

## **R68. Agriculture and Food, Plant Industry.**

### **R68-28. Cannabis Processing.**

#### **R68-28-1. Authority and Purpose.**

1) 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), 4-41a-801(1), and 4-2-103(1)(i), this rule establishes the application process, qualifications and requirements to obtain and maintain a cannabis processing license.

#### **R68-28-2. Definitions.**

1) "Applicant" means any person or business entity who applies for a cannabis processing facility license.

2a) "Cannabis" means any part of a marijuana plant.

b) "Cannabis" does not mean, for the purposes of this rule, industrial hemp.

3) "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.

4) "Cannabis concentrate" means the product of any chemical or physical process applied to cannabis biomass that concentrates or isolates the cannabinoids contained in the biomass.

5) "Department" means the Utah Department of Agriculture and Food.

6) "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.

7) "Cannabis cultivation byproduct" means any portion of a cannabis plant that is not intended to be sold as a cannabis plant product.

8) "Cannabis derivative product" means a product made using cannabis concentrate.

9) "Cannabis plant product" means any portion of a cannabis plant intended to be sold by a medical cannabis pharmacy in a form that is recognizable as a portion of a cannabis plant.

10) "Cannabis processing facility" means a person that:

a) acquires or intends to acquire cannabis from a cannabis production establishment;

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 concentrate; and

d) sells or intends to sell a cannabis product to a medical cannabis pharmacy.

11) "Cannabis processing facility agent" means an individual who:

a) is an employee of a cannabis processing facility; and

b) holds a valid cannabis production establishment agent registration card.

12) "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 is authorized to act as an agent.

13) "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.

14) "Total THC" means the sum of the determined amounts of delta-9-THC and delta-9-THCA, according to the formula: Total THC = delta-9-THC + (delta-9-THCA x 0.877).

### **R68-28-3. Cannabis Processing Facility License.**

1) A cannabis processing facility license allows the licensee to receive cannabis from a cannabis production facility.

2) A Tier 1 cannabis processing facility license allows the licensee to:

a) create cannabis concentrate;

b) create cannabis derivative product; and

c) package and label final product.

3) A Tier 2 cannabis processing facility license allows the licensee to package and label cannabis and cannabis final product.

4) A complete application shall include the required fee, statements, forms, diagrams, operation plans, copy of current Utah manufactured food establishment registration, and other applicable documents required in the application packet to be accepted and processed by the department.

5) Prior to approving an application, the department may contact the applicant and request additional supporting documentation or information.

6) Prior to issuing a license, the department shall inspect the proposed premises to determine if the applicant complies with state laws and rules.

7) Each cannabis processing facility license shall expire one calendar year from the date of licensure.

8) An application for renewals shall be submitted to the department 30 days prior to expiration.

9) If the renewal application is not submitted 30 days prior to the expiration date, the licensee may not continue to operate.

10) A license may not be sold or transferred.

### **R68-28-4. Cannabis Processing Facility Requirements.**

1) A cannabis processing facility operating plan shall contain a blue print of the facility containing the following information:

a) the square footage of the areas where cannabis is to be extracted;

b) the square footage of the areas where cannabis or cannabis products are to be packaged and labeled;

c) the square footage of the areas where cannabis products are manufactured;

d) the square footage and location of storerooms for cannabis awaiting extraction;

e) the square footage and location of storerooms for cannabis awaiting further manufacturing;

f) the area where finished cannabis and cannabis products are stored;

- g) the location of toilet facilities and hand washing facilities;
  - h) the location of a break room and location of personal belonging lockers;
  - i) the location of the areas to be used for loading and unloading of cannabis and cannabis products; and
  - j) the total square footage of the overall cannabis processing facility.
- 2) A cannabis processing facility shall have written emergency procedures to be followed in case of:
- a) fire;
  - b) chemical spill; or
  - c) other emergency at the facility.
- 3) A cannabis processing facility shall have a written plan to handle potential recall and destruction of cannabis due to contamination.
- 4) A cannabis processing facility shall use a standardized scale that is registered with the department when cannabis is:
- a) packaged for sale by weight;
  - b) bought and sold by weight; or
  - c) weighed for entry into the inventory control system.
- 5) A cannabis processing facility shall compartmentalize each area in the facility based on function and shall limit access between compartments.
- 6) A cannabis processing facility shall limit access to the compartments to the appropriate agents.
- 7) A cannabis processing facility creating cannabis derivative product shall develop standard operating procedures.

**R68-28-5. Cannabis Extraction Requirements.**

- 1) A cannabis processing facility shall ensure hydrocarbons n-butane, isobutane, propane, or heptane are of at least ninety-nine percent purity.
- 2) A cannabis processing facility shall use a professional grade closed loop extraction system designed to recover the solvents, work in an environment with proper ventilation, and control each source of ignition where a flammable atmosphere is or may be present.
- 3) A cannabis processing facility using carbon dioxide (CO<sub>2</sub>) gas extraction system shall use a professional grade closed loop CO<sub>2</sub> gas extraction system where each vessel is rated to a minimum of six hundred pounds per square inch and CO<sub>2</sub> shall be at least ninety-nine percent purity.
- 4) Closed loop systems hydrocarbon or CO<sub>2</sub> extraction systems shall be commercially manufactured and bear a permanently affixed and visible serial number.
- 5) A cannabis processing facility using a closed loop system shall, upon request, provide the department with certification from a licensed engineer stating the system is:
- a) safe for its intended use;
  - b) commercially manufactured, and
  - c) built to conform to recognized and generally accepted good engineering practices, such as:
    - i) the American Society of Mechanical Engineers (ASME);
    - ii) American National Standards Institute (ANSI);
    - iii) Underwriters Laboratories (UL); or
    - iv) The American Society for Testing and Materials (ASTM).

6) The certification document shall contain the signature and stamp of the certifying professional engineer and the serial number of the extraction unit being certified.

7) A cannabis processing facility shall use food grade ingredients to create cannabis derivative product.

8) A cannabis processing facility may use heat, screens, presses, steam distillation, ice water, and other mechanical methods which do not employ solvents or gases.

9) A cannabis processing facility shall ensure each solvent, with the exception of CO<sub>2</sub>, is extracted in a manner to recapture the solvent and ensure that it is not vented into the atmosphere.

10) A cannabis establishment agent using solvents or gases in a closed loop system shall be fully trained in the use of the system and have direct access to applicable material safety data sheets.

11) Parts per million for one gram of finished extract cannot exceed residual solvent or gas levels provided in Rule R68-29.

#### **R68-28-6. Security Requirements.**

1) At a minimum, each cannabis processing facility shall have a security alarm system on each perimeter entry point and perimeter window.

2) At a minimum, a licensed cannabis processing facility shall have a complete video surveillance system:

a) with minimum camera resolution of 1280 x 720 pixels or pixel equivalent for analog; and

b) that retains footage for at least 45 days.

3) each camera shall be fixed and placement shall allow for the clear and certain identification of any person and activities in controlled areas.

4) Controlled areas included:

a) any entrances and exits, or ingress and egress vantage points;

b) any areas where cannabis or cannabis products are stored;

c) any areas where cannabis or cannabis products are extracted;

d) any areas where cannabis or cannabis products are manufactured, packaged, or labeled; and

e) any areas where cannabis waste is being moved, processed, stored or destroyed.

5) Each camera shall record continuously.

6) For locally stored footage, 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 theft.

7) For footage stored on a remote server, access shall be restricted to protect from employee tampering.

8) Any gate or entry point must have lighting sufficient to record activity occurring in low light conditions.

9) Each visitor to a cannabis processing facility shall be required to display an identification badge issued by the facility while on the premises.

10) At all times, visitors shall be escorted by a cannabis processing facility agent.

11) A cannabis processing facility shall keep and maintain a visitors log showing:

a) the full name of each visitor entering the facility;

b) the time of arrival;

- c) the time of departure; and
- d) the purpose of the visit.

12) The cannabis processing facility shall keep the visitors log for a minimum of one year.

13) The cannabis processing facility shall make the visitor log available to the department upon request.

#### **R68-28-7. Inventory Control.**

1) Each batch or lot of cannabis, cannabis derivative product, cannabis product, test sample, or cannabis waste shall have a unique identifier in the inventory control system.

2) Each batch or lot of cannabis, cannabis derivative product, cannabis product, sample, or cannabis waste shall be traceable to the lot.

3) Unique identification numbers may not be reused.

4) Each batch, lot, or sample of cannabis shall have a unique identification number that is displayed on a physical tag.

5) The tag shall be legible and placed in a position that can be clearly read.

6) The following shall be reconciled in the inventory control system at the close of each business each day:

a) date and time material containing cannabis are being transported to a cannabis production establishment or medical cannabis pharmacy;

b) each sample used for testing and the test results;

c) a complete inventory of material containing cannabis;

d) cannabis product by unit count;

e) weight per unit of product;

f) weight and disposal of cannabis waste materials;

g) the identity of who disposed of the cannabis waste and the location of the waste receptacles; and

h) theft or loss or suspected theft or loss of material containing cannabis.

7) A receiving cannabis processing facility shall document in the inventory control system any material containing cannabis received, and any difference between the quantity specified in the transport manifest and the quantity received.

8) A cannabis processing facility shall immediately upon receipt of THC extract from a licensed industrial hemp processor enter the following information into the inventory control system:

a) the amount of THC extract received;

b) the name, address, and licensing number of the industrial hemp processor;

c) the weight per unit of product received; and

d) the assigned unique identification number.

#### **R68-28-8. Cannabis Processing Facility Agents.**

1) A cannabis processing facility shall apply to the department for a cannabis establishment agent on a form provided by the department.

2) An application is not considered complete until the background check has been completed and the facility has paid the registration fee.

3) The cannabis processing facility agent registration card shall contain:

a) the full name of the agent;

- b) the name of the cannabis processing establishment;
  - c) the job title or position of the agent; and
  - d) a photograph of the agent.
- 4) A cannabis processing facility is responsible to ensure that each agent has received:
- a) the department approved training as specified in Section 4-41a-301; and
  - b) any task specific training as outlined in the operating plan submitted to the department.
- 5) A cannabis processing facility agent shall have a properly displayed identification badge which has been issued by the department at all times while on the facility premises or while engaged in the transportation of cannabis.
- 6) Each cannabis production establishment agent shall have their state issued identification card in their possession to certify the information on their badge is correct.
- 7) Upon termination, the identification badge of an agent shall be immediately returned to the department.

#### **R68-28-9. Minimum Storage and Handling Requirements.**

- 1) A cannabis processing facility shall store cannabis, cannabis concentrate, or cannabis product in a separate location from outdated, damaged, deteriorated, misbranded, or adulterated product or product whose containers or packaging have been opened or breached.
- 2) Cannabis, cannabis concentrate, and cannabis product shall be stored at least six inches off the ground.
- 3) Storage areas shall:
- a) be maintained in a clean and orderly condition; and
  - b) be free from infestation by insects, rodents, birds, or vermin.
- 4) A cannabis processing facility shall:
- a) track and label each cannabis plant product and cannabis concentrate;
  - b) ensure each unfinished product is stored in a secure location; and
  - c) immediately after completion of the process or at the end of the scheduled business day return to a secure location.
- 5) If a manufacturing process cannot be completed at the end of a working day, the processor shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing cannabis inside an area or room that affords adequate security.

#### **R68-28-10. Product Appearance and Flavor.**

- 1) A cannabis processing facility may not produce a cannabis product that is designed to mimic a candy product.
- 2) A cannabis processing facility may not produce a product that includes a candy-like flavor or another flavor the facility knows or should know appeals to children.
- 3) A cannabis processing facility may use only the following artificial flavors:
- a) apple;
  - b) banana;
  - c) cherry;
  - d) grape;
  - e) lemon;
  - f) mint;
  - g) orange;

- h) raspberry;
  - i) strawberry;
  - j) vanilla; or
  - k) watermelon.
- 4) Cannabis or cannabis product may retain the natural flavor provided the flavor is not candy-like or another flavor the facility knows or should know appeals to children.
- 5) A cannabis processing facility may not shape a cannabis product in any way to appeal to children.

**R68-28-11. Processing of Cannabis and Cannabis Product.**

- 1) A cannabis processing facility shall process, manufacture, package, and label cannabis and cannabis product in accordance with 21 CFR 111, "Current Good Manufacturing, Packaging, Labeling, or Holding Operation for Dietary Supplements."
- 2) Cannabis and cannabis product shall be packaged in child-resistant packaging in accordance with 16 CFR 1700.
- 3) A cannabis processing facility shall package cannabis or cannabis product[s] in accordance with this rule and Section 4-41a-602 prior to transportation to a medical cannabis pharmacy.
- 4) Any container or packaging containing cannabis or cannabis product shall protect the product from contamination and shall not impart any toxic or deleterious substance to the cannabis or cannabis product.
- 5) Cannabis cultivation byproduct shall either be:
- a) chemically or physically processed to produce a cannabis concentrate for incorporation into cannabis derivative product; or
  - b) destroyed according to Section 4-41a-405.
- 6) Cannabis concentrate and product produced by cannabis processing facilities shall be tested pursuant to Rule R68-29.

**R68-28-12. Labeling of Cannabis and Cannabis Product.**

- 1) The text used on all labeling shall be printed in at least 8-point font and may not be in italics.
- 2) A cannabis processing facility shall label cannabis and cannabis product before the sale of the cannabis or cannabis product to a medical cannabis pharmacy.
- 3) The label shall be securely affixed to the package and be in legible English.
- 4) A label for cannabis flower shall include the following information in the order as listed:
- a) the name of the cannabis cultivation facility;
  - b) the name of the cannabis processing facility;
  - c) the cannabis processing establishment licensing number;
  - d) the lot number;
  - e) the date of harvest;
  - f) the date of final testing;
  - g) the batch number;
  - h) the date on which the product was packaged;
  - i) the cannabinoid profile, potency levels, and terpenoid profile as determined by the independent testing laboratory,

- j) the expiration date; and
- k) the quantity of cannabis being sold.
- 5) THC potency levels for cannabis flower shall be listed as total THC.
- 6) A label for cannabis product shall include the following information:
  - a) the name of the cannabis processing facility;
  - b) the cannabis processing facility licensing number;
  - c) the batch number;
  - d) the date of production;
  - e) the date of the final testing;
  - f) the date on which the product was packaged;
  - g) the cannabinoid profile;
  - h) the expiration date;
  - i) the total amount of THC measured in milligrams;
  - j) a list of each ingredient and each major food allergen as identified in 21 U.S.C. 343;
  - k) the net weight of the product; and
  - l) a disclosure of the type of extraction process used and any solvent, gas, or other chemical used in the extraction process.
- 7) Each cannabis and cannabis product label shall contain the following warning: "WARNING: Cannabis has intoxicating effects and may be addictive. Do not operate a vehicle or machinery under its influence. KEEP OUT OF REACH OF CHILDREN. This product is for medical use only. Use only as directed by a qualified medical provider."
- 8) A cannabis processing facility may include a logo or brand name on the label, as long as it does not obscure the information required on the label.
- 9) No other information, illustration, or depiction shall appear on the label.

**R68-28-13. Transportation.**

- 1) A printed transport manifest shall accompany each 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 receiving cannabis production establishment or medical cannabis pharmacy.
- 5) The receiving cannabis processing facility, independent laboratory, or medical cannabis pharmacy shall ensure that the cannabis material received is as described in the transport manifest and shall:
  - a) record the amounts received for each strain into the inventory control system; and
  - b) document any differences between the quantity specified in the transport manifest and the quantities received in the inventory control system.

- 6) During transportation, cannabis shall be:
  - a) shielded from the public view;
  - b) secured; and
  - c) temperature controlled if perishable.
- 7) A cannabis production facility shall contact the department within 24 hours if a vehicle transporting cannabis is involved in an accident that involves product loss.
- 8) Only the registered agents of the cannabis processing facility may occupy a transporting vehicle.

**R68-28-14. Recall Protocol.**

- 1) The department may initiate a recall of cannabis or cannabis products if:
  - a) evidence exists that pesticides not approved by the department are present on or in the cannabis or cannabis product;
  - b) evidence exists that residual solvents are present on or in cannabis or cannabis product;
  - c) evidence exists that harmful contaminants are present on or in cannabis or cannabis product; or
  - d) the department believes or has reason to believe the cannabis or cannabis product is unfit for human consumption.
- 2) The recall plan of a cannabis processing facility shall include, at a minimum:
  - a) a designation of at least one member of the staff who serves as the recall coordinator;
  - b) procedures for identifying and isolating product to prevent or minimize distribution to patients;
  - c) procedures to retrieve and destroy product; and
  - d) a communications plan to notify those affected by the recall.
- 3) The cannabis processing facility must track the total amount of affected cannabis or cannabis product and the amount of affected cannabis or cannabis product returned to the facility as part of the recall.
- 4) The cannabis processing facility shall coordinate the destruction of the cannabis or cannabis product with the department and allow the department to oversee the destruction of the affected product.
- 5) The department has authority to monitor the progress of the recall until the department declares an end to the recall.
- 6) A cannabis production facility shall notify the department before initiating a voluntary recall.

**R68-28-15. Cannabis Waste Disposal.**

- 1) Solid and liquid wastes generated during cannabis processing shall be stored, managed, and disposed of in accordance with applicable state laws and regulations.
- 2) Wastewater generated during the cannabis production and processing shall be disposed of in compliance with applicable state laws and regulations.
- 3) Cannabis waste generated from the cannabis plant, trim, and leaves is not considered hazardous waste unless it has been treated or contaminated with a solvent, or pesticide.
- 4) Cannabis waste shall be rendered unusable prior to leaving the cannabis processing facility.

5) Cannabis waste, which is not designated as hazardous, shall be rendered 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.

#### **R68-28-16. Change in Operation Plans.**

1) A cannabis processing facility shall submit a notice, on a form provided by the department, prior to making any changes to:

- a) ownership or financial backing of the facility;
- b) the facility's name;
- c) a change in location;

d) any modification, remodeling, expansion, reduction or physical, non-cosmetic alteration of a facility; or

e) change to the number of production lines.

2) A cannabis processing facility may not implement changes to the initial approved operation plan without department approval.

3) The department shall respond to the request for changes within 15 business days.

4) The department shall approve of requested changes unless approval would lead to a violation of the applicable laws and rules of the state.

5) The department shall specify reason for the denial of approval for a change to the operation plan.

#### **R68-28-17. Renewals.**

1) A cannabis processing facility shall submit a notice of intent to renew and the licensing fee to the department within 30 days of license expiration.

2) If the licensing fee and intent to renew are not submitted within 30 days of license expiration, the licensee may not continue to operate.

3) The department may take into consideration violations issued in determining license renewals.

**R68-28-18. 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 to an unlicensed source;
- b) cannabis purchased from an unlicensed source;
- c) refusal to allow inspection;
- d) failure to comply with testing requirements;
- e) a test result for high pesticide residue in the cannabis produced or cannabis product;
- f) a test result for high residual solvents, heavy metal, microbials, molds, or other harmful contaminants;
- g) failure to maintain required cleanliness and sanitation standards;
- h) unauthorized personnel on the premises;
- i) permitting criminal conduct on the premises;
- j) possessing, manufacturing, or distributing cannabis products that the person knows or should know appeal to children; or
- k) engaging in or permitting a violation of the Title 4, Chapter 41a, Cannabis Production Establishments, which 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;
- c) failure to maintain traceability;
- d) failure to follow transportation requirements;
- e) failure to follow the waste and disposal requirements;
- f) engaging in or permitting a violation of Title 4, Chapter 41a, Cannabis Production Establishments or this rule which amounts to a regulatory violation as described in this Subsection; or
- g) failure to maintain standardized scales.

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;
- 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 41a, Cannabis Production Establishments which 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.

5) The department may enhance or reduce the penalty based on the seriousness of the violation.

**KEY: cannabis processing, cannabis production establishment**

**Date of Enactment or Last Substantive Amendment: 2020**

**Authorizing, and Implemented or Interpreted Law: 4-41a-103(5); 4-41a-404(3); 4-41a-701(3); 4-41a-302(3)(b)(ii); 4-2-103(1)(i); 4-41a-405(2)(b)(iv); 4-41a-801(1)**