

R68. Agriculture and Food, Plant Industry.

R68-36. Industrial Hemp Testing Laboratory.

R68-36-1. Authority and Purpose.

1) Pursuant to Section 4-41-103.4, this rule establishes the application process, qualifications, and requirements to obtain and maintain an industrial hemp testing laboratory permit.

R68-36-2. Definitions.

1) "Acceptable hemp THC level" means a total composite tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis if laboratory testing confirms a result within a measurement of uncertainty that includes the total composite tetrahydrocannabinol concentration of 0.3%.

2) "Applicant" means any person or business entity who applies for an industrial hemp testing laboratory permit.

3) "Batch" means a quantity of:

a) industrial hemp extract produced on a particular date and time, following clean up until the next clean up during which lots of industrial hemp are used;

b) industrial hemp product produced on a particular date and time, following clean up to the next clean up during which industrial hemp extract is used; or

c) industrial hemp dried and cured on a particular date and time

4) "Cannabinoid product" means a chemical compound extracted from a hemp product that:

a) is processed into a medicinal dosage form; and

b) contains an acceptable hemp THC level.

5) "CBD" means cannabidiol.

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

7) "DEA registration" means a laboratory that has an active registration and is certified to handle controlled substances as an industrial hemp testing laboratory with the Drug Enforcement Authority (DEA).

8) "Industrial hemp testing laboratory" means a facility or business who:

a) conducts a chemical or other analysis of industrial hemp or an industrial hemp product; or

b) acquires, possesses, and transports industrial hemp or industrial hemp product with the intent to conduct a chemical or other analysis of the industrial hemp or industrial hemp product.

9) "Industrial hemp" means any part of a cannabis plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.

10) "Industrial hemp testing laboratory permit" means a permit that the department issues to a laboratory qualified to test industrial hemp under the state hemp production plan.

11) "Industrial hemp retailer permit" means a permit that the department issues to a retailer who sells or markets any industrial hemp product.

12) "Industrial hemp product" means a product derived from, or made by processing industrial hemp plants or industrial hemp plant parts.

13) "Licensee" means a person authorized by the department to grow, process or possess industrial hemp.

14) "Lot" means the hemp crop acreage designated by a licensed hemp grower and as reported in the grower report.

15) "Measurement of Uncertainty" means the parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.

16) "Non-compliant material" means a hemp plant or hemp product that does not comply with Title 4, Chapter 41, Hemp and Cannabinoid Act, including a cannabis plant or product that contains a concentration of 0.3% tetrahydrocannabinol or greater by dry weight.

17) "Remediated Biomass" means hemp that has failed an initial test that is combined with shredded plant material for the purpose of remediation.

18) "Tetrahydrocannabinol" or "THC" means total composite tetrahydrocannabinol, including delta-9 tetrahydrocannabinol, tetrahydrocannabinolic acid, and any THC analogs as defined in Subsection 58-37-4(2)(a)(iii)(AA).

R68-36-3. Industrial Hemp Testing Laboratory Permit.

1) An applicant wishing to test industrial hemp shall apply on a form provided by the department for a permit to become an industrial hemp testing laboratory.

2) An industrial hemp testing laboratory permit shall allow a laboratory to receive industrial hemp or industrial hemp product from a licensed industrial hemp grower or processor in order to conduct compliance testing as required by Section 4-41-103.1, Rule R68-22, and Sections R68-24-6, R68-25-9, R68-26-4, R68-26-6, and R68-32-8.

3) An industrial hemp testing laboratory permit shall allow a laboratory to receive industrial hemp from a licensed industrial hemp grower or processor to conduct non-compliance testing as requested by the licensee.

4) A complete application shall include:

a) the required fee as approved by the legislature in the fee schedule;

b) a copy of a current DEA registration; and

c) statements, forms, diagrams, operation plans, 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 any applicant and request additional supporting documentation or information.
- 6) Prior to issuing an industrial hemp testing laboratory permit, the department shall inspect the proposed premises to determine if the applicant complies with state law.
- 7) The department may conduct face-to-face interviews with an applicant if needed to determine the best-qualified applicants for the number of permits needed.
- 8) An industrial hemp testing laboratory permit shall expire on December 31 of the year of issue.
- 9) An industrial hemp testing laboratory permit may not be sold or transferred.

R68-36-4. Industrial Hemp Testing Laboratory Requirements.

1) On or after January 1, 2022, an industrial hemp testing laboratory shall be registered with the DEA in accordance with the Controlled Substances Act, 21 USC 823 (f), 21 CFR 1301.13, and 7 CFR 990.

- 2) An industrial hemp testing laboratory shall:
 - a) establish written standard operating procedures (SOPs) for each test being conducted;
 - b) establish an internal SOP that shall address testing and retesting industrial hemp material;
 - c) ensure that any SOPs are consistent with Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control, 2014 Revisions, published by the American Herbal Pharmacopoeia;
 - d) establish quality assurance protocols that:
 - i) ensure the validity and reliability of test results;
 - ii) ensure consistent, accurate, analytical performance; and
 - iii) include an effective disposal procedure, in accordance with state and federal laws for non-compliant samples;
 - e) require grinding of any pre- or post-harvest testing sample to ensure homogeneity of plant material prior to testing;
 - f) ensure that:
 - i) pre-harvest testing measures the total THC concentration in a sample submitted for analysis;
 - ii) the laboratory performs chemical analysis on the sample using post-decarboxylation or other similarly reliable methods where total THC concentration level considers the potential to convert delta-9-tetrahydrocannabinolic acid (THCA) into THC;
 - iii) test results reflect the total available THC derived from the sum of the THC and THCA content; and
 - iiii) testing of final products measures total composite tetrahydrocannabinol, and that the total delta-9 tetrahydrocannabinol concentration level is determined and reported on a dry weight basis;
 - g) calculate and include the measurement of uncertainty when THC concentration test results are reported and that:
 - i) the method used to calculate the measurement of uncertainty may include one listed in the AOAC Standard Method Performance Requirements 2019.003 found at <https://www.aoac.org/resources/smpr-2019003/>, or any equivalent method approved by the department;
 - ii) the measurement of uncertainty is estimated and reported with test results;
 - iii) each industrial hemp testing laboratory uses appropriate, validated methods and procedures for testing activities and evaluating the measurement of uncertainty; and
 - iv) the range of the measurement of uncertainty is reported as a +/- value and uses the same unit as the hemp THC threshold, such as +/- 0.05, following best practices for significant figures and rounding;
 - h) follow validated analytical methods, such as those published by AOAC, American Herbal Pharmacopoeia, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), or another reputable scientific organization, or notify the department of an alternative scientifically valid testing methodology the lab is following for each required test:
 - i) an industrial hemp testing laboratory may not use an alternative testing method without prior review from the department;
 - ii) an alternative testing protocol shall only be considered if it is comparable to the baseline mandated in the 2018 Farm Bill and established under the United States Department of Agriculture (USDA) Final Rule establishing a Domestic Hemp Production Program published at 7 CFR Part 990;
 - iii) alternative procedures shall be validated by the USDA in writing;
 - iv) the department shall review any monograph or analytical method followed by an industrial hemp testing laboratory to ensure the methodology produces scientifically accurate results prior to the use of an alternative testing methods to conduct the required tests; and
 - v) method performance specifications shall ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this rule;
 - i) provide the department with documentation showing that the industrial hemp testing laboratory has obtained and maintained the International Organization for Standardization (ISO) 17025:2017 accreditation. An industrial hemp testing laboratory may be permitted prior to ISO 17025:2017 accreditation provided the industrial hemp testing laboratory:
 - i) adopts and follows 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
 - ii) becomes ISO 17025:2017 accredited within 18 months.

3) 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 version, published by the Organization for Economic Co-operation and Development.

R68-36-5. Information Sharing.

- 1) An industrial hemp testing laboratory performing THC testing to ensure compliance with this rule shall share the test results with the licensee, the department, and the USDA.
- 2) An industrial hemp testing laboratory shall:
 - a) report each test result, whether passing or failing;
 - b) ensure that each testing report used to determine compliance shall be marked "official compliance test";
 - c) ensure that any THC testing used for the purpose of monitoring THC levels throughout the growing season should not be marked "official compliance test";
 - d) ensure that any testing that shows THC levels above 1% are provided to the department; and
 - e) retain a legible copy of each test result marked as an "official compliance test" for a period of three years from the date of analysis and is made available to the department upon request.

R68-36-6. Security Requirements.

- 1) An industrial hemp testing laboratory shall have a locked and secured storage area with limited access provided only to employees that are approved to access non compliant material.
- 2) Any material shall be stored in the locked and secured area until it can be destroyed according to the industrial hemp testing laboratory disposal plan.
- 3) An industrial hemp testing laboratory shall identify each employee who will have access to noncompliant material.
- 4) An industrial hemp testing laboratory shall provide a nationwide criminal history from the FBI, completed within three months of the application, for each employee who will have access to noncompliant material.

R68-36-7. Test Results Exceeding 0.3% THC Concentration in Pre-Harvest Testing.

- 1) Any sample test result where the total THC concentration of the sample is higher than the acceptable hemp THC level shall be conclusive evidence that one or more cannabis plants or plant products from the lot represented by the sample contain a THC concentration in excess of that allowed.
- 2) If the results of a test conclude that the THC concentration levels of a sample are higher than the acceptable hemp THC level, the industrial hemp testing laboratory shall promptly notify the producer, the department and the USDA.
- 3) A noncompliant sample may be re-tested, at the expense of the licensee, if they believe that the original THC concentration levels were in error.
- 4) An industrial hemp testing laboratory shall follow the same procedures used in the initial test for any retests.
- 5) Re-test results will be shared with the licensee, the department, and the USDA.
- 6) If the industrial hemp material is >1% total THC content the industrial hemp testing laboratory must notify law enforcement.
- 7) Remediated biomass submitted for official compliance testing shall follow the same procedures used to conduct the initial test.

R68-36-8. Inventory Log Failed Samples.

- 1) Industrial hemp samples submitted to the industrial hemp testing laboratory that are noncompliant shall be tracked and monitored in an inventory log until each laboratory test has been completed.
- 2) The inventory log under Subsection (1) shall include the following:
 - 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) the weight and disposal of the noncompliant materials;
 - e) the identity of who disposed of the noncompliant material; and
 - f) any theft or loss or suspected theft or loss of noncompliant material.

R68-36-9. Destruction of Noncompliant Material.

- 1) An industrial hemp testing laboratory shall destroy any noncompliant material in accordance with state and federal laws and regulations.
- 2) The noncompliant material shall be rendered unusable prior to leaving the industrial hemp testing laboratory.
- 3) Noncompliant material shall be rendered unusable by grinding and incorporating the noncompliant material with other ground materials so the resulting mixture is at least fifty percent non-hemp waste by volume or by other methods approved by the department before implementation.
- 4) Materials used to grind and incorporate with noncompliant hemp material fall into two categories:
 - a) compostable; or
 - b) non-compostable.
- 5) Compostable waste is hemp 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.
- 6) Non-compostable waste is industrial hemp 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.
- 7) If a laboratory needs to transport noncompliant material they must first obtain a transport permit from the department.
- 8) Noncompliant material may be held by a laboratory for no longer than 90 days.

R68-36-10. Change in Operation Plans.

- 1) An independent hemp testing laboratory shall notify the department prior to making any changes to:
 - a) the facility's name;
 - b) a location;
 - c) testing methods, equipment, remodeling, expansion, reduction or physical, non-cosmetic alteration of the lab; or
 - d) written operating procedures.
- 2) An industrial hemp testing laboratory may not implement changes to the 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 requested changes unless approval would lead to a violation of the applicable laws and rules of the state.
- 5) The department shall specify the reason for the denial of a change to the operation plan.

R68-36-11. Renewals.

- 1) A licensee shall resubmit the documents required in Section R68-36-3 with updated information, before December 31st of the current year.
- 2) The department may deny a renewal for an incomplete application.
- 3) The department may deny renewal for any licensee who has violated any portion of this rule or state law.
- 4) If the industrial hemp testing laboratory DEA registration expires or is revoked by the DEA, the industrial hemp testing permit issued by the department shall also be revoked.
- 5) The department shall renew a permit unless renewal would lead to a violation of the applicable laws and rules of the state.

R68-36-12. Proficiency Testing.

- 1) The department shall establish a proficiency testing program for hemp testing laboratories.
- 2) Each laboratory shall participate in the designated proficiency testing program with satisfactory performance as determined by the department.

R68-36-13. Violation Categories.

Pursuant to Title 4, Chapter 2, Administration, the department may issue the following violations:

- 1) Public Safety Violations: \$3,000 - \$5,000 per violation. This category is for violations that present a direct threat to public health or safety including:
 - a) refusal to allow inspection;
 - b) refusal to participate in proficiency testing;
 - c) failure to comply with testing requirements;
 - d) failure to report testing results;
 - e) unauthorized personnel on the premises;
 - f) permitting criminal conduct on the premises;
 - g) engaging in or permitting a violation of Title 4, Chapter 41, Hemp and Cannabinoid Act, 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 DEA registration;
 - c) failure to keep and maintain records;
 - d) failure to follow the waste and disposal requirements; or
 - e) engaging in or permitting a violation of Title 4, Chapter 411, Hemp and Cannabinoid Act, or this rule that amounts to a regulatory violation as described in this subsection.
- 3) Permitting Violations: \$500- \$5,000 per violation. This category is for violations involving industrial hemp testing laboratory permitting 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 follow the operating plan as approved by the department;
 - d) engaging in or permitting a violation of this rule or Title 4, Chapter 4, Hemp and Cannabinoid Act that amounts to a licensing violation as described in this subsection; or
 - e) 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.

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