R66. Agriculture and Food, [~~Medical Cannabis and Industrial Hemp~~]Specialized Products.
R66-4. Independent Cannabis Testing Laboratory.
R66-4-1. Authority and Purpose.
Pursuant to Subsections 4-41a-103(5), 4-41a-302(3)(b)(ii), [~~4-41a-404(3), 4-41a-405(2)(b)(iv),~~] 4-41a-701([~~3~~]1), 4-41a-801(1), and 4-2-103(1)(i), this rule establishes the application process, qualifications, and requirements to obtain and maintain an independent cannabis testing laboratory license.

R66-4-2. Definitions.
(1) "Applicant" means any person or business entity who applies for [~~a cannabis processing facility~~] an independent cannabis testing laboratory license.
(2) [~~"Batch" means a quantity of:~~
~~(a) cannabis extract produced on a particular date and time, following clean up until the next clean up during which lots of cannabis are used;~~
~~(b) cannabis product produced on a particular date and time, following clean up until the next clean up during which cannabis extract is used; or~~
~~(c) cannabis flower packaged on a particular date and time, following clean up until the next clean up during which lots of cannabis are being used.~~
~~(3) "Cannabis" means any part of a marijuana plant.~~
~~(4) "Cannabis cultivation facility" means a person that:~~
~~(a) possesses cannabis;~~
~~(b) grows or intends to grow cannabis; and~~
~~(c) sells or intends to sell cannabis to a cannabis cultivation facility or to a cannabis processing facility.~~
~~(5) "Cannabis processing facility" means a person that:~~
~~(a) acquires or intends to acquire cannabis from a cannabis production establishment or a holder of an industrial hemp processor license under Title 4 Chapter 41, Hemp and Cannabinoid Act;~~
~~(b) possesses cannabis with the intent to manufacture a cannabis product;~~
~~(c) manufactures or intends to manufacture a cannabis product from unprocessed cannabis or a cannabis extract; and~~
~~(d) sells or intends to sell a cannabis product to a medical cannabis pharmacy or the state central fill medical cannabis pharmacy.~~
~~(6) "Cannabis production establishment agent registration card" means a registration card that the department issues that:~~
~~(a) authorizes an individual to act as a cannabis production establishment agent; and~~
~~(b) designates the type of cannabis production establishment for which an individual may act as an agent.~~
~~(7) "Department" means the Utah Department of Agriculture and Food.~~
~~(8) "Independent cannabis testing laboratory" means a person who:~~
~~(a) conducts a chemical or other analysis of cannabis or a cannabis product; or~~
~~(b) acquires, possesses, and transports cannabis or a cannabis product with the intent to conduct a chemical or other analysis of the cannabis or cannabis product.~~
~~(9) "Independent cannabis testing laboratory agent" means an individual who:~~
~~(a) is an employee of an independent cannabis testing laboratory; and~~
~~(b) holds a valid cannabis production establishment agent registration card.~~
~~(10)~~] "Lot" means the quantity of:
(a) flower produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or
(b) trim, leaves, or other plant matter from cannabis plants produced on a particular date and time, following clean up until the next clean up.
[~~(11) "Medical cannabis research licensee" means a person who holds a license to perform academic medical cannabis research pursuant to Section 4-41a-901and Rule R68-35.~~]

R66-4-3. Independent Testing Laboratory License.
(1) An independent testing laboratory license allows the licensee to receive cannabis from a licensed cannabis cultivation facility to conduct testing as required by Subsection 4-41a-701[~~(2)~~] and Rule R6[~~8-29~~]6-3.
(2) An independent testing laboratory license allows the licensee to receive cannabis from a licensed cannabis processing facility to conduct testing as required by Subsection 4-41a-701[~~(2)~~] and Rule R6[~~8-29~~]6-3.
(3) An independent testing laboratory license allows the licensee to receive cannabis from a licensed cannabis cultivation facility and a cannabis processing facility to conduct the additional test as requested.
(4) [~~A complete application shall include the required fee, statements, forms, diagrams, operation plans, and other applicable documents required in the application packet to be accepted and processed by the department.~~
~~(5) Before approving an application, the department may contact any applicant and request additional supporting documentation or information.~~
~~(6) Before issuing a license, the department shall inspect the proposed premises to determine if the applicant complies with state laws and rules.~~
~~(7) The department may conduct face-to-face interviews with an applicant if needed to determine the best-qualified~~

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~~applicant for the number of licenses needed.~~
~~(8)~~] The license shall expire 12 months from the date on which the license is issued.
[~~(9) An application for renewals shall be submitted to the department no later than 30 days before the license expiration date.~~
~~(10)If the renewal application is not submitted 30 days before the expiration date the licensee may not continue to operate.~~
~~(11) An independent cannabis testing laboratory license is not transferable or assignable. If the ownership of an independent cannabis testing laboratory changes by 50% or more, the requirements of Subsection 4-41a-201(15) shall be followed.~~]

R66-4-4. Independent Cannabis Testing Laboratory Requirements.
(1) An independent testing laboratory shall employ a scientific director responsible for:
(a) ensuring that the laboratory achievement and maintenance of quality standards of practice; and
(b) supervising laboratory staff.
(2) The scientific director for an independent laboratory shall have:
(a) a doctorate in chemical or biological sciences from an accredited college or university and have at least 2 years of post-degree laboratory experience;
(b) a master's degree in chemical or biological sciences from an accredited college or university and have at least 4 years of post-degree laboratory experience; or
(c) a bachelor's degree in chemical or biological sciences from an accredited college or university and have at least 6 years of post-degree laboratory experience.
(3) An independent cannabis testing laboratory shall follow validated analytical methods, such as those published by the Association of Official Agricultural Chemists (AOAC), American Herbal Pharmacopoeia, EPA, FDA, or other reputable scientific organizations or notify the department of alternative scientifically valid testing methodology the lab is following for each required test.
(4) An independent cannabis testing laboratory may not use an alternative testing method without earlier review from the department.
(5) The department shall review any monograph or analytical method followed by an independent cannabis testing laboratory to ensure the methodology produces scientifically accurate results before the use of alternative testing methods to conduct the required tests.
(6) An independent cannabis testing laboratory shall establish written standard operating procedures for each test being conducted.
(7) An independent cannabis testing laboratory shall maintain an average testing turnaround time below ten business days within any three- month period.
(8) An independent cannabis testing laboratory shall obtain and keep the International Organization for Standardization (ISO) 17025:2017 accreditation.
(9) An independent cannabis testing laboratory may be licensed before ISO 17025:2017 accreditation provided the independent cannabis testing laboratory:
(a) adopt and follow minimum good laboratory practices which satisfy the OECD Principles of Good Laboratory Practice and Compliance Monitoring published by the Organization for Economic Co-operation and Development; and
(b) becomes ISO 17025:2017 accredited within 24 months.
(10) The department incorporates the following materials by reference:
(a) Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control (2014 Revisions) published by the American Herbal Pharmacopoeia; and
(b) OECD Principles of Good Laboratory Practice and Compliance Monitoring (1997) published by the Organization for Economic Co-operation and Development.
[~~(11) An independent cannabis testing laboratory shall have written emergency procedures to be followed in case of:~~
~~(a) fire;~~
~~(b) chemical spill; or~~
~~(c) other emergencies at the laboratory.~~
~~(12) An independent cannabis testing laboratory shall compartmentalize each area in the facility based on function and shall limit access to the compartments to the appropriate authorized agents.~~]

R66-4-5. Security Requirements.
(1) [~~At a minimum, a licensed independent cannabis testing laboratory shall have a security alarm system on each perimeter entry point and perimeter window.~~
~~(2)~~] At a minimum, a licensed independent cannabis testing laboratory shall have a complete video surveillance system:
(a) with minimum camera resolution of 640 x 470 pixels or pixel equivalent for analog; and
(b) ~~[that retains footage for at least 45 days.~~
~~(3) Cameras shall:~~
~~(a) be fixed and placement shall~~]that allows for the clear and certain identification of any person and activity[~~ies in controlled areas; and~~
~~(b) record continuously.~~
~~(4) Controlled areas included:~~

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~~(a) entrances and exits;~~
~~(b) any areas where cannabis or cannabis products are stored;~~
~~(c) any areas where cannabis or cannabis products are being tested; and~~
~~(d) any areas where cannabis waste is being moved, processed, stored, or destroyed.~~
~~(5) If an independent cannabis testing facility stores footage locally, the surveillance system storage device shall be secured in the facility in a lockbox, cabinet, closet, or secured in another manner to protect from employee tampering or criminal theft.~~
~~(6) If an independent cannabis testing laboratory stores footage on a remote server, access shall be restricted to protect from employee tampering.~~
~~(7) Any entry point shall be lighted in low-light conditions sufficient to record activity occurring.~~
~~(8)~~] (2) Any visitors to an independent cannabis testing laboratory shall be required to have a properly displayed identification badge issued by the facility at all times while on the premises of the facility.
[~~(9)~~](3) Any visitors shall be escorted by an independent cannabis facility agent at all times while in the facility.
[~~(10)~~] (4) An independent cannabis testing laboratory shall keep and maintain a visitor's log showing:
(a) the full name and age of each visitor entering the facility;
(b) the badge number issued;
(c) the time of arrival;
(d) the time of departure; and
(e) the purpose of the visit.
[~~(11)~~] (5) The independent cannabis testing laboratory shall keep the visitors log for a minimum of a year.
[~~(12)~~] (6) The independent cannabis testing laboratory shall make the visitor log available to the department upon request.

R66-4-6. Inventory Control.
(1) Each test sample shall have a unique identification number in the inventory control system.
(2) Each test sample shall be traceable to the lot or batch used as the base material from the cannabis production establishment.
(3) Unique identification numbers may not be reused.
(4) Each test sample that has been issued a unique identification number shall have a physical tag placed on it with:
(a) the unique identification number;
(b) the license number and name of the lab receiving the test sample;
(c) the license number and name of the cannabis production establishment name;
(d) the date the test sample was collected; and
(e) the weight of the sample.
(5) The tag shall be legible and placed in a position that can be clearly read and shall be kept free from dirt and debris.
(6)[~~The following shall be reconciled in the inventory control system at the close of business each day:~~
~~(a) the date and time the test sample was received;~~
~~(b) each sample used for testing and the test results;~~
~~(c) the identity of the agent conducting the test;~~
~~(d) a complete inventory of cannabis test samples;~~
~~(e) the weight and disposal of cannabis waste materials;~~
~~(f) the identity of who disposed of the cannabis waste; and~~
~~(g) the theft or loss or suspected theft or loss of test sample.~~
~~(7)~~]An independent cannabis testing laboratory shall document in the inventory tracking system any test samples received, and any difference between the quantity specified in the transport and quantities received.

R66-4-7. Independent Cannabis Testing Laboratory Agents.
(1)[~~A prospective independent cannabis testing laboratory agent shall apply to the department for a cannabis testing laboratory agent registration card on a form provided by the department.~~
~~(2) An application is not considered complete until the background check has been completed, the registration fee has been paid, and the prospective agent has submitted the required training certificate.~~
~~(3) The cannabis establishment agent registration card shall contain:~~
~~(a) the agent's full name;~~
~~(b) identifying information; and~~
~~(c) a photograph of the agent.~~
~~(4)~~] An independent cannabis testing laboratory is responsible to ensure that each agent has received any task-specific training as outlined in the operating plan submitted to the department.
[~~(5)~~] (2) An independent cannabis testing agent shall have a properly displayed identification badge which has been issued by the department while on the facility premises or while engaged in the transportation of cannabis.
[~~(6)~~](3) Cannabis testing laboratory agents shall have their state-issued identification card in their possession to certify the information on their badge is correct.
[~~(7) Each cannabis testing laboratory shall maintain a list of each employee that holds a cannabis testing laboratory agent registration card and provide the list to the department upon request.~~]

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[~~**R66-4-8. Transportation.**~~
~~(1) A printed transport manifest shall accompany every transport of cannabis.~~
~~(2) The manifest shall contain the following information:~~
~~(a) the cannabis production establishment address and license number of the departure location;~~
~~(b) physical address and license number of the receiving location;~~
~~(c) strain name, quantities by weight, and unique identification numbers of each cannabis material to be transported;~~
~~(d) date and time of departure;~~
~~(e) estimated date and time of arrival; and~~
~~(f) name and signature of each agent accompanying the cannabis.~~
~~(3) The transport manifest may not be voided or changed after departing from the original cannabis production establishment.~~
~~(4) A copy of the transport manifest shall be given to the independent laboratory.~~
~~(5) The receiving independent laboratory shall ensure that the cannabis material received is as described in the transport manifest and shall record the amounts received for each strain into the inventory control system.~~
~~(6) The receiving independent laboratory shall document at the time of receipt any differences between the quantity specified in the transport manifest and the quantities received in the inventory control system.~~
~~(7) During transport an independent cannabis testing laboratory agent shall ensure the cannabis is:~~
~~(a) shielded from the public view;~~
~~(b) secured; and~~
~~(c) temperature controlled if perishable.~~
~~(8) An independent cannabis testing laboratory shall contact the department within 24 hours if a vehicle transporting cannabis is involved in an accident that involves product loss.~~
~~(9) Only the registered agents of the independent cannabis testing laboratory may occupy a transporting vehicle.~~]

R66-4-[9]8. Cannabis Waste Disposal.
(1) Solid and liquid wastes generated during cannabis testing shall be stored, managed, and disposed of in accordance with applicable state law.
(2) Waste water generated during cannabis testing shall be disposed of in compliance with applicable state law.
~~(3) Cannabis waste generated from the cannabis plant, trim, and leaves are not considered hazardous waste unless it has been treated or contaminated with a solvent, or pesticide.~~
~~(4) Cannabis waste shall be made unusable before leaving the independent cannabis testing laboratory, except as provided for in Subsection R68-30-9(10) and Subsection R68-30-9(11).~~
~~(5) Cannabis waste, which is not designated as hazardous, shall be made unusable by grinding and incorporating the cannabis waste with other ground materials so the resulting mixture is at least 50% non-cannabis waste by volume or other methods approved by the department before implementation.~~
~~(6) Materials used to grind and incorporate with cannabis fall into two categories:~~
~~(a) compostable; or~~
~~(b) non-compostable.~~
~~(7) Compostable waste is cannabis waste to be disposed of as compost or in another organic waste method mixed with:~~
~~(a) food waste;~~
~~(b) yard waste; or~~
~~(c) vegetable-based grease or oils.~~
~~(8) Non-compostable waste is cannabis waste to be disposed of in a landfill or another disposal method, such as incineration, mixed with:~~
~~(a) paper waste;~~
~~(b) cardboard waste;~~
~~(c) plastic waste; or~~
~~(d) soil.~~
~~(9) Cannabis waste includes:~~
~~(a) cannabis plant waste including roots, stalks, leaves, and stems;~~
~~(b) excess cannabis or cannabis products from any quality assurance testing;~~
~~(c) cannabis or cannabis products that fail to meet testing requirements; and~~
~~(d) cannabis or cannabis products subject to a recall.~~
~~(10)~~] (3) An independent cannabis testing laboratory may transfer cannabis waste material to a cannabis testing laboratory operated by the department for use by a medical cannabis research licensee if:
(a) the laboratory operated by the department agrees to accept the material;
(b) the licensee that submitted the material to the laboratory for testing allows the use of their material for medical cannabis research;
(c) the material passed all required tests or is clearly labeled "not for human consumption" and is accompanied by a list of known contaminants; and
(d) the material has met the sample retention requirements of the laboratory.

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([~~11~~]4) The cannabis testing laboratory operated by the department may transfer any cannabis waste material to a medical cannabis research licensee if:
(a) the licensee that submitted the material to the laboratory for testing agrees to the use of their material for medical cannabis research;
(b) the material passed all required tests or is clearly labeled "not for human consumption" and is accompanied by a list of known contaminants; and
(c) the material has met the sample retention requirements of the laboratory.

R66-4-[~~10~~]9. Change in Operation Plans.
(1) An independent cannabis testing laboratory shall submit a notice, on a form provided by the department, before making any changes to:
(a) ownership or financial backing of the facility;
(b) the facility's name;
(c) a change in location;
(d) change in testing methods, equipment, remodeling, expansion, reduction or physical, non-cosmetic alteration of the lab; or
(e) change in written operating procedures.
(2) An independent cannabis testing laboratory may not implement changes to the approved operation plan without department approval.
(3) The department shall approve of requested changes unless approval would lead to a violation of the applicable laws and rules of the state.
(4) The department shall specify the reason for the denial of approval for a change to the operation plan.

R66-4-1[~~1~~]0. Renewals.
(1) An independent cannabis testing laboratory shall submit a notice of intent to renew and the licensing fee to the department by their license expiration date.
(2) If the licensing fee and intent to renew are not submitted [~~on or before the expiration date~~]by the day of license expiration, the licensee may not continue to operate.
(3) The department shall renew a license unless renewal would lead to a violation of the applicable laws and rules of the state.

R66-4-12.[~~ Proficiency Testing.~~] Additional Testing.
(1) The department [~~shall~~] may establish a [~~proficiency~~] testing program for [~~independent cannabis testing laboratories~~] the purpose of conducting a study.
(2) Each independent cannabis testing laboratory shall participate in the [~~designated proficiency testing program with satisfactory performance~~] study as determined by the [~~D~~]department.

R66-4-1[~~3~~](1). Violation Categories.
(1) Public Safety Violations: $3,000- $5,000 per violation. This category is for violations which present a direct threat to public health or safety including:
(a) cannabis [~~sold~~] sent to an [~~unlicensed~~] unapproved source;
(b) cannabis [~~purchased~~] received from an [~~unlicensed~~] unapproved source;
(c) refusal to allow inspection;
(d) refusal to participate in proficiency testing;
(e) failure to comply with testing requirements;
(f) failure to report testing results;
(g) unauthorized personnel on the premises;
(h) permitting criminal conduct on the premises;
(i) engaging in or permitting a violation of the Title 4, Chapter 41a, Cannabis Production Establishments, that amounts to a public safety violation as described in this subsection.
(2) Regulatory Violations: $1,000-$5,000 per violation. This category is for violations involving this rule and other applicable state rules including:
(a) failure to maintain alarm and security systems;
(b) failure to keep and maintain records for at least two years;
(c) failure to maintain traceability;
(d) failure to follow transportation requirements;
(e) failure to follow the waste and disposal requirements; or
(f) engaging in or permitting a violation of Title 4, Chapter 41a, Cannabis Production Establishments or this rule that amounts to a regulatory violation as described in this subsection.
(3) Licensing Violations: $500- $5,000 per violation. This category is for violations involving licensing requirements including:
(a) an unauthorized change to the operating plan;
(b) failure to notify the department of changes to the operating plan;

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(c) failure to notify the department of changes to financial or voting interests of greater than 2%;
(d) failure to follow the operating plan as approved by the department;
(e) engaging in or permitting a violation of this rule or Title 4, Chapter 41, Cannabis Production Establishments, that amounts to a licensing violation as described in this subsection; or
(f) failure to respond to violations.
(4) The department shall calculate penalties based on the level of violation and the adverse effect or potential adverse effect at the time of the incidents giving rise to the violation.

KEY: cannabis laboratory, cannabis testing
Date of Last Change: [~~July 19, 2024~~]2025
Authorizing, and Implemented or Interpreted Law: 4-41a-701(3); 4-41a-404(3); 4-41a-405(2)(b)(iv); 4-41a-103(5)

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