in a manner that allows the records to be made available upon request to the Commission or its employees.

(5) Records shall be legible and accurate.

(6) No person may intentionally misrepresent or falsify records, including the use of software or other methods, to manipulate or alter the accuracy of growing or production data.

(7) Records, whether physical or virtual, shall be stored in a secured area where the records are protected from debris, moisture, contamination, hazardous waste, fire, and theft.

(8) Records shall be kept of all regulated cannabis produced, manufactured, transferred, recalled, and disposed of by the production licensee.

(9) A production licensee shall maintain all inventory, sales, and financial records in accordance with generally accepted accounting principles.

(10) A production licensee shall retain a copy of all shipping manifests for at least three (3) years.

(11) A production licensee shall retain records of all testing, certificate(s) of analysis, and samples of each batch for at least twelve (12) months.

(12) A production licensee shall maintain records identifying the source of each ingredient used in the production and manufacturing of regulated cannabis, including:

(a) The originating source of each ingredient;

(b) The date of receipt of the ingredient;

(c) The contractor's name and address;

(d) The grade and quantity of said ingredient; and

(e) The name of the ingredient and the contractor's control number or other identifying number or symbol, if any, used by the contractor to identify the ingredient.

Cite as Ga. Comp. R. & Regs. R. 351-4-.11
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-213.
History. Original Rule entitled "Records" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-4-.12. Product Recall Procedures.

(1) If the Commission receives information demonstrating that a recall is necessary to protect patients or to protect public health and safety, and a production licensee does not initiate a recall, then the Commission may order such recall until the risk to such health and safety is no longer present.

(2) A production licensee shall establish, maintain, and follow standard operating procedures for licensee-initiated or Commission-ordered recalls of product in final packaged form. Such procedures shall address, at a minimum, the following:

(a) Factors that necessitate a recall;

(b) Employees responsible for implementing the recall procedures;

(c) Notifications to patients, caregivers, the public, and the Commission and its employees;

(d) The collection and transport of such recalled product from a dispensing licensee or pharmacy to the originating production licensee; and

(e) Factors determining when a licensee-initiated recall may be terminated.

(3) Prior to a licensee-initiated recall, a production licensee shall provide notice to the Commission and its employees, with such notice including, at a minimum, the following:

(a) Information that necessitates a recall, including a summary of any adverse events and symptoms experienced by patients;

(b) Details of the product in final packaged form subject to the recall, including the brand name(s), unique identifying manufactured batch number(s), and the expiration date(s) of such product;

(c) The total number of product in final packaged form that are subject to the recall, including the locations of dispensaries and pharmacies which may be dispensing such product; and

(d) A detailed plan for the recall and the recalled product, including whether the licensee plans to quarantine, remediate, retest, or dispose of such product in accordance with the rules of the Commission.

(4) When a recall is initiated, whether by the production licensee or ordered by the Commission, then such licensee shall post a notice of such recall within twenty-four (24) hours of initiating a recall in a prominent location on the licensee's website and social media until the recall is terminated. Copies of such notice shall be provided to dispensaries and pharmacies that dispensed such recalled product. Such notice shall include, at a minimum, the following:

(a) The brand name(s), unique identifying manufactured batch number(s), and the expiration date(s) of the recalled product in final packaged form.

(b) The contact information of such licensee, including the designated phone number, electronic mail address, and website for information about such recall and recalled product; and

(c) Readily accessible information regarding patient health, safety, treatment, disposal, poison control, or overdose, which may be made available.

(5) During a recall, whether initiated by the licensee or ordered by the Commission, a production licensee shall submit a report to the Commission and its employees, on a weekly basis, with the following information:

(a) The number of patients contacted who may be impacted by the recall;

(b) Summary of adverse events, including symptoms, experienced by patients;

(c) Efforts to retrieve the recalled product from dispensing licensees and pharmacies;

(d) The amount of recalled product in final packaged form that have been returned;

(e) The amount of recalled product in final packaged form outstanding; and

(f) The progress of implementing such licensee's plan for the recall and the recalled product.

(6) At the conclusion of a recall, whether initiated by the licensee or ordered by the Commission, the production licensee shall:

(a) Complete an internal investigation to determine the cause(s) and issue(s) leading to the recall;

(b) Submit a summary of findings from such investigation to the Commission;

(c) Submit a plan to address the causes and issues, including prevention efforts, to the Commission; and

(d) Inform the impacted dispensaries and pharmacies of the termination of such recall by providing them with written notice.

Cite as Ga. Comp. R. & Regs. R. 351-4-.12
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212, 16-12-213.
History. Original Rule entitled "Product Recall Procedures" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Chapter 351-5. SEED-TO-SALE TRACKING.

Rule 351-5-.01. Tracking System Operations.

(1) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall select a vendor approved by the Commission for their respective seed-to-sale tracking systems capable of utilizing an Application Programming Interface ("API") designed to integrate with the Commission's state tracking system.

(2) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall provide the Commission and its employees with access to their respective seed-to-sale tracking systems.

(3) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall be responsible for their respective selected vendor. Violations of the Act and these rules shall result in citations and fines up to and including revocation.

(4) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall:

(a) Establish a Commission-approved tracking system prior to engaging in any regulated cannabis production, transfer, testing, or dispensing;

(b) Use a Commission-approved tracking system as the primary inventory tracking system of record;

(c) Use the tracking system to ensure regulated cannabis is identified and tracked from the point the regulated cannabis is propagated from seed or cutting to the point the product in final packaged form is dispensed or is otherwise disposed of;

(d) Maintain accurate and comprehensive records regarding regulated cannabis waste that accounts for, reconciles, and evidences all waste activity related to the disposal of regulated cannabis; and

(e) Reconcile all on-premises and in-transit regulated cannabis inventories each day in the tracking system by the close of business.

(5) All inventory tracking activities at the premises shall be tracked through the use of a Commission-approved tracking system and on any forms as may be required by the Commission.

(6) Class 1 production licensees, Class 2 production licensees, and dispensing licensees are responsible for the accuracy and completeness of all data and information entered into a Commission-approved tracking system.

(7) Class 1 production licensees, Class 2 production licensees, and dispensing licensees are accountable for all actions their respective employees take while logged into the tracking system or while otherwise conducting cannabis inventory tracking activities.

Cite as Ga. Comp. R. & Regs. R. 351-5-.01
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212, 16-12-213.
History. Original Rule entitled "Tracking System Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-5-.02. Approved Tracking System Requirements.

(1) Any seed-to-sale tracking vendor shall not have a direct or indirect financial interest in any licensee or registrant of the Commission.

(2) A Commission-approved tracking system vendor shall:

(a) Provide the Commission and its employees access to real-time tracking data;

(b) Utilize an Application Programming Interface designed to integrate with the Commission's state tracking system to include:

1. Inventory management and tracking systems to shipping manifests;

2. Test results; and

3. Dispensing point-of-sale data.

(c) Establish, document, and maintain procedures to prevent fraud, abuse, and other unlawful or prohibited activities associated with the production and dispensing of regulated cannabis in this state, and the ability to provide additional tools for the administration and enforcement of the Act and these rules; and

(d) Institute procedures to ensure that the information in the system shall not be disclosed or used for any purpose other than to ensure public health and safety, product quality and efficacy, and compliance with the Act and these rules.

(3) The tracking system shall be capable of:

(a) Tracking all plants, products, packages, amounts dispensed to patients, waste disposals, transfers, conversions, and returns that, if practicable, are linked to unique identification numbers;

(b) Tracking batch information throughout the entire chain of custody;

(c) Tracking all regulated cannabis throughout the entire chain of custody;

(d) Tracking regulated cannabis destruction;

(e) Performing complete batch recall tracking that clearly identifies all of the following details relating to the specific batch subject to the recall:

1. Amount of product in final packaged form dispensed;

2. Amount of product in final packaged form that has been used for the potential therapeutic treatment of program participants;

3. Amount of product in final packaged form inventory that is finished and available for dispensing;

4. Amount of regulated cannabis being processed into another form; and

5. Amount of post-harvest regulated cannabis, such as regulated cannabis that is in the drying, trimming, or curing process.

(f) Reporting and tracking loss, theft, or diversion of regulated cannabis;

(g) Reporting and tracking all inventory discrepancies;

(h) Reporting and tracking adverse patient responses or dose related efficacy issues;

(i) Reporting and tracking all transfers and returns;

(j) Receiving electronically submitted information required to be reported under the Act;

(k) Receiving testing results electronically within twenty-four (24) hours of completion from an independent laboratory via a secured API into the tracking system and directly linking the testing results to each applicable source batch and sample;

(l) Flagging test results that have characteristics indicating that they may have been altered;

(m) Providing information to ensure that the product in final packaged form has been dispensed to a patient or caregiver, and that the product in final packaged form received and passed the required testing;

(n) Providing the Commission and its employees with real-time access to information in the tracking system; and

(o) Providing real-time information to the Commission and its employees regarding key performance indicators, including:

1. Total regulated cannabis in production;

2. Total daily transfers of product in final packaged form;

3. Total product in final packaged form dispensed;

4. Total regulated cannabis destroyed; and

5. Total inventory adjustments.

Cite as Ga. Comp. R. & Regs. R. 351-5-.02
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-213.

History. Original Rule entitled "Approved Tracking System Requirements" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-5-.03. Plant and Product Tags.

(1) Class 1 and Class 2 production licensees shall only use plant and product tags that comply with the Act and the rules of the Commission.

(2) Class 1 and Class 2 production licensees shall only use plant and product tags assigned by the tracking system to that licensee and shall not transfer unused tags to any other licensee.

(3) Class 1 and Class 2 production licensees shall maintain a sufficient supply of plant and product tags to support tagging in accordance with this chapter.

(4) Plant and product tags shall be indelible and tamper-evident.

(5) Plant and product tags shall not be reused.

(6) All plants, samples, harvest batches, and manufactured batches shall be issued a unique batch number in the inventory tracking system.

(a) Batch numbers cannot be reused.

(b) Each plant, sample, harvest batch, and manufactured batch shall have a tag, with the correct unique batch number listed, placed on or otherwise affixed to it.

(c) The plant tag shall be legible, placed in a position that can be clearly read, and shall be kept free from dirt and debris.

(d) Each batch packaged in bulk together shall be easily identifiable with a bulk package tag attached.

(7) Class 1 and Class 2 production licensees shall not transfer any product in final packaged form that does not have a product tag or bulk package tag attached and entered in the tracking system.

(8) Dispensing licensees shall not dispense any product in final packaged form that does not have a product tag attached and entered in the tracking system.

Cite as Ga. Comp. R. & Regs. R. 351-5-.03
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-211, 16-12-212, 16-12-213.
History. Original Rule entitled "Plant and Product Tags" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-5-.04. Loss of Access.

(1) If a Class 1 production licensee, Class 2 production licensee, or dispensing licensee loses access to the tracking system for any reason, then the respective licensee shall:

(a) Notify the Commission and its employees if the loss of access exceeds twelve (12) hours; and

(b) Prepare and maintain comprehensive tracking records detailing all licensed business that was conducted during the loss of access.

(2) Once access has been restored, the Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall:

(a) Notify the Commission and its employees when access has been restored;

(b) Enter all regulated cannabis production, transfer, testing, or dispensing that occurred during the loss of access into the tracking system, within three (3) days; and

(c) Document the cause for loss of access, and the dates and times of the duration of loss of access.

Cite as Ga. Comp. R. & Regs. R. 351-5-.04
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-213.
History. Original Rule entitled "Loss of Access" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-5-.05. Review and Auditing.

(1) The Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall review the inventory recorded in the Commission-approved tracking system at least once every thirty (30) days to ensure its accuracy, including, at a minimum:

(a) Reconciling recorded inventory with physical inventory of regulated cannabis in the tracking system; and

(b) Reviewing the Class 1 production licensee's, Class 2 production licensee's, or dispensing licensee's authorized users to document and remove access for any users who are no longer authorized to enter information into the tracking system.

(2) The Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall document its inventory reviews which shall include:

(a) The name of the person(s) completing the review; and

(b) The results of the inventory reconciliation.

(3) If a Class 1 production licensee, Class 2 production licensee, or dispensing licensee finds a discrepancy in the inventory review between the physical inventory and the inventory data in the tracking system, then the Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall conduct an audit.

(a) The Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall notify the Commission and its employees of the initiation of an audit within twenty-four (24) hours.

(b) Audit findings shall be reported to the Commission and its employees within three (3) days of the completion of the audit.

(c) All review and audit records shall be maintained for at least three (3) years and shall be provided to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-5-.05
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-213.
History. Original Rule entitled "Review and Auditing" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Chapter 351-6. DISPENSING LICENSEES.

Rule 351-6-.01. Dispensing Preliminary Inspection.

(1) After issuance of an initial dispensing license, a dispensing licensee shall schedule and pass a preliminary inspection by the Commission or its employees within one hundred and eighty (180) days of the date its dispensing license is issued. Such licensee shall not begin operations until after a successful and passing preliminary inspection is completed by the Commission or its employees.

(2) As part of the preliminary inspection, a dispensing licensee shall provide the Commission or its employees with a copy of a certificate of occupancy or other proof that the licensee has completed the required inspections to allow such space in the dispensary to be occupied.

(3) A dispensing licensee may submit a written request to the Commission for an extension to schedule and pass a preliminary inspection. The Commission hereby delegates the authority and responsibility to determine whether such request should be granted and the duration of such extension to the GMCC Executive Director.

(4) A preliminary inspection, as set forth in this rule, is not required for the renewal of a dispensing license.

Cite as Ga. Comp. R. & Regs. R. 351-6-.01
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-217.
History. Original Rule entitled "Dispensing Preliminary Inspection" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-6-.02. General Dispensing License Rules.

(1) A dispensing licensee shall prominently display the following on the premises:

(a) The dispensing license issued by the Commission;

(b) Hours of operation; and

(c) A sign stating "No products can be administered, applied, ingested, or consumed on the premises" or other similar sign.

(2) Failure to remain fully operational during licensure shall constitute a break in supply of product, and may result in citations and fines up to and including revocation.

(3) Dispensing licensees shall continue to provide the Commission and its employees with current contact information and notify the Commission and its employees, in writing, of any changes to the mailing addresses, phone numbers, or electronic mail addresses.

(4) A dispensing licensee shall notify the Commission and its employees within ten (10) days of the initiation and/or conclusion of any new citations, fines, judgments, lawsuits, legal proceedings, charges, or government investigations, involving cannabis-related operations, whether initiated, pending, or concluded, against the licensee and its owners in Georgia and in any other state.

(5) A dispensing licensee shall have a continuing responsibility to ensure that persons employed by such licensee can either demonstrate a lack of a felony conviction within the previous ten (10) years or that a felony conviction within the previous ten (10) years has been expunged, the person has been pardoned, or the person had his or her civil rights restored.

Cite as Ga. Comp. R. & Regs. R. 351-6-.02
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-223.
History. Original Rule entitled "General Dispensing License Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-6-.03. Security.

(1) The dispensing licensee is responsible for the security of all products on the premises, including providing adequate safeguards against theft or diversion of product in final packaged form.

(2) The dispensing licensee shall have a comprehensive security system to prevent and detect diversion, theft, or loss of product in final packaged form utilizing commercial grade equipment, which shall, at a minimum, include:

(a) An alarm system that provides:

1. A perimeter alarm;

2. A duress alarm;

3. A panic alarm;

4. A holdup alarm; and

5. Sensors at all possible points of entry into the dispensary, to include all doors, windows, roof hatches, and skylights.

(b) A surveillance system that includes:

1. Motion detectors;

2. Video cameras in all areas that may contain product in final packaged form and at all points of entry and exit, appropriate for the conditions of the area under surveillance;

(i) The dispensing licensee shall direct video cameras at:

(I) All safes and vaults;

(II) The retail point of dispensing;

(III) All other areas where product in final packaged form is being stored or handled;

(IV) All restricted access areas;

(V) The entrance to the video surveillance room;

(VI) The loading dock or area, if applicable;

(VII) All parking lots or parking areas; and

(VIII) All entry and exit points, which shall be angled so as to allow for the capture of clear and certain identification of all persons entering or exiting the dispensary.

(ii) Video cameras shall operate twenty-four (24) hours a day, seven (7) days a week, recording interior and exterior;

(I) The dispensing licensee shall make all recordings available to the Commission or its employees upon request.

(II) The dispensing licensee shall retain all recordings for a minimum of forty-five (45) days.

(III) Editing or altering the recordings at any point is strictly prohibited and doing so shall result in penalties, up to and including revocation.

(IV) The physical media or storage device on which surveillance recordings are stored shall be secured in a manner to protect the recording from decay, tampering, or theft.

(iii) All video cameras shall:

(I) Have a minimum digital resolution of 2560 x 1440 pixels or pixel equivalent for analog;

(II) Record continuously twenty-four (24) hours per day, or on a motion-sensor system, at a minimum of fifteen (15) frames per second;

(III) Have the ability to produce a still photo that is clear, unobstructed, and in color from either live or from a recording;

(IV) Have an embedded date-and-time stamp on all recordings that shall be synchronized and not obscure the picture; and

(V) Continue to operate during a power outage.

3. Surveillance recording and monitoring equipment shall be housed in a designated, locked, and secured room or other enclosure with restricted access.

(c) Exterior lighting sufficient to deter nuisance activity and facilitate surveillance; and

(d) A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the dispensing licensee within five (5) minutes of the failure, either by telephone, electronic mail, or text message.

(3) The dispensing licensee shall notify the Commission and its employees, within twenty-four (24) hours, of any security system failure.

(a) The dispensing licensee shall keep a log of any security system failure.

(b) The security system failure log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system failure log shall be provided to the Commission or its employees upon request.

(4) A dispensing licensee shall keep all security equipment in good-working order and shall test the function of all such equipment at least quarterly.

(a) The dispensing licensee shall keep a log of all security systems tests completed, which shall include:

1. Date security systems test was completed;

2. Name(s) of the individual(s) who completed the testing;

3. Details regarding tests completed; and

4. Any issues found during the testing.

(b) The security system testing log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system testing log shall be provided to the Commission or its employees upon request.

(5) A dispensing licensee shall ensure that product in final packaged form is stored in a restricted access area separated by tight, floor-to-ceiling-high walls.

(6) At any time the dispensary is not open for dispensing, a dispensing licensee shall ensure that:

(a) The dispensary is securely locked with commercial-grade, non-residential door locks;

(b) All product in final packaged form is locked in a secure storage area;

(c) The dispensary is equipped with an active alarm system, which shall be activated when the dispensing licensee employees are not at the dispensary; and

(d) Only employees of the dispensing licensee and other authorized individuals are allowed access into restricted access areas of the dispensary. For the purposes of this section, authorized individuals include individuals employed by the

dispensing licensee as well as any outside contractors or other individuals conducting business that requires access to the restricted access areas.

(7) A dispensing licensee shall ensure the use of secure electronic access and non-residential door locks with the ability to remain operational during a power outage at all restricted access entry and exit points.

(8) While inside the dispensary, all dispensing licensee employees shall wear a form of identification that clearly identifies them as such to the public.

(9) Employee identification shall contain:

(a) The name of the employee;

(b) Job title;

(c) The date of issuance;

(d) The expiration date, which shall not exceed the expiration date of the dispensing license;

(e) The name of the dispensing licensee;

(f) The license number of the dispensing license;

(g) An alphanumeric identification number that is unique to the employee;

(h) A photographic image of the employee; and

(i) Security measures to prevent unauthorized duplication of the identification.

(10) Upon termination of an employee, a dispensing licensee shall:

(a) Immediately disable the employee's access to any restricted access areas of the dispensing license facility;

(b) Immediately disable the employee's access to the Commission-approved tracking system and all other security access systems; and

(c) Obtain and destroy the terminated employee's identification within twenty-four (24) hours of termination of employment.

(11) A dispensing licensee shall have at least two (2) employees physically present at the dispensary during all hours that the dispensary is open to patients and caregivers.

(12) A dispensing licensee shall maintain a daily log of employees for at least three (3) years.

(13) Any non-employee, prior to entering a restricted access area, shall obtain a visitor identification badge from management employees of the dispensing licensee.

(a) Visitors shall visibly display the badge while in the restricted access area.

(b) A dispensing licensee employee shall escort and monitor visitors at all times.

(c) A visitor shall return the visitor identification badge to a dispensing licensee's employee upon exiting the dispensary.

1. The dispensary shall maintain a current and accurate inventory of all visitor identification badges.

2. Any loss of a visitor identification badge shall be documented separately and maintained with the visitor log.

(d) The dispensing licensee shall log all visitors in and out, and shall maintain a log that includes the date, time, and purpose of the visit.

1. The log shall retain a photocopy of the government-issued photo identification for each visitor.

2. The log shall include the name and identification number of the employee escorting the visitor.

3. The visitor log shall be maintained for at least three (3) years.

4. The log shall be made available to the Commission or its employees upon request.

(e) Nothing shall prohibit the Commission or its employees, or local, state, or federal law enforcement from entering restricted access areas.

(f) All restricted access areas shall have a sign posted on or near the door indicating that access to the area is restricted to employees only.

(14) A dispensing licensee shall keep a surveillance equipment maintenance activity log at the dispensary to record all service activity including the identity of any individual performing the service, the service date and time, and the reason for service to the surveillance system.

(a) The security equipment maintenance activity log shall be made available to the Commission or its employees upon request.

(b) The security equipment maintenance activity log shall be maintained for at least three (3) years.

(15) A dispensing licensee shall maintain documentation in an auditable form for a period of at least three (3) years for:

(a) Any alarm activation or other event which requires response by public safety employees; and

(b) Any unauthorized breach of security.

(16) A dispensing licensee shall notify the Commission and its employees as well as the appropriate law enforcement authorities within twenty-four (24) hours after discovering any of the following:

(a) Discrepancies identified during inventory reconciliation;

(b) Diversion, theft, loss, or any criminal activity pertaining to the operation of the dispensing licensee;

(c) Diversion, theft, loss, or any criminal activity by any agent or employee of the dispensing licensee pertaining to the operation of the dispensing licensee;

(d) The loss or unauthorized alteration of records related to products, patients, caregivers, or employees or agent of the dispensing licensee; and

(e) Any other breach of security.

Cite as Ga. Comp. R. & Regs. R. 351-6-.03
Authority: O.C.G.A. §§ 16-12-203, 16-12-206.
History. Original Rule entitled "Security" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-6-.04. Inventory.

(1) A dispensing licensee shall conduct an initial comprehensive inventory of all products at each dispensary on the date the dispensing licensee first dispenses product in final packaged form.

(2) A dispensing licensee shall maintain an accurate record of its inventory. A dispensing licensee shall provide the Commission and its employees with the record of inventory upon request.

(a) In conducting an inventory reconciliation, a dispensing licensee shall verify that the dispensing licensee's physical inventory is consistent with the dispensing licensee's records in the Commission-approved tracking system.

(b) The result of inventory reconciliation shall be retained in the dispensing licensee's records for twelve (12) months and shall be made available to the Commission or its employees upon request.

(3) All inventory stored at the dispensary shall be secured in a restricted access area, unless in the process of being dispensed to a patient or caregiver.

(4) A dispensing licensee shall track its inventory in the Commission-approved tracking system, including data on the products in the final packaged form it receives, returns, transfers, and dispenses in accordance with the Act and these rules.

(5) Upon commencing business, a dispensing licensee shall conduct a monthly inventory of product in final packed form. The inventory documentation shall include, at a minimum, the following:

(a) Date of the inventory;

(b) A summary of the inventory findings;

(c) The name, signature, and title of the individual(s) who conducted the inventory;

(d) The date of receipt of product in final packaged form;

(e) The name, license number, and address of the production licensee from whom the product in final packaged form was received; and

(f) The kind and quantity of product in final packaged form received.

(6) Monthly inventories shall be maintained for at least three (3) years and shall be provided to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-6-.04
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210.
History. Original Rule entitled "Inventory" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-6-.05. Dispensing License Operations.

(1) All rooms on the premises shall be identified on the respective doors or the exterior of such rooms so as to indicate the purposes of such rooms.

(2) Common areas in the dispensary, including but not limited to, a designated area for the consumption of food and beverages for employees, toilet and lavatory facilities, office or meeting space, or a lobby, shall conform to the following requirements:

(a) The common areas shall be separated from restricted access areas by floor-to-ceiling-high walls;

(b) The door separating the common areas from the restricted access areas shall have secure electronic controls to restrict access; and

(c) Toilet and lavatory facilities shall be equipped with toilet tissue, soap dispenser with soap or other hand cleaning material, sanitary towels or drying device, and at least one (1) waste receptacle.

(3) All areas where product in final packaged form is stored shall be:

(a) Dry;

(b) Sufficiently lit;

(c) Well-ventilated;

(d) Maintained in a clean and orderly fashion; and

(e) Maintained at temperatures and lighting conditions which will ensure the integrity of product in final packaged form prior to dispensing.

(4) Upon receipt of transported product in final packaged form from a licensee, the receiving dispensing licensee shall do all of the following:

(a) Submit to the Commission-approved tracking system a record verifying its receipt of the shipment and the details of the shipment.

(b) Ensure that the product in final packaged form received is as described in the shipping manifest and shall immediately adjust its records to reflect the receipt of inventory. If such product is damaged, then such licensee:

1. May accept the damaged product only if such product can be properly recorded in its inventory and quarantined at the dispensary.

2. Separately document the receipt of any damaged product in final packaged form on the shipping manifest and the quantities received in the Commission-approved tracking system.

(5) A dispensing licensee shall establish, maintain, and follow standard operating procedures for the accurate and safe dispensing of product in final packaged form to patients and caregivers. Such procedures, and changes to such procedures, shall be maintained on the premises and made available to employees of such licensee.

(6) Prior to dispensing product in final packaged form to a patient or caregiver, a dispensing licensee shall ensure a patient or caregiver has an active and valid registration card as referenced in Code Section 16-12-191 and proof of identification.

(7) If a dispensing licensee receives information about a patient's adverse event, then such licensee shall notify the originating production licensee, as well as the Commission and its employees, within twenty-four (24) hours of such licensee's receipt of information.

(8) For product in final packaged form that cannot be dispensed, a dispensing licensee shall establish, maintain, and follow standard operating procedures which shall address, at a minimum, the following:

(a) Identification and storage of any product in final packaged form that are:

1. Expired or no longer have a current and passing certificate of analysis;

2. Not properly labeled or packaged; or

3. Quarantined due to damage, evidence of tampering, a part of a recall, or as otherwise required to be quarantined pursuant to the rules of the Commission or procedures established by the licensee.

(b) Security and storage protocols to ensure that, prior to returning such product to the originating production licensee, product in final packaged form will be stored in:

1. A securely enclosed and locked container; and

2. A restricted access area of the dispensary.

(9) A dispensing licensee shall not do any of the following:

(a) Accept, store, or dispense any product not in final packaged form;

(b) Use the Commission's name or logo on any sign at the premises, on the business' website, or in any advertising or social media, except to the extent that the Commission's name or logo is contained on the proof of licensure or is incorporated into warnings, signage, or other documents required by these rules;

(c) Sublet any portion of the dispensary;

(d) Provide samples of or free products to any person;

(e) Allow products to be administered, applied, ingested, or otherwise consumed inside of or on the premises of the dispensary;

(f) Offer any tours of restricted access areas to the general public; or

(g) Display product in final packaged form in windows or in public view.

Cite as Ga. Comp. R. & Regs. R. 351-6-.05
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210.
History. Original Rule entitled "Dispensing License Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-6-.06. Labeling and Exit Packaging.

(1) Dispensing licensees are prohibited from removing, altering, covering, or otherwise tampering with the originating production licensee's product label affixed to product in final packaged form as set forth in Rule 351-4-.07.

(2) A dispensing licensee shall use weather-resistant and tamper-resistant labels for all product in final packaged form and shall include the following information on such labels:

(a) The date the product in final packaged form is dispensed to the patient;

(b) Patient identification information, including:

1. Name, address, and license number of the dispensing licensee;

2. The unique patient registry serial number of the patient, assigned by the Georgia Department of Public Health;

3. Patient's first and last name;

4. Patient's date of birth; and

5. Where applicable, the caregiver's first and last name and unique patient registry serial number, assigned by the Georgia Department of Public Health.

(c) Directions for use of the product; and

(d) Any cautionary statements or symbols as may be required by the Commission.

(3) A dispensing licensee shall use approved exit packaging for all product in final packaged form prior to dispensing such product in final packaged form to a patient or caregiver. Prior to use, all exit packaging shall meet the following:

(a) Reviewed and approved by the GMCC Executive Director;

(b) Only use trademarks, licensed logos, or imagery previously approved by the Commission or the GMCC Executive Director; and

(c) Be plain-colored, light-resistant, and opaque.

Cite as Ga. Comp. R. & Regs. R. 351-6-.06
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210.
History. Original Rule entitled "Labeling and Exit Packaging" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-6-.07. Advertising and Marketing.

(1) A dispensing licensee shall ensure that information regarding all product in final packaged form that is dispensed to patients shall be accurate, truthful, and appropriately substantiated as permissible by Commission rules.

(2) No dispensing licensee shall advertise or market product in final packaged form to patients, caregivers, or the public as set forth in Code Section 16-12-215(b).

(3) A dispensing licensee may provide information regarding product in final packaged form directly to physicians as set forth in Code Section 16-12-215, via:

(a) Electronic communication;

(b) Printed mail pieces; or

(c) In-person communication.

Cite as Ga. Comp. R. & Regs. R. 351-6-.07
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-215.
History. Original Rule entitled "Advertising and Marketing" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-6-.08. Records.

(1) Dispensing licensees shall keep all documents required by the Commission at the dispensary.

(2) All required records shall be provided upon request to the Commission or its employees.

(3) Records shall be kept for at least five (5) years from the date of creation unless a shorter time is specified.

(4) Records shall be legible and accurate.

(5) Records, whether physical or electronic, shall be stored in a secure or restricted access area where the records are protected from debris, moisture, contamination, hazardous waste, and theft.

(6) A dispensing licensee is prohibited from utilizing software or other methods to manipulate or alter dispensing data or other required records.

(7) Dispensing licensees shall maintain the following records at the dispensary:

(a) Each day's beginning and ending inventory, monthly inventory, and comprehensive annual inventory;

(b) Detailed records of sales to registered patients, including:

1. Registry ID number;

2. Product name;

3. Batch number; and

4. Quantity.

(c) Detailed financial reports of proceeds and expenses;

(d) Detailed receiving, shipping, inventory, and dispensing records;

(e) All financial records in accordance with generally accepted accounting principles;

(f) All maintenance inspections, tests, servicing, modifications, and upgrades performed on the security alarm system, including, at a minimum:

1. Date of the action;

2. Summary of the actions performed; and

3. Name, signature, and title of the individual(s) who performed the actions.

(g) Any alarm activation or other event which requires response by public safety employees;

(h) Any unauthorized breach of security; and

(i) Any refusal of services to patients and caregivers.

Cite as Ga. Comp. R. & Regs. R. 351-6-.08
Authority: O.C.G.A. §§ 16-12-203, 16-12-206.
History. Original Rule entitled "Records" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-6-.09. Recall Procedures.

(1) A dispensing licensee shall establish, maintain, and follow standard operating procedures for licensee-initiated or Commission-ordered recalls of product in final packaged form. Such procedures shall address, at a minimum, the following:

(a) Notifications to patients, caregivers, and the public;

(b) Reporting adverse events and symptoms experienced by patients to the originating production licensee and the Commission and its employees;

(c) The collection of such recalled product;

(d) The quarantine and storage of such recalled product that have not been dispensed;

(e) The quarantine and storage of such recalled product that would be returned; and

(f) The return of such recalled product to the originating production licensee.

(2) The dispensing licensee shall display a public notice of a licensee-initiated or Commission-ordered recall until the termination of the recall. Such notice shall be:

(a) Received from the originating production licensee responsible for the recall;

(b) Posted within twenty-four (24) hours of the recall being initiated;

(c) Displayed in a conspicuous location, unobstructed, and easily viewable for patients and caregivers; and

(d) Posted in a prominent location of the dispensing licensee's website and social media, if the dispensary impacted by the recall has a website separate from the originating production licensee.

(3) Upon receipt of a written notice for a recall, a dispensing licensee shall ensure product in final packaged form subject to the recall is:

(a) Removed from availability for retail purchase or transfer; and

(b) Quarantined and stored from all other product in final packaged form that is not part of the recall.

Cite as Ga. Comp. R. & Regs. R. 351-6-.09
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210.
History. Original Rule entitled "Recall Procedures" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-6-.10. Changes.

(1) Changes to a dispensing licensee's name, owner(s), or agent require:

(a) A complete change application;

(b) A secure and verifiable document as set forth in Code Section 50-36-2;

(c) The required fee, as set forth in the fee schedule;

(d) Other documents and information as may be required by this rule;

(e) Other documents upon request by the Commission or its employees; and

(f) Commission approval. The Commission hereby delegates the authority and responsibility to determine whether changes to a dispensing licensee's name, owner, or agent are approved, or denied, to the GMCC Executive Director.

(2) If a dispensing licensee submits a change application to add an owner or remove an owner listed on the dispensing license, then such application shall include the following, to the extent applicable:

(a) To add an owner, provide the following information for the new owner:

1. Name;

2. Title;

3. Role, if different from the owner's current title;

4. Whether the person has served or is currently serving as an owner, officer, or agent for another entity licensed by the Commission;

5. Whether another like entity with which the owner or officer is associated has had a license revoked, disciplined, or the equivalent thereof, in this state or any other jurisdiction;

6. The ownership interest or financial interest in any other entity licensed by the Commission, if any; and

7. A copy of the new owner's secure and verifiable document as set forth in Code Section 50-36-2.

(b) To remove an owner, due to an owner being deceased, or due to an owner being ineligible due to a drug related felony conviction, provide the following about such owner:

1. A copy of the obituary or death certificate of the owner to be removed; or

2. A certified copy of the final disposition from the court in which the drug related felony conviction occurred.

(c) To remove an owner for any other reason, provide the following:

1. A signed and notarized affidavit from the respective owner attesting that they no longer hold any ownership interest in the dispensary; or

2. A signed and notarized affidavit from the applicant or agent, as listed on the application, attesting that an owner no longer holds any ownership interest in the dispensary.

(3) A request to change the location of a dispensing license shall be made by submitting a new dispensing license application as set forth in Rule 351-3-.02. Such application shall include the dispensing license number.

(a) If such application is approved, then the dispensing license number shall remain the same. However, the dispensing licensee shall not begin licensed operations at the new and approved location until after a successful and passing preliminary inspection as set forth in Rule 351-6-.01.

(b) A dispensing licensee receiving approval from the Commission for a change of location shall have a transition period of thirty (30) days from the date of approval unless a written extension for a longer period is issued by the Commission. The Commission hereby delegates the authority and responsibility to determine whether an extension is made and its duration, if any, to the GMCC Executive Director.

(c) In order to transfer inventory of product in final packaged form and begin operations at the new location, the following restrictions apply:

1. No product in final packaged form may be transferred to the new location prior to the beginning date of the approved transition period;

2. All product in final packaged form transferred to the new location shall be documented in the tracking system;

3. The licensee shall notify the Commission and its employees in writing or by electronic transmission once the transfer of inventory is complete; and

4. Any product in final packaged form remaining at the original location past the thirty (30) day transition period shall be destroyed and documented in the tracking system.

(4) If a change application contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

Cite as Ga. Comp. R. & Regs. R. 351-6-.10
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-217, 16-12-219.

History. Original Rule entitled "Changes" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Chapter 351-7. INDEPENDENT LABORATORIES.

Rule 351-7-.01. Independent Laboratory Registration and Renewal.

(1) An independent laboratory shall be approved by the Commission prior to testing product in final packaged form from production licensees. The Commission hereby delegates the authority and responsibility to approve or deny registration forms submitted by independent laboratories to the GMCC Executive Director.

(2) To request approval by the Commission, the requesting independent laboratory shall submit the following to the Commission:

(a) A complete independent laboratory registration form as required by the Commission;

(b) The required non-refundable registration fee as listed on the fee schedule;

(c) The legal name of the independent laboratory as reflected in the articles of incorporation or organizational documents filed with the Georgia Secretary of State, including:

1. The type of corporation or entity of the independent laboratory;

2. A copy of the independent laboratory's articles of incorporation, articles of organization, or partnership document; and

3. The trade name of the independent laboratory, if applicable and if different from the legal name.

(d) The physical address, county, and global positioning satellite coordinates where the independent laboratory is located;

(e) The U.S. Postal Service mailing address of the independent laboratory;

(f) The name(s) of the independent laboratory owner(s) and the director or agent;

(g) The telephone number(s) of the independent laboratory director or agent;

(h) The electronic mail address of the independent laboratory director or agent;

(i) A copy of the secure and verifiable document as set forth in Code Section 50-36-2for the independent laboratory owner;

(j) Attestation that, upon registration with the Commission, the independent laboratory will maintain compliance with all local ordinances, rules, or regulations adopted by the locality where the independent laboratory is located, which are in effect at the time of submitting the registration form, including copies of any required local registration, license, or permit of the locality where the independent laboratory is located;

(k) Documentation related to a certificate of accreditation for International Organization for Standardization ("ISO")/International Electrotechnical Commission ("IEC") 17025:2017 or higher:

1. A copy of such certificate for each required testing field as set forth in Rule 351-7-.08; or

2. Records demonstrating that such certificate for each required testing field as set forth in Rule 351-7-.08 has been applied for, including all of the following:

(i) A copy of the application to the accrediting body for ISO/IEC 17025:2017 (or higher) accreditation;

(ii) Documentation of the payment receipt(s) for accreditation with the accrediting body;

(iii) Documentation acknowledging receipt of the application and payment(s) by the accrediting body;

(iv) Tentative schedule of any remaining steps in obtaining such certificate, including supporting documentation; and

(v) Documentation from the accrediting body for all accreditation audit(s), including dates and status, that have been scheduled and completed.

(l) A copy of the United States Department of Justice, Drug Enforcement Administration Controlled Substances Act Certificate of the independent laboratory.

(m) A current copy of its standard operating procedures which shall address, at a minimum, the following:

1. Oversight of the independent laboratory, including, but not limited to, documentation of the reporting and management structure of the independent laboratory;

2. Accurate record keeping;

3. Employee safety and security;

4. Safety and security plans, including a disaster plan with procedures to be followed in case of fire or other emergencies;

5. Secure transportation plan and techniques for crime prevention;

6. A job description or employment contract developed for all employees which includes duties, responsibilities, authority, qualification, and supervision;

7. Alcohol and drug-free workplace policies;

8. Storage of product in final packaged form prior to testing which ensure product quality and efficacy are maintained;

9. Testing of product in final packaged form, including:

   (i) Each batch of product in final packaged form produced by a production licensee; and

   (ii) Product in final packaged form from a dispensing licensee, when necessary.

10. A detailed description of how the product in final packaged form will be tested, including:

    (i) The process detailing how samples are collected by the independent laboratory;

    (ii) The number of samples tested;

    (iii) The size of sample tested;

    (iv) The tests conducted;

    (v) Creation and reporting of the certificate of analysis to the production licensee;

    (vi) Reporting results to the Commission; and

    (vii) Disposal of samples.

11. An inventory of equipment and the methods used for the testing of product in final packaged form to detect the following for a certificate of analysis as set forth in Rule 351-7-.08:

(i) Potency;

(ii) Cannabinoid profile;

(iii) Heavy metals;

(iv) Pesticides;

(v) Residual solvents;

(vi) Visible foreign material;

(vii) Microbiological contaminants and mycotoxins; and

(viii) Terpenes.

(n) Attestation that the registration form and its required documentation are true and current at the time of submission to the Commission and its employees.

(o) Other information upon request by the Commission or its employees.

(3) The Commission or the GMCC Executive Director may require a satisfactory compliance inspection prior to the approval of a registration.

(4) An independent laboratory shall submit a complete registration form, fee, and required documentation as set forth in this rule, for each location of such laboratory.

(5) If an independent laboratory applied for registration as set forth in Rule 351-7-.01(2)(k)(2), then documentation of ISO accreditation for each required testing field as set forth in Rule 351-7-.08 shall be received by the Commission and its employees within (180) days of the date of which the registration is approved.

(a) If additional time is necessary to submit such documentation, then the independent laboratory shall submit a written request to the GMCC Executive Director for an extension of up to ninety (90) days to submit such documentation. Such a request shall include information to support such an extension and the time frame of which such documentation may be submitted to the Commission and its employees.

(b) The Commission hereby delegates the authority and responsibility to determine whether an extension should be granted and to extend the time frame for the independent laboratory to submit such documentation to the GMCC Executive Director. If an extension is granted, then the independent laboratory shall submit to progress inspections by the Commission or its employees during the time frame of such extension.

(6) The Commission may remove or not add an independent laboratory to the Commission's list of approved independent laboratories for noncompliance with the rules of the Commission.

(7) An independent laboratory shall renew its registration annually, during an open renewal period announced by the Commission, by submitting to the Commission:

(a) A complete independent laboratory registration renewal form;

(b) Payment of the required non-refundable annual renewal fee;

(c) Results of any internal or external audits conducted in the preceding twelve months; and

(d) Results of the most recent third-party proficiency testing obtained by the independent laboratory as set forth in Rule 351-7-.02(6).

(8) A registrant who does not submit a complete and timely renewal registration form shall be removed from the Commission's list of approved independent laboratories.

Cite as Ga. Comp. R. & Regs. R. 351-7-.01
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "Independent Laboratory Registration and Renewal" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-7-.02. General Rules.

(1) A valid registration from the Commission authorizes an independent laboratory to test regulated cannabis from a production licensee.

(2) A current list of approved and registered independent laboratories shall be maintained by the Commission and made available to the public on the Commission's website.

(3) All costs and expenses incurred to test product in final packaged form shall be paid by the production licensee and not by the Commission.

(4) An independent laboratory is prohibited from any other activities regulated by the Commission including production, selling, or dispensing of products.

(5) A person with a financial interest in an independent laboratory is prohibited from holding a financial interest in any other type of license or registration issued by the Commission under the Act.

(6) All independent laboratories on the Commission's current list shall participate in a third-party proficiency-testing program provided by an ISO/IEC 17043:2010 or higher-accredited proficiency test provider, at least semi-annually.

(7) The independent laboratory shall ensure that copies of all ISO/IEC audits and inspection reports are submitted to the Commission and its employees within twenty-four (24) hours of completion.

(8) An independent laboratory shall continue to provide the Commission and its employees with current contact information and notify the Commission and its employees, in writing, of any changes to the mailing addresses, phone numbers, or electronic mail addresses.

(9) An independent laboratory shall not use the Commission's name or logo on any sign on its premises, website, or any advertising or social media, except to the extent that information is contained on the proof of registration or is contained in part of warnings, signage, or other documents required by these rules.

(10) An independent laboratory shall create and maintain employee policies and procedures, including, at a minimum, the following:

(a) Code of ethics;

(b) Whistle-blower policy;

(c) A policy which notifies persons with disabilities of their rights, which includes provisions prohibiting discrimination and providing reasonable accommodations; and

(d) All applicable state and federal Department of Labor regulations for posting required notices in the workplace.

(11) An independent laboratory shall take reasonable measures and precautions to ensure all employees working with direct access to product in final packaged form shall use hygienic practices while on duty for the prevention of contamination, including:

(a) Ensuring handwashing facilities are located within all testing areas, equipped with effective hand-cleaning and sanitizing preparations, and sanitary towel service or electronic drying devices;

(b) Requiring employees wash hands thoroughly with soap before starting work and at any other time when hands have become soiled or contaminated; and

(c) Responding reasonably and promptly to reports or concerns of any employee who has been diagnosed with, or has displayed or experienced symptoms of, a contagious illness or a communicable disease.

(12) The independent laboratory shall notify the Commission and its employees of the following:

(a) The initiation or conclusion of any new judicial decisions, lawsuits, legal proceedings, charges, or government investigation and enforcement actions, whether initiated, pending, or concluded, that involve the registrant within ten (10) days of such initiation or conclusion.

(b) The loss or suspension of its required accreditation, within twenty-four (24) hours of such loss or suspension.

1. If the accreditation is not restored within thirty (30) days of such loss or suspension, then the independent laboratory shall be removed from the Commission's list of approved independent laboratories.

2. An independent laboratory shall be required to submit a new registration form to the Commission if such laboratory has been removed from the Commission's list of approved independent laboratories.

Cite as Ga. Comp. R. & Regs. R. 351-7-.02
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "General Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-7-.03. Security.

(1) An independent laboratory is responsible for the security of regulated cannabis on its premises, including providing adequate safeguards against theft or diversion of product in final packaged form and records for chain of custody that are required to be kept.

(2) An independent laboratory shall implement appropriate security and safety measures to deter and prevent unauthorized entrance into areas containing product in final packaged form and the theft of such product. Such measures shall include the following:

(a) Access from outside the premises shall be kept to a minimum and be well controlled;

(b) The outside perimeter of the premises shall be well lit;

(c) Entry into any area where product in final packaged form is held shall be limited to authorized employees;

(d) An independent laboratory shall have a security alarm system that will provide suitable protection against theft and diversion;

(e) Video surveillance shall record access areas and anywhere the product in final packaged form is handled; and

(f) An independent laboratory shall ensure that product in final packaged form is stored in a locked area with adequate security.

(3) The independent laboratory shall log all local, state, and federal government officials, contractors, and visitors in and out, and shall maintain a log that includes the date, time, and purpose of the visit.

(a) An independent laboratory shall maintain a copy of the daily log required by this rule for a period of at least three (3) years; and

(b) The daily log shall be made available upon request to the Commission or its employees.

Cite as Ga. Comp. R. & Regs. R. 351-7-.03
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "Security" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-7-.04. Independent Laboratory Operations.

(1) An independent laboratory shall establish, maintain, and follow standard operating procedures, meeting the minimum standards set forth in these rules, detailing the performance of all methods employed by the facility used to test the analytes it reports, and made available for testing analysts to follow at all times.

(2) The standard operating procedures shall include, at a minimum, procedures for:

(a) Sample collecting;

(b) Sample increments;

(c) Sample receiving;

(d) Sample accessioning;

(e) Sample storage;

(f) Identifying and rejecting unacceptable samples;

(g) Recording and reporting discrepancies;

(h) Security of samples, aliquots, extracts, and records;

(i) Validating a new or revised method prior to testing samples to include:

1. Accuracy;
2. Precision;
3. Analytical sensitivity;
4. Analytical specificity (interferences);
5. Limit of Detection ("LOD");
6. Limit of Quantitation ("LOQ"); and
7. Verification of the reportable range.

(j) Aliquoting samples to avoid contamination and carry-over;

(k) Sample retention to assure stability, as follows:

1. For samples that comprise test batches submitted for testing other than pesticide contaminant testing, sample retention for fourteen (14) days; and
2. For samples that comprise test batches submitted for pesticide contaminant testing, sample retention for ninety (90) days.

(l) Disposal of samples and hazardous waste;

(m) The theory and principles behind each assay;

(n) Preparation and identification of reagents, standards, calibrators, and controls and ensure all standards are traceable to National Institute of Standards of Technology ("NIST");

(o) Special requirements and safety precautions involved in performing assays;

(p) Frequency and number of control and calibration materials;

(q) Recording and reporting assay results;

(r) Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;

(s) Pertinent literature references for each method;

(t) Current step-by-step instructions, with sufficient detail to perform the assay, to include equipment operation and any abbreviated versions used by a testing analyst;

(u) Acceptability criteria for the results of calibration standards and controls as well as between two (2) aliquots or columns;

(v) A documented system for reviewing the results of testing calibrators, controls, standards, and subject tests results, as well as reviewing for clerical errors, analytical errors, and any unusual analytical results; and

(w) Laboratory and sample contamination prevention.

(3) The independent laboratory director or agent shall approve, sign, and date each procedure. If any modifications are made to those procedures, then the independent laboratory director or agent shall approve, sign, and date the revised version prior to use.

(4) The independent laboratory's standard operating procedures shall be kept on the independent laboratory premises, be accessible to all employees during all hours of operation, and be made available upon request to the Commission or its employees.

(5) An independent laboratory shall establish, monitor, and document on an ongoing basis the quality control measures taken by the independent laboratory to ensure the proper functioning of equipment, validity of standard operating procedures, and accuracy of results reported. Such quality control measures shall include the following, at a minimum:

(a) Documentation of instrument preventive maintenance, repair, troubleshooting, and corrective actions taken when performance does not meet established levels of quality;

(b) Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;

(c) Cleaning, maintaining, and calibrating as needed the analytical balances, and in addition, verifying the performance of the balance annually using certified weights to include three (3) or more weights bracketing the ranges of measurement used by the independent laboratory;

(d) Annually verifying and documenting the accuracy of thermometers using a NIST traceable reference thermometer;

(e) Recording temperatures on all equipment when in use where temperature control is specified in the standard operating procedures, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;

(f) Properly labeling reagents as to the identity, concentration, date of preparation, storage conditions, lot number tracking, expiration date, and identity of the preparer(s);

(g) Avoiding mixing different lots of reagents in the same analytical run;

(h) Performing and documenting a calibration curve with each analysis using, at minimum, five (5) calibrators throughout the reporting range;

(i) For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of samples analyzed;

(j) For quantitative analyses, analyzing, at minimum, a negative and two (2) levels of controls that challenge the linearity of the entire curve;

(k) Using a control material or materials that differ in either source, lot number, or concentration from the calibration material used with each analytical run;

(l) For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;

(m) Analyzing an appropriate matrix blank and control with each analytical run, when available;

(n) Analyzing calibrators and controls in the same manner as unknowns;

(o) Documenting the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the standard operating procedure is met;

(p) Documenting all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the standard operating procedure;

(q) Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and

(r) Performing validation testing to ensure that current standard operating procedures are followed for the test or tests to be performed.

(6) The independent laboratory shall conduct an internal audit at least once per year or in accordance with the accrediting body's requirements for such laboratory's ISO/IEC 17025:2017 (or higher) accreditation, whichever interval occurs more frequently, and

submit the results of the internal audit to the Commission and its employees within three (3) days of completing the internal audit.

(7) An independent laboratory shall ensure adequate training will be provided to every employee who performs a task, or set of tasks, referenced in the standard operating procedures.

(8) An independent laboratory is prohibited from testing product in final packaged form or providing results to a production licensee during the time that its accreditation is lost or suspended.

(a) An independent laboratory shall reestablish accreditation within one hundred eighty (180) days of the effective date of the loss or suspension of accreditation. If an independent laboratory fails to reestablish its accreditation within one hundred eighty (180) days of the loss or suspension, then the independent laboratory's registration shall become invalid and the respective laboratory shall be removed from the Commission's list of approved independent laboratories for the purpose of testing regulated cannabis.

(b) An independent laboratory shall notify the Commission and its employees of the reestablishment of its accreditation within twenty-four (24) hours of the effective date of reaccreditation.

Cite as Ga. Comp. R. & Regs. R. 351-7-.04
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "Independent Laboratory Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-7-.05. Sample Collection Requirements.

(1) An independent laboratory shall maintain and practice sampling methods that are ISO/IEC 17025:2017 or higher accredited.

(2) The sample method chosen shall achieve a ninety-five percent (95%) or greater confidence level of the batch for the testing of the following:

(a) Total THC content;

(b) Cannabinoid compounds;

(c) Heavy metals;

(d) Pesticides;

(e) Residual solvents;

(f) Visible foreign material;

(g) Microbial impurities;

(h) Mycotoxins; and

(i) If tested, terpenes.

(3) An independent laboratory shall develop and document which scientifically defensible incremental sampling method is utilized for testing.

(4) The independent laboratory shall:

(a) Maintain a document of the sample method selection at the premises during the term of the registration;

(b) Document any changes to the sample method chosen and submit the changes to the Commission and its employees within twenty-four (24) hours; and

(c) Provide the document of sample method selection to the Commission and its employees.

(5) The sample increments shall be combined into a controlled sample, completing the same procedure with a second set of equivalent sample increments to form the reserve sample.

(6) The amount of controlled sample supplied to the independent laboratory shall be large enough to complete all required testing, to complete a replicate test, and to create a homogenized sample that is representative of the manufactured batch.

(7) The sample collector shall collect samples of product in final packaged form that are representative of the manufactured batch and that are relative to the size of such batch

(a) An equal number of controlled samples of product in final packaged form for testing as set forth in Rule 351-7-.08 and reserve samples as set forth in Rule 351-4-.06, shall be collected concurrently and within an unobstructed view of security cameras at the production facility premises.

(b) The controlled sample and reserve sample of product in final packaged form shall each consist of the following minimum number of sample unit increments taken:

1. Eight (8) units for a sample product batch with up to 500 products;

2. Twelve (12) units for a sample product batch with 501-1,000 products;

3. Sixteen (16) units for a sample product batch with 1,001-5,000 products; and

4. Twenty (20) units for a sample product batch with more than 5,000 products.

(c) The sample collector may collect a greater number of units if necessary to perform the required testing or to ensure that the samples collected are representative.

(8) A sample collection form shall be utilized for each batch sample, establishing the chain of custody, and shall contain the following information:

(a) Date and time sample was collected;

(b) Name and license number of the originating production licensee;

(c) Batch number of the batch from which the representative sample was obtained and assigned unique sample identifier;

(d) Total batch size, by weight, or unit count;

(e) Total weight, or unit count of the representative sample;

(f) Type of product in final packaged form for which samples are collected;

(g) Sampling conditions or problems encountered during the sampling process, if any;

(h) Printed name and signature of the authorized agent of the production licensee;

(i) Printed name and signature of the sample collector from the independent laboratory; and

(j) The date, time, and the names and signatures of persons involved, each time a sample changes custody, is transported, or is destroyed.

(9) Once the independent laboratory removes the sample from the production licensee's premises, the sample collection form may not be altered.

(10) After a sample is collected, but prior to testing, an independent laboratory shall:

(a) Label the batch with the following information:

1. The independent laboratory's name and registration number;

2. The date the samples were taken; and

3. In bold, all capitalized letters: "PRODUCT NOT TESTED".

(b) Apply a custody seal to each laboratory test sample container or bulk package containing a single facility's laboratory test samples in a manner which prevents tampering.

Cite as Ga. Comp. R. & Regs. R. 351-7-.05
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "Sample Collection Requirements" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-7-.06. Transportation of Samples.

(1) An independent laboratory registrant shall have an ongoing duty to ensure security and oversight throughout any transfer of product in final packaged form, and to comply with Commission rules, and applicable local, state, and federal transportation, traffic, and vehicle safety laws.

(a) The transfer of product in final packaged form from the production licensee's premises to an independent laboratory shall be completed via secure transportation:

1. By an authorized employee of the independent laboratory or a production licensee; and

2. Sealed and labeled as a sample.

(b) Registrants are prohibited from transporting product in final packaged form outside the state of Georgia.

(c) Vehicles and trailers transporting product in final packaged form are subject to inspection by the Commission or its employees at any time.

(d) A registrant shall notify the Commission and its employees immediately:

1. If a vehicle transporting product in final packaged form is involved in a motor vehicle crash or other incident involving product damage or loss;

2. If there is a stop at a location that is not licensed or registered with the Commission that exceeds one (1) hour in duration and is not already listed in the shipping manifest; or

3. If a mechanical issue involving the transport vehicle necessitates the transfer of product in final packaged form to an alternate vehicle to complete the transport.

(e) Registrant employees' personal vehicles may not be utilized to transport product in final packaged form under any circumstances.

(f) Registrants are prohibited from utilizing third-party transportation.

(2) The registrant shall provide current information about such registrant's drivers who transport product in final packaged form, upon request by the Commission or its employees.

(a) Each employee authorized by the registrant to transport product in final packaged form shall:

1. Possess a valid state-issued driver's license; and

2. Be at least twenty-one (21) years of age.

(b) The registrant shall maintain a list of such registrant's drivers, including the following information of each employee:

1. First, middle, and last name;

2. Date of birth;

3. Valid state-issued driver license number, state, and expiration date;

4. Photograph; and

5. Contact information including telephone number.

(c) The registrant shall notify the Commission and its employees within twenty-four (24) hours of any addition to or removal from the list of the registrant's drivers who transport product in final packaged form.

(d) Registrants shall have a continuing duty to provide the Commission and its employees with current contact information for drivers and shall notify the Commission and its employees in writing of any changes to the contact information they provide the Commission.

(3) Any vehicle used for the transportation of product in final packaged form by a registrant shall comply with the following:

(a) A registrant shall register each vehicle or vehicle-trailer combination used for the transportation of product in final packaged form by submitting the following to Commission and its employees:

1. A copy of the vehicle registration or lease which shall include the VIN assigned by the vehicle manufacturer;

2. A copy of the vehicle's annual safety inspection;

3. A copy of the vehicle's unique vehicle number assigned by the registrant; and

4. Photos of the vehicle:

   (i) Left front corner;

   (ii) Right front corner;

   (iii) Right rear corner;

   (iv) Rear, including the affixed, government-issued license plate;

   (v) Left rear corner; and

   (vi) Vehicle Identification Number ("VIN") plate.

(b) All vehicles utilized for transporting product in final packaged form shall contain a global positioning system ("GPS") device for identifying the geographic location of the transport vehicle.

1. The device shall be permanently affixed to the transport vehicle.

2. The device shall remain active at all times during transportation of product in final packaged form.

3. At all times, the registrant shall be able to identify the geographic location of all transportation vehicles and employees who are transporting product in final packaged form.

4. The registrant shall provide the GPS information upon request by the Commission or its employees.

5. The use of cellular telephones as a device for GPS tracking does not meet the requirements of this rule.

(c) All vehicles shall be equipped with:

1. Climate control capabilities to ensure the integrity of the product in final packaged form being transported;

2. An alarm system; and

3. Permanently installed video cameras which shall:

(i) Constantly record during the transport of product in final packaged form;

(ii) Provide constant coverage of the driver and product being transported;

(iii) Be capable of maintaining video recordings for no less than forty-five (45) days; and

(iv) Be accessible or capable of producing video recordings upon request to the Commission or its employees.

(d) All transport vehicles shall be insured as set forth in Code Section 40-2-137.

(4) Independent laboratories are prohibited from transporting any product in final packaged form without a valid sampling form.

(a) The independent laboratory shall prepare a sampling form prior to transferring product in final packaged form off of the production premises.

(b) During transportation, the independent laboratory shall maintain a physical copy of the sampling form and make it available upon request to the Commission or its employees.

1. An independent laboratory may elect to use a paper copy or digital copy of the sampling form.

2. Independent laboratories are required to ensure all information is preserved with valid and verified signatures on any digital copy of a sampling form.

(5) Upon arrival at the independent laboratory's premises, the independent laboratory shall:

(a) Submit to the Commission-approved tracking system a record verifying receipt of the samples and the details of the samples; and

(b) Ensure that the product in final packaged form received are as described in the sampling form and shall immediately adjust its records to reflect the receipt of the samples.

(6) An independent laboratory shall create security standards for transportation, including ensuring that:

(a) Product in final packaged form shall only be transported inside of a vehicle or trailer that meets the requirements of the rules of the Commission and shall not be visible or identifiable from outside of the vehicle or trailer;

(b) Product in final packaged form shall be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle or trailer, and shielded from view from the exterior of the vehicle. No portion of the enclosed box, container, or cage shall be comprised of any part of the body of the vehicle or trailer. For the purposes of this section, the inside of the vehicle also includes, but is not limited to, the trunk and cargo areas;

(c) The vehicle transporting the product in final packaged form shall not contain any marks, logos, brands, or other illustrations on the exterior of the vehicle, other than those affixed to the vehicle by the vehicle manufacturer or dealership, or required placards and signage;

(d) All transport times and routes are randomized and within the borders of the state of Georgia; and

(e) An independent laboratory shall staff all transport vehicles with a minimum of two (2) employees. At least one (1) transport team member shall remain with the vehicle at all times that the vehicle contains product in final packaged form.

1. An employee shall carry the employee's identification at all times when transporting or delivering product in final packaged form.

2. The employee shall produce the identification to the Commission or its employees or to a law enforcement officer acting in the course of official duties.

Cite as Ga. Comp. R. & Regs. R. 351-7-.06
Authority: O.C.G.A. §§ 16-12-203, 16-21-210, 16-12-217.
History. Original Rule entitled "Transportation of Samples" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-7-.07. Testing Requirements.

(1) All products intended for dispensing shall be tested in final packaged form.

(2) The independent laboratory shall test any part of the product in final packaged form that will be consumed or used internally or externally by a patient.

(3) The independent laboratory shall follow the methodologies, ranges, and parameters which are contained in the scope of the accreditation for testing product in final packaged form.

(4) An independent laboratory shall develop, implement, and validate test methods for the analyses of samples. If an Association of Official Analytical Collaboration (AOAC) International Standard Method Performance Requirement (SMPR) exists, then the selected testing method shall meet the SMPR.

(5) The independent laboratory shall analyze the representative sample of product in final packaged form to determine whether foreign material is present.

(6) The independent laboratory shall report the results of each test performed by the independent laboratory on the certificate of analysis.

(7) If a sample of product in final packaged form passes the required testing, then an independent laboratory shall certify the batch for dispensing.

(8) If a sample of product in final packaged form failed required testing, then the independent laboratory shall:

(a) Notify the originating production licensee who submitted the controlled sample for testing; and

(b) Report the failure in accordance with the Commission-approved tracking system reporting requirements.

(9) For the testing of sample of product in final packaged form from a remediated batch, an independent laboratory shall test such sample in accordance with the rules of the Commission. If such sample passes testing, then the independent laboratory shall conduct a second test within twenty-four (24) hours of the issuance of such certificate of analysis for the first test in order to certify the batch for dispensing.

(10) An independent laboratory shall destroy the remains of the samples of product in final packaged form upon completion of the test.

Cite as Ga. Comp. R. & Regs. R. 351-7-.07
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "Sample Collection Requirements" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-7-.08. Certificate of Analysis.

(1) An independent laboratory shall only test and certify homogenized, controlled samples of product in final packaged form collected as set forth in Rule 351-7-.05.

(2) An independent laboratory shall issue to the production licensee a certificate of analysis for each batch of product in final packaged form tested for that production licensee.

(3) The certificate of analysis shall, at a minimum, include the results with supporting data for the following:

(a) The chemical profile of the following cannabinoid compounds:

1. Total tetrahydrocannabinol ("THC") sum percentage by weight of:

(i) Delta-9-tetrahydrocannabinol (D9-THC);

(ii) Delta-9-tetrahydrocannabinolic acid (THCA); and

(iii) Delta-9-tetrahydrocannabivarin (THCV).

2. Cannabichromene (CBC);

3. Cannabichromene acetate (CBCA);

4. Cannabidiol (CBD);

5. Cannabidiolic acid (CBDA);

6. Cannabigerol (CBG);

7. Cannabigerol acetate (CBGA);

8. Cannabinol (CBN); and

9. Cannabidivarin (CBDV).

(b) If an abnormality is found during the required testing listed above in subparagraph (a) of this rule, then the certificate of analysis shall also show test results for the presence of the following isomers and esters:

1. THC isomers, which have published peer-reviewed proficiency standards and measurements that have been validated for cannabis testing by an independent third party:

(i) Delta-6a(7)-tetrahydrocannabinol (D6a(7)-THC);

(ii) Delta-6a(10a)-tetrahydrocannabinol (D6a(10a)-THC);

(iii) Delta-7-tetrahydrocannabinol (D7-THC);

(iv) Delta-8-tetrahydrocannabinol (D8-THC);

(v) Delta-9(11) exo-tetrahydrocannabinol (Exo-THC); and

(vi) Delta-10-tetrahydrocannabinol (D10-THC).

2. THC esters, which have published peer-reviewed proficiency standards and measurements that have been validated for cannabis testing by an independent third party:

(i) THC-O acetate (THCOA);

(ii) THC-O-phosphate;

(iii) THC hemisuccinate (THC-HS); and

(iv) THC morpholinyl butyrate (SP-111).

(c) If tested, terpenes.

(d) Residual solvents, which shall not exceed the following action levels, measured in parts per billion (ppb), for the following analytes:

1. Acetones: 800,000;
2. Benzene: 1,000;
3. Butane: 800,000;
4. Ethanol: 5,000,000;
5. Heptane: 500,000;
6. Hexane: 100,000;
7. Pentane: 5,000,000;
8. Toluene: 1,000; and
9. Total Xylenes: 1,000
   (i) Meta-xylene (m-xylene);
   (ii) Para-xylene (p-xylene); and
   (iii) Ortho-xylene (o-xylene).

(e) The presence of the following heavy metals, which shall not exceed the following action levels, measured in parts per billion (ppb), for the following analytes by product:

1. Arsenic
   (i) Low-THC oil and products for nasal use such as nasal sprays: 200;

(ii) Low-THC oil and products for sublingual use such as oils and tinctures: 500;

(iii) Low-THC oil and products for ingestion such as capsule, lozenges, or other dissolvable solid dosage forms: 500; and

(iv) Low-THC oil and products for topical use such as lotions, topicals, and transdermal patches: 500.

2. Cadmium

(i) Low-THC oil and products for nasal use such as nasal sprays: 200;

(ii) Low-THC oil and products for sublingual use such as oils and tinctures: 500;

(iii) Low-THC oil and products for ingestion such as capsule, lozenges, or other dissolvable solid dosage forms: 500; and

(iv) Low-THC oil and products for topical use such as lotions, topicals, and transdermal patches: 500.

3. Chromium

(i) Low-THC oil and products for nasal use such as nasal sprays: 500,000;

(ii) Low-THC oil and products for sublingual use such as oils and tinctures: 500,000;

(iii) Low-THC oil and products for ingestion such as capsule, lozenges, or other dissolvable solid dosage forms: 1,100,000; and

(iv) Low-THC oil and products for topical use such as lotions, topicals, and transdermal patches: 500,000.

4. Lead

(i) Low-THC oil and products for nasal use such as nasal sprays: 500;

(ii) Low-THC oil and products for sublingual use such as oils and tinctures: 500;

(iii) Low-THC oil and products for ingestion such as capsule, lozenges, or other dissolvable solid dosage forms: 500; and

(iv) Low-THC oil and products for topical use such as lotions, topicals, and transdermal patches: 500.

5. Mercury

(i) Low-THC oil and products for nasal use such as nasal sprays: 200;

(ii) Low-THC oil and products for sublingual use such as oils and tinctures: 500;

(iii) Low-THC oil and products for ingestion such as capsule, lozenges, or other dissolvable solid dosage forms: 500; and

(iv) Low-THC oil and products for topical use such as lotions, topicals, and transdermal patches: 500.

(f) Pesticides regulated by the United States Environmental Protection Agency, including, but not limited to, the following, which shall not exceed an action level of 100 parts per billion (ppb) or the independent laboratory's lowest possible limit of quantitation (LOQ) for such respective analyte, whichever is lower:

1. Abamectin;
2. Acephate;
3. Acequinocyl;
4. Acetamiprid;
5. Aldicarb;
6. Azoxystrobin;
7. Bifenazate;
8. Bifenthrin;
9. Boscalid;
10. Carbaryl;
11. Carbofuran;
12. Chlorantraniliprole;

13. Chlordane;
14. Chlormequat Chloride;
15. Chlorpyrifos;
16. Coumaphos;
17. Cyfluthrin;
18. Cypermethrin;
19. Daminozide;
20. Diazinon;
21. Dichlorvos;
22. Dimethoate;
23. Dimethomorph;
24. Ethoprophos;
25. Etofenprox;
26. Etoxazole;
27. Fenoxycarb;
28. Fenhexamid;
29. Fipronil;
30. Flonicamid;
31. Fludioxonil;
32. Fluoxastrobin;
33. Hexythiazox;
34. Imazalil;
35. Imidacloprid;
36. Kresoxim Methyl;

37. Malathion;
38. Metalaxyl;
39. Methiocarb;
40. Methomyl;
41. Mevinphos;
42. Myclobutanil;
43. Oxamyl;
44. Paclobutrazol;
45. Permethrin;
46. Phosmet (Imidan);
47. Prallethrin;
48. Propiconazole;
49. Propoxur;
50. Pyridaben;
51. Spinetoram;
52. Spiromesifen;
53. Spirotetramat;
54. Spiroxamine;
55. Tebuconazole;
56. Thiacloprid;
57. Thiamethoxam; and
58. Trifloxystrobin.

(g) Any visible foreign material that is not intended to be part of the product being produced, including, but not limited to, filth, hair, insects, metal, or plastic.

(h) Microbial impurities, which shall not exceed the following action levels, measured in colony-forming unit per gram (cfu/g), for each of the following analytes:

1. Total viable aerobic bacteria: 100,000;
2. Total yeast and mold: 10,000;
3. Total coliforms: 1,000;
4. Bile-tolerant gram negative bacteria: 1,000;
5. Shiga-toxin producing escherichia coli (STEC) and salmonella spp.*:* 1.0; and
6. Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, and Aspergillus terreus: 1.0.

(i) Mycotoxins, which shall not exceed an action level of 20 parts per billion (ppb) for each of the following analytes:

1. Aflatoxin B1;
2. Aflatoxin B2;
3. Aflatoxin G1;
4. Aflatoxin G2; and
5. Ochratoxin A.

(4) The independent laboratory shall submit the certificate of analysis to the Commission and its employees at the same time the certificate of analysis is submitted to the originating production licensee.

(5) The independent laboratory shall upload the certificate of analysis into a Commission-approved tracking system within twenty-four (24) hours of the completion of tests.

(6) In addition to the requirements of this rule, the Commission may make available, via its website or other public means, additional bulletins outlining any contaminants and their actionable levels.

Cite as Ga. Comp. R. & Regs. R. 351-7-.08
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "Certificate of Analysis" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-7-.09. Records.

(1) An independent laboratory shall establish a system to create, retain, and maintain all required records.

(2) For the testing of products in final packaged form, an independent laboratory shall maintain the following records and shall produce such records upon request by the Commission or its employees:

(a) Records of sample collection for a minimum of twelve (12) months from the date such sample is collected;

(b) Records of laboratory testing results for a minimum of twelve (12) months from the date of such testing; and

(c) Copies of the certificate of analysis for each test performed for a minimum of twenty-four (24) months from the respective dates of issuance.

(3) An independent laboratory shall establish an account with a Commission-approved tracking system to document the complete chain of custody for samples, from receipt through disposal or return to the originating production licensee, before receiving or testing any product in final packaged form.

(4) An independent laboratory shall track and submit into the Commission-approved tracking system any information the Commission determines necessary for tracking product in final packaged form, including, but not limited to, transportation of samples, sample inventory, and certificates of analysis.

Cite as Ga. Comp. R. & Regs. R. 351-7-.09
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-217.
History. Original Rule entitled "Records" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.
Amended: F. Nov. 9, 2023; eff. Nov. 29, 2023.

Rule 351-7-.10. Changes.

(1) Changes to a registrant's name, location, or agent require:

(a) A written notice to the Commission of any proposed change at least sixty (60) days prior to the proposed effective date of the change;

(b) A complete registration change form;

(c) A secure and verifiable document as set forth in Code Section 50-36-2;

(d) The required fee, as set forth in the fee schedule, within thirty (30) days of any written notice of change; and

(e) Commission approval. The Commission hereby delegates the authority and responsibility to determine whether changes to a registration are approved, or denied, to the GMCC Executive Director.

(2) A change of location for an independent laboratory shall require a new form.

(a) An independent laboratory cannot begin registered operations at the new location until a preliminary inspection of the proposed independent laboratory has been completed.

(b) An independent laboratory receiving approval from the Commission, as set forth in these rules, for a change of location shall have a transition period of thirty (30) days from the date of approval, unless an extension is granted at the discretion of the GMCC Executive Director, to begin operations at the new independent laboratory.

(c) In order to transfer inventory and begin operations at the new location, the following restrictions apply:

1. No product in final packaged form may be transferred to the new location prior to the beginning date of the approved transition period;

2. Any product in final packaged form remaining at the original location past the thirty (30) day transition period shall be destroyed; and

3. The independent laboratory shall notify the Commission and its employees, in writing or by electronic transmission, once the transfer of inventory is complete.

(3) If a registration change form and supporting documentation contains information that the independent laboratory claims to be confidential, then the independent laboratory shall submit a redacted and an unredacted version of the form, along with an affidavit explaining or justifying such redactions.

Cite as Ga. Comp. R. & Regs. R. 351-7-.10
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-215, 16-12-217.
History. Original Rule entitled "Changes" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Chapter 351-8. ENFORCEMENT.

Rule 351-8-.01. Authority to Investigate, Inspect, and Levy Fines.

(1) The Commission and its employees shall have the authority to:

(a) Investigate violations, or suspected violations, of the Act and any rules promulgated pursuant to it;

(b) Refer complaints to the Georgia Bureau of Investigation, the Georgia Drugs and Narcotics Agency, local law enforcement, and other appropriate government authorities, and to cooperate with such entities in their respective investigations and processes;

(c) Serve all orders, summonses, administrative citations, notices, or other processes relating to the enforcement of the Act and the rules of the Commission;

(d) Conduct on-demand and scheduled inspections and investigations of the premises of licensees and registrants; and

(e) Exercise any other power or duty authorized by law.

(2) Prior notice of an inspection, investigation, review, or audit is not required.

(3) During an inspection or investigation, the Commission and its employees shall have the authority to:

(a) Have full and immediate access to enter and inspect the entire premises of the licensee or registrant, and all locations, vehicles, and equipment associated with the operations, storage, and records of a licensee or registrant;

(b) Question any individual on the premises;

(c) Obtain and test any regulated cannabis possessed by, in the control of, or used by a licensee or registrant and its employees;

(d) Access, review, request, and receive copies of any physical or electronic data, materials, books, or records of any licensee or registrant and its employees; and

(e) Provide a written notice of specific violations found during the inspection or investigation.

(4) Nothing in this rule prohibits the Commission or its employees from investigating or inspecting the premises of a licensee or registrant at any time, or from referring potential criminal activity to law enforcement.

(5) Pursuant to, and consistent with, Code Section 16-12-203(17), the Commission hereby delegates the authority and responsibility to determine and levy fines to the GMCC Executive Director.

(a) Fines levied may be progressively structured up to the maximum amount as set forth in Code Section 16-12-203(17) and as may be identified on the inspection report or a Commission order.

(b) A fine schedule may be established and published on the Commission's website.

Cite as Ga. Comp. R. & Regs. R. 351-8-.01
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-213, 16-12-216, 16-12-217.
History. Original Rule entitled "Authority to Investigate, Inspect, and Levy Fines" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-8-.02. Production License Inspections.

(1) A production licensee shall provide and deliver records upon request by the Commission or its employees.

(2) A production licensee shall ensure that the Commission and its employees have immediate access to their premises. If the Commission or its employees are denied access to the premises for any reason, then the licensee shall be subject to citations and fines up to and including revocation.

(3) No licensee shall interfere with, obstruct, or impede the Commission or its employees from exercising their duties as set forth in the Act and these rules. This includes, but is not limited to, the following:

(a) Denying or delaying the Commission or its employees access to the premises, during business hours or times of operation, where the licensee's regulated cannabis is grown, stored, cultivated, manufactured, tested, or transferred;

(b) Providing false or misleading statements, documents, data, or records;

(c) Failing to timely produce documents, data, or records that are required to be maintained by the licensee;

(d) Failing to timely respond to any other request for information made by the Commission or its employees in connection with an investigation of the qualifications, conduct, or compliance of a licensee; or

(e) Threatening force or violence against the Commission or its employees, or otherwise endeavoring to intimidate, obstruct, or impede the Commission or its employees from exercising their duties. The term "threatening force" includes the threat of bodily harm to such individual or to a member of his or her family.

(4) If an inspection report has findings of any non-compliance of the laws, rules, or regulations of the Commission, then the production licensee shall develop and submit a corrective action plan in writing to the Commission within seven (7) days after the licensee's receipt of the inspection report, unless a written extension is issued by the Commission. The Commission hereby delegates the authority and responsibility to determine whether an extension is made, and the duration to develop and submit such corrective action plan(s), if any, to the GMCC Executive Director.

(a) The corrective action plan shall respond to the deficiencies and/or violations found in the inspection report and include specific steps the licensee has taken, or will take, to address such findings.

(b) The production licensee shall perform and complete such steps identified in its corrective action plan within fourteen (14) days of the date of inspection. A production licensee is subject to additional inspections by the Commission or its employees to confirm the corrective action plan has been completed and that all deficiencies and violations have been resolved.

(5) Nothing in this subsection shall be construed to prohibit an appropriate local, state, or federal administrative authority from conducting an inspection of the facilities or operations of a production licensee as provided by law, rule, or regulation of a local, state, or federal government.

Cite as Ga. Comp. R. & Regs. R. 351-8-.02
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-213, 16-12-217.
History. Original Rule entitled "Production License Inspections" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-8-.03. Dispensing License Inspections.

(1) Prior notice of an inspection, investigation, review, or audit is not required.

(2) Dispensing licensees shall provide and deliver records to the Commission or its employees upon request.

(3) Dispensing licensees shall ensure that the Commission and its employees have immediate access to their dispensary. If the Commission or its employees are denied access to a dispensary for any reason, then the dispensing licensee shall be subject to citations and fines up to and including revocation.

(4) No dispensing licensee shall interfere with, obstruct, or impede the Commission or its employees from exercising their duties as set forth in the Act and these rules. This includes, but is not limited to:

(a) Denying or delaying the Commission or its employees access to the dispensary, where the licensee's product in final packaged form are stored, during business hours or times of apparent operation;

(b) Providing false or misleading statements;

(c) Providing false or misleading documents and records;

(d) Failing to timely produce requested books and records required to be maintained by the licensee;

(e) Failing to timely respond to any other request for information made by the Commission or its employees in connection with an investigation of the qualifications, conduct, or compliance of the licensee; or

(f) Threatening force or violence against the Commission or its employees, or otherwise endeavoring to intimidate, obstruct, or impede the Commission or its employees from exercising their duties. The term "threatening force" includes the threat of bodily harm to such individual or to a member of his or her family.

(5) Upon receipt of an inspection report with deficiencies, violations, or fines, the dispensing licensee shall develop a corrective action plan for each deficiency and/or violation and submit the plan in writing to the Commission within seven (7) days after receipt of the statement of deficiencies and/or violations, unless a written extension is issued by the Commission. The Commission hereby delegates the authority and responsibility to determine whether an extension is made and its duration to develop and submit such corrective action plan(s), if any, to the GMCC Executive Director.

(a) The corrective action plan shall include specific requirements for corrective action that will be performed within fourteen (14) days of the date of the inspection.

(b) A dispensing licensee is subject to additional inspections by the Commission or its employees to confirm that the corrective action plan has been implemented and the deficiencies or violations have been resolved.

(6) Nothing in this rule shall be construed to prohibit an appropriate local, state, or federal administrative authority from conducting an inspection of the dispensary or operations of a dispensing licensee as provided by law, rule, or regulation of a local, state, or federal government.

Cite as Ga. Comp. R. & Regs. R. 351-8-.03
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-215, 16-12-217, 16-12-223.
History. Original Rule entitled "Dispensing License Inspections" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-8-.04. Complaints.

Complaints submitted to the Commission shall include the following information:

(a) The name and contact information of the complainant;

(b) The name and license number, if applicable, of the person or entity that is the subject of the complaint;

(c) A detailed description of the alleged violation of law(s) or rule(s);

(d) The date of the alleged violation or, if such date is unknown, the date that the alleged violation was identified or became known by the complainant;

(e) The address or description of the location where the alleged violation occurred; and

(f) Information, documentation, or evidence to support the complaint.

Cite as Ga. Comp. R. & Regs. R. 351-8-.04
Authority: O.C.G.A. §§ 16-12-203, 16-12-210.
History. Original Rule entitled "Complaints" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-8-.05. Violations of the Act and Rules.

(1) At the conclusion of an inspection or investigation, the completed inspection form shall serve as the initial written notice of specific violations of the Act and these rules.

(a) If the licensee fails to remedy the specified violations within fourteen (14) days of the issuance date of such written notice, then the GMCC Executive Director shall provide a final written notice of such unresolved violations and fine(s) levied.

(b) The licensee shall pay the levied fine, in full, within thirty (30) days of the date of the final written notice.

(c) Failure to pay such levied fine(s) in full within thirty (30) days shall constitute a separate violation and shall be subject to additional action by the Commission pursuant to the Act and these rules.

(2) Upon receipt of the final written notice, and within thirty (30) days of such notice, the licensee may submit a written request for a hearing before the Commission to be heard on the specific violations and the levied fine(s) stated in such notice. The Commission may designate a hearing officer to serve in the hearing(s).

(a) If a written request for a hearing has been received and such hearing has been scheduled, then the payment of the levied fine(s) shall remain pending until the Commission issues a decision from the hearing, and such decision may, as applicable, provide the due date for the payment of the remaining fine(s).

(b) If the licensee does not submit a written request for a hearing before the Commission, then the final written notice and fine(s) levied shall stand and such levied fines shall remain due.

(3) The Commission or its employees may forward information regarding violations of the Act or these rules to any other local, state, or federal law enforcement agency, district attorney or attorney general, and the prosecutor for the local jurisdiction in which the alleged violation occurred.

Cite as Ga. Comp. R. & Regs. R. 351-8-.05
Authority: O.C.G.A. §§ 16-12-203, 16-12-210, 16-12-216.
History. Original Rule entitled "Violations of the Act and Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Rule 351-8-.06. Suspensions.

(1) For the purpose of this Rule 351-8-.06, the term "licensee" shall mean a Class 1 production licensee, a Class 2 production licensee, or a dispensing licensee.

(2) Consistent with Code Section 16-12-203(17), the Commission shall provide a licensee with notice and an opportunity to be heard on the violations of the Act and these rules prior to entering an order to suspend a license for a period of up to thirty (30) days.

(3) A licensee whose license has been suspended shall conspicuously and continuously display two (2) notices at the licensee's premises during the term of the suspension, with one (1) on the exterior and one (1) on the interior.

(a) The notices shall read: NOTICE OF SUSPENSION The Georgia Access to Medical Cannabis Commission license(s) issued to [name of licensee] [license number] has been suspended for violation of state law and/or rules.

(b) The Commission may require the licensee to prominently display the notice on the homepage of the licensee's website and social media.

Cite as Ga. Comp. R. & Regs. R. 351-8-.06
Authority: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210.
History. Original Rule entitled "Suspensions" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.