

Table of contents

1. Overview
2. Definitions
3. Laboratory Certification Application
4. Standards for Laboratory Certification
5. Quality Management System (QMS)
6. Certificate of Analysis, Acceptance of Samples, Documentation, and Method for Moisture Analysis
7. Reporting by Certified Laboratories
8. Certified Laboratory Deficiencies and Complaints
9. Certification Withdrawal, Suspension, and Revocation
10. Laboratory Certification: Changes in Ownership, Location, and Name
11. Suggested References
12. Tables of Requirements
 - 12.1. Table 1. Sampling guidance for laboratories
 - 12.2. Table 2. Testing requirements for hemp
 - 12.3. Table 3. Potency parameters and limits for hemp: crops, trim flower, products, and infused-products
 - 12.4. Table 4. Moisture parameters and limits for hemp and cannabis
 - 12.5. Table 5. Microbiological parameters and limits for hemp and cannabis
 - 12.6. Table 6. Metal parameters and limits for hemp and cannabis
 - 12.7. Table 7. Pesticide parameters and limits for hemp and cannabis
 - 12.8. Table 8. Residual solvent parameters and limits for hemp and cannabis
 - 12.9. Table 9. Cannabinoid labeling requirements for hemp and cannabis

1. Overview

- 1.1. Under 6 V.S.A. § 567, the Agency of Agriculture, Food and Markets shall establish a cannabis quality control program for the following purposes:
 - a. to develop potency and contaminant testing protocols for hemp, hemp-infused products, cannabis, and cannabis products as defined in 7 V.S.A. § 831;
 - b. to verify cannabinoid label guarantees of hemp, hemp-infused products, cannabis, and cannabis products as defined in 7 V.S.A. § 831;
 - c. to test for pesticides, solvents, heavy metals, mycotoxins, and bacterial and fungal contaminants in hemp, hemp-infused products, cannabis, and cannabis products as defined in 7 V.S.A. § 831; and
 - d. to certify testing laboratories that can offer the services for b. and c. above.
- 1.2. The Program will review lab procedures and protocols to verify that a laboratory seeking certification from the Agency of Agriculture, Food & Markets meets the certification requirements and the following standards:

- a. has reviewed the Vermont Hemp Rules;
 - b. understands the testing requirements on hemp crops, hemp products and hemp-infused products;
 - c. has knowledge of the action levels of contaminants and potency requirements for regulatory compliance;
 - d. maintains required documentation;
 - e. participates in third-party proficiency testing and if provided, non-ISO based interlaboratory comparisons with the Agency; and
 - f. reports required information to the Hemp Program.
- 1.3. A person must register with the Agency to operate a certified laboratory to test hemp crops, hemp infused-products, cannabis, and cannabis products for compliance purposes and must meet laboratory certification requirements.

2. **Definitions**

- 2.1. Acceptable potency level means a hemp crop that has a delta-9 tetrahydrocannabinol concentration of 0.3 percent or less on a dry weight basis. This initial requirement accords with the federal 2014 Farm Bill. As an additional policy limitation implemented to protect public safety, the Agency also requires that the total theoretical tetrahydrocannabinol concentration not exceed one percent on a dry weight basis. The acceptable potency level may change as the law develops following the 2020 growing season.
- 2.2. Action limit means the maximum allowable amount of a contaminant in a hemp crop, hemp concentrate, or hemp product.
- 2.3. Agency means the Vermont Agency of Agriculture, Food and Markets.
- 2.4. Cannabinoid means any of a group of closely related chemical compounds which include THC (tetrahydrocannabinol), THCA (tetrahydrocannabinolic acid), CBD (cannabidiol), CBDA (cannabidiolic acid), CBN (cannabinol), CBG (cannabigerol), CBC (cannabichromene), CBL (cannabicyclol), CBV (cannabivarin), THCV (tetrahydrocannabivarin), CBDV (cannabidivarin), CBCV (cannabichromevarin), CBGV (cannabigerovarin), CBGM (cannabigerol monomethyl ether), CBE (cannabielsoin), CBT (cannabicitran), and other active constituents that are naturally occurring in the Cannabis sativa L. plant.
- 2.5. Cannabinoid content refers to the test-verified levels of specific cannabinoids in a harvest or process lot.
- 2.6. Cannabis (as defined in 7 V.S.A. § 831) means all parts of the plant Cannabis sativa L., except as provided by 2.6 d. below, whether growing or harvested, and includes:
- a. the seeds of the plant;
 - b. the resin extracted from any part of the plant; and
 - c. any compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin.
 - d. Cannabis does not include: the mature stalks and fiber produced from the stalks; oil or cake made from the seeds of the plant; any compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, fiber, oil, or cake; the sterilized seed of the plant that is incapable of germination; or hemp or hemp products, as defined in 6 V.S.A. § 562. For definition of hemp see section 2.19.

- 2.7. Cannabis product means concentrated cannabis and a product that is composed of cannabis and other ingredients and is intended for use or consumption, including an edible product, ointment, and tincture. Cannabis product shall include a vaporizer cartridge containing cannabis oil that is intended for use with a battery-powered device.
- 2.8. Certificate of analysis (CoA) means a laboratory's report describing its analytical testing and results.
- 2.9. Certified laboratory means a laboratory that is certified by the Agency under 6 V.S.A. § 564 and 567.
- 2.10. Chain of custody (COC) means a record that fully documents the possession of samples and any transfers of custody from the time of collection to receipt in the laboratory. This record generally includes the number and types of containers, the mode of collection, the identity of the collector(s), the time of collection, preservation steps, the identity of any transporters, and requested analyses.
- 2.11. Consumption means ingesting, inhaling, or topically applying to skin or hair.
- 2.12. Contaminant means a pesticide, solvent, heavy metal, or microbiological impurity introduced through cultivation or processing.
- 2.13. Decarboxylated means the completion of the conversion of THCA or CBDA, into THC or CBD. The decarboxylated value for THC can be calculated using the total theoretical tetrahydrocannabinol calculation in these definitions.
- 2.14. Decarboxylation means the removal or elimination of carboxyl group from a molecule or organic compound.
- 2.15. Delta-9 tetrahydrocannabinol, ("THC", or "delta-9-THC") is the principal psychoactive cannabinoid found in the Cannabis sativa L. plant.
- 2.16. Dry weight means the weight of plant material with no greater than 13% moisture content.
- 2.17. Harvest lot means a grower's harvested hemp produced during a single growing season in a contiguous area containing the same cultivar or variety.
- 2.18. Harvest lot number means a unique numerical identifier that begins with the last four digits of a grower's registration number, followed by the year of harvest, and a unique number to identify the harvest lot.
- 2.19. Hemp means the plant Cannabis sativa L. and any part of the plant, including the seeds and all derivatives, extracts, cannabinoids, acids, salts, isomers, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. The cultivation of hemp shall be subject to and comply with the required agricultural practices adopted pursuant to 6 V.S.A. § 4810. For definition of cannabis see section 2.6.
- 2.20. Hemp concentrate means a process intermediate obtained by separating cannabinoids from hemp crops using a mechanical, chemical or other process, and which consists primarily of cannabinoids. Hemp concentrate is not a hemp product or hemp-infused product as defined by these rules.
- 2.21. Hemp product or Hemp-infused product means all product that satisfies the required tetrahydrocannabinol concentration level for hemp, derived from, or made by, processing hemp plants and/or plant parts, that are prepared in a form available for commercial sale, including cosmetics, personal care products, food intended for animal or human consumption, cloth,

cordage, fiber, fuel, paint, paper, construction materials, plastics, and any product containing one or more hemp-derived cannabinoids, such as cannabidiol.

- 2.22. Hemp crop means a standing or harvested crop or biomass. Use of “hemp crop” or “hemp crops” includes both the singular and plural usages whenever appropriate and shall be read to be inclusive of both forms whenever possible.
- 2.23. Measurement of uncertainty (MU) 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 the measurement.
- 2.24. Process lot means any amount of hemp concentrate, hemp product or hemp-infused product of the same type, processed at the same time using the same ingredients and same standard operating procedures.
- 2.25. Process lot number means a unique numerical identifier that begins with the last five digits of a Processor’s registration number, followed by the year of processing, and a unique number to identify the process lot.
- 2.26. Postdecarboxylation in the context of testing methods for THC, means a value determined after decarboxylation that determines the total theoretical THC content derived from the sum of THC and THCA. The postdecarboxylation value of THC can be calculated using gas chromatography (where THCA is converted to THC), or by high-performance liquid chromatography (followed by the total theoretical THC calculation).
- 2.27. Registrant means a person registered with the Hemp Program.
- 2.28. Sample means an amount of a harvest lot or process lot collected from a registrant provided to a certified laboratory for the purpose of regulatory compliance testing.
- 2.29. Standard Operating Procedure(s) (SOPs) are written documents that detail the method for an operation, action, or analysis, thoroughly prescribing techniques and steps. SOPs are officially approved as the methods for performing routine tasks.
- 2.30. Tetrahydrocannabinolic acid (THCA) is the precursor of delta-9 THC.
- 2.31. Total theoretical tetrahydrocannabinol content (“total theoretical THC”, or “total THC”) is the maximum amount of possible delta-9 tetrahydrocannabinol in a hemp crop if total conversion were to occur. The calculated amount is determined as follows:

the sum of the concentration of delta-9 tetrahydrocannabinol added to the amount of tetrahydrocannabinolic acid after it is multiplied by 0.877 on a dry weight basis and reported to two significant figures. The mathematical equation follows:

$$\text{Total theoretical THC} = ([\text{delta 9 THC}] + ([\text{THCA}] * 0.877))$$

3. **Laboratory Certification Application**

- 3.1. To become a certified laboratory under the Cannabis Quality Control Program an applicant must complete and submit the Agency’s application form, provide all required documentation, and the registration fee (collectively, the “application”).
- 3.2. The application is not complete unless and until all requested documents are provided, and the Agency receives the registration fee.
- 3.3. The required documentation for laboratory certification shall include:

- a. The laboratory's current accreditation certificate (if acquired) and scope of testing;
 - b. The laboratory's Quality Assurance (QA) manual or system of documenting performance of the laboratory's Quality Control System, please also see section 5;
 - c. The laboratory's method validation summary (abstract/ bulleted report/ or table) for each new test seeking certification (since the last application) for hemp crops, hemp products, and hemp infused products, which include
 - i. potency;
 - ii. moisture, water activity;
 - iii. mycotoxins, total aerobic microbial count, total combined yeast and mold count;
 - iv. heavy metals;
 - v. pesticides; and
 - vi. residual solvents;
 - d. Documented Standard Operating Procedures for hemp/cannabis testing including but not limited to, sample handling, homogenization/ extraction, and analysis. A master list of analytical and non-analytical (i.e. safety and training) SOPs indicating latest revision and current effective dates;
 - e. Resumé or qualifications of key laboratory and management personnel, including training and education;
 - f. The last Quality Assurance/Quality Control audit (internal or external) and a report on the status of response/corrective actions;
 - g. The latest proficiency testing results for hemp testing in each area requesting certification (potency, mycotoxins, microbial, yeast/mold, heavy metals, pesticides, and residual solvents). Alternatively, similar matrix (food, solids) proficiency test results may be sent if hemp results are not available;
 - h. A sample CoA report to be issued by the laboratory for each area of testing requesting certification; and
 - i. A current organizational chart that includes reporting relationships.
- 3.4. To process a registration application, the Agency will review all submitted information, and may request additional information. The Agency may verify application documents through interviews with laboratory personnel and/or site visits.
- 3.5. Laboratory certification registration expires one year from the date of initial certification by the Agency. To maintain uninterrupted certification, the laboratory must file an application within 30 days of expiration. The Agency will review the application, clarify, and comment as necessary, requesting any additional information within 30 days of the receipt of the application. CoAs for compliance samples may only be issued by a laboratory with a valid certificate. A late fee will be assessed for renewing expired certificates.
- a. Laboratories must identify and explain significant changes to validated and verified laboratory methods on the renewal application form filed with the Agency. Please note these changes in the Analytical Methods Worklist notes section of the application.
- 3.6. To issue CoAs to document compliance with the Vermont Hemp Rules, a laboratory must register for each type of testing that it will perform. If a certified laboratory seeks to add testing area competencies to an existing certification, it must notify the Vermont Cannabis Quality Control Program. The expiration date for added test areas shall be the same date indicated on the certificate currently in effect for the laboratory.

- 3.7. A laboratory certified with the Agency to test hemp crops, and/or hemp products, and hemp-infused products shall allow the Agency access to inspect the laboratory for certification, random inspections, and investigations.
- 3.8. There is no reciprocity with out of State laboratories. Laboratories located outside Vermont must meet the criteria in sections 4.1a. and produce hemp/cannabis compliance documentation from their respective States. The complete application outlined in 3.1 is required from all laboratories requesting certification.
- 3.9. The Agency may deny any incomplete application. An applicant whose application is denied as incomplete may reapply for registration at any time.

4. **Standards for Laboratory Certification**

- 4.1. A laboratory may become certified by the Vermont Cannabis Quality Control Program to test hemp crops, hemp concentrates, hemp products, and hemp-infused products in accordance with Vermont Hemp Rules Sections 7 and 8, or cannabis, and cannabis products, when the laboratory satisfies the requirements enumerated in this section.
 - a. The laboratory is eligible when it has one of the following annual accreditations:
 - i. a specific cannabis accreditation program following the ISO/IEC 17025 format, including CANNALAP (through the American Council of Independent Laboratories, Inc.) or the Cannabis Testing Laboratory Accreditation Program (through A2LA, PJLA and ANAB), or an ISO/IEC 17025 based accreditation (i.e. through NELAP, ANAB, or a recognized scientific organization or ISO accreditor), with the accreditation including hemp analysis; or
 - ii. an ISO/IEC 17025 based accreditation (i.e. NELAP, A2LA, ANAB, or a recognized scientific organization) without accreditation in hemp analysis.
 - b. The laboratory may also be eligible when it is working towards or has applied for an ISO/IEC 17025 based accreditation as described in subsection 4.1.a above. A certified non-accredited laboratory may only perform potency, moisture, and pesticide testing on hemp crops, hemp trim flower, hemp concentrates, hemp products, hemp infused products, cannabis, and cannabis products for compliance requirements. A certified non-accredited laboratory may not perform compliance testing for microbiological, metals, and residual solvents. Laboratories should meet AOAC International Standard Method Performance Requirements (SMPRs) for selecting an appropriate method for potency.
- 4.2. The laboratory shall also use appropriately validated or verified methods for each hemp/cannabis analysis, and those approved methods and related guidelines (for validations and methods) must be derived from recognized industry sources. Recognized agencies for sources include (but are not limited to) AOAC International, FDA, USDA, EPA, ISO, AHP, USP, ASTM, and APHL. (A manufacturer's validation is acceptable when following these recognized sources.) ISO/IEC 17025 based formats are followed for all hemp testing.
 - a. All validated and verified methods shall have written Standard Operating Procedures (SOPs).
 - i. The Agency recommends following approved cannabis/hemp methods such as AOAC Official Methods 2018.10 and 2018.11 or similarly rigorous methods for liquid chromatography potency testing.

- ii. The Agency recommends following updated industry and standard methods for testing, including drying, grinding, extraction and analysis changes that improve recoveries of test compounds.
- 4.3. Certified laboratories must participate in proficiency testing for potency and other parameters as proficiency tests become available. The Agency encourages laboratories to follow their own proficiency testing system, based on accreditation requirements. At a minimum, proficiency testing must be done annually.
- a. Proficiency testing must be run using the same validated methods for samples.

5. **Quality Management System**

- 5.1. The Vermont Cannabis Quality Control Program requires certified laboratories to follow an overall Quality Management System (QMS), which must include the following components and accompanying documentation:
- a. a quality assurance (QA) manual or procedures explaining the laboratory's quality control system;
 - b. general requirements and responsibilities of staff and management;
 - c. personnel education, experience, training, and qualifications, including demonstration of capability for hemp testing;
 - d. Standard Operating Procedures (SOPs) for all laboratory operations and all validated test methods with effective dates, revision numbers, and the approving authority's signature;
 - e. laboratory logbooks;
 - f. instrument data and records, including calibrations;
 - g. instrument maintenance logs;
 - h. reference materials and standards, including traceability, and preparation records;
 - i. storage of data;
 - j. software control;
 - k. proper actions and data integrity reporting;
 - l. sample handling and storage, subsampling and extracts storage, and demonstrated chain of custody (COC);
 - m. data quality indicators related to precision, accuracy, representativeness, comparability, and sensitivity;
 - n. validation of methods including fit for purpose, Limit of Quantitation (LOQ), linear range, accuracy, precision, and selectivity/ specificity;
 - o. validation requirements for each testing area; for chromatographic chemical analysis this includes retention times, peak resolution symmetry and purity;
 - p. Quality Control samples and procedures including control limits, data review and documentation, equipment, and reagents and standards records;
 - q. Quality Assurance activities must include procedures for preventative actions, complaints, non-conformances, corrective actions, audits, oversight, proficiency testing, management review, data review, treatment of out of specification results, amended reports, and audits;
 - r. reporting of results including significant figures, non-detect results, report amendments, and measurement of uncertainty (MU) if calculated. USDA IFR requires the calculation and reporting of MU for THC test results; and
 - s. references cited for Quality Management System.

6. **Certificate of Analysis, Acceptance of Samples, Documentation, and Method for Moisture Analysis**
- 6.1. Certificates of Analysis (CoAs) for proof of compliance with the Vermont Hemp Rules will only be accepted from laboratories certified by the Cannabis Quality Control Program. A test result from a laboratory not certified in the specific testing area at issue shall not be considered a certified result nor accepted as proof to establish compliance with the Vermont Hemp Rules.
- 6.2. Laboratories certified by the Cannabis Quality Control Program may accept hemp samples for harvest lot and or process lots for analysis.
 - a. All harvest lot samples submitted to a certified laboratory shall be fresh plant material and accompanied by a completed pre-harvest sampling form to reflect appropriate sampling procedures, a completed chain of custody form, and a laboratory analysis/test request form.
 - b. All process lot samples submitted to a certified laboratory shall be accompanied by a completed chain of custody form and a laboratory analysis/test request form that includes information about the type of sample submitted, and whether the requested analysis is for compliance purposes.
- 6.3. The chain of custody and analysis/test request forms may be a single form developed by the certified laboratory conducting the testing.
- 6.4. All documentation that accompanies a sample submission shall be retained by the certified laboratory conducting the testing.
- 6.5. CoAs shall contain the following information:
 - a. laboratory certification number;
 - b. Hemp Program registrant's name, address, and registration number, unless it is a CoA for cannabis or a cannabis product;
 - c. harvest lot or process lot number of the sample being tested and a description of the sample;
 - d. date sample was taken;
 - e. date laboratory received the sample;
 - f. date of analysis; and
 - g. date of report.
- 6.6. CoAs for harvest lots or process lots for hemp or cannabis trim flower shall include:
 - a. the name of the cultivar;
 - b. potency results reported on a dry weight basis (see Section 6.11), including measurement of uncertainty (MU) values;
 - c. moisture results;
 - d. microbiological results for trim flower reported as analyzed, not as dry weight;
 - e. reporting units will follow Section 6.10; and
 - f. any label guarantees must meet Table 9 requirements.
- 6.7. CoAs for process lots for hemp products, hemp-infused products, and cannabis products such as oils, salves, tinctures, and food products tested for potency, metals, pesticides, residual solvents and microbiological components shall be reported as packaged, and not as dry weight. See Section 6.10 for reporting units. Label guarantees must meet Table 9 requirements.
- 6.8. CoAs for process lots for hemp concentrate and cannabis concentrate (in liquid and solid form) tested for potency, metals, pesticides, residual solvents, and microbiological components shall be

reported as the finished product, not as dry weight. See Section 6.10 for reporting units. Label guarantees must meet Table 9 requirements.

- 6.9. CoAs demonstrating potency of hemp, hemp products, hemp-infused products, cannabis, and cannabis products shall:
 - a. report concentrations for delta-9-THC, THCA, and total THC; or
 - b. report analysis of decarboxylated samples as total THC concentration, quantitated as delta-9 - THC. This total THC value for hemp crops, hemp products, and hemp-infused products must meet delta-9-THC action limits in Table 3; and
 - c. All potency concentrations shall be reported as a percentage.
- 6.10. Contaminant results on CoAs for hemp crops, hemp products, hemp-infused products, cannabis, and cannabis products (microbiological, metals, pesticides, and residual solvents) shall be reported in the same units that Tables 4 through 8 utilize. Measurement of uncertainty (MU) values for contaminant results will be reported when calculated by the laboratory.
- 6.11. Method for moisture analysis: AOAC Official Method 2018.11 (revised first action 2020, Section H, Determination of Plant Material Dry Weight). This method shall be used or one which gives similar results when compared in the laboratory. The value determined by this analysis, shall be used in the potency and contaminant calculations for dry weight.

7. Reporting by Certified Laboratories

- 7.1. If a hemp harvest lot exceeds the acceptable potency level or action limits as outlined in Tables 3 thru 7 then the following conditions apply:
 - a. The certified laboratory shall send the CoA containing the result and the testing request form within 24 hours of completing the harvest lot test to:
 - i. the Agency by certified mail or electronically to an individual identified by the Agency, and
 - ii. the registrant who requested the testing.
- 7.2. Reporting requirements in Section 7 do not apply to cannabis and cannabis products.

8. Certified Laboratory Deficiencies and Complaints

- 8.1. Deficiencies in laboratory practices include but are not limited to those described below:
 - a. Failure to maintain two (2) acceptable proficiency studies for a testing method out of the most recent three (3) studies as determined by the proficiency provider or the accrediting board. This includes failure to participate in a scheduled study. A laboratory may be decertified for a test area;
 - i. Remedial proficiency tests outside of the scheduled studies may be done as part of the corrective action and may count towards the two out of three acceptance criteria.
 - ii. Hemp/cannabis proficiency samples must be used for potency.
 - b. Incomplete documentation (CoA, COC, analysis/test requests) maintained for analyzed hemp, hemp concentrate, hemp products, or hemp infused products (see Section 6);
 - c. Failure to follow the documented protocols in the laboratory Quality Management System, Quality Assurance Manual, or active SOPs (see Section 5);
 - d. Loss of accreditation;

- e. Failure to meet the personnel qualifications for laboratory staff as required by accrediting bodies. These qualifications shall include education, training, experience, and demonstration of capability requirements; and
 - f. Failure to report action level exceedances. To participate in the Cannabis Quality Control Program, certified laboratories must report hemp harvest crop exceedances to the Agency.
- 8.2. Complaints received by a certified laboratory must be recorded and kept with the laboratory Quality Management System documentation and must identify the person who received the complaint and include an explanation of the complaint.
- 8.3. Agency site visits or document review may be required to verify correction of deficiencies or to address complaints.
- 8.4. Corrective actions or procedures are used by a certified laboratory to address major or systematic deficiencies and nonconformances. Laboratories must document and follow corrective procedures as outlined in their Quality Management System.
9. **Certification Withdrawal, Suspension or Revocation**
- 9.1. If a hemp certified laboratory wishes to withdraw from the Cannabis Quality Control Laboratory certification program, in total or in part, it must notify the Agency no later than 30 calendar days before the end of the certification year. Any fees submitted to the Agency up to the time of the notification shall not be refunded.
- 9.2. A laboratory's certification shall be suspended (in total or in part) for failure to correct deficiencies outlined in Section 8.1. Suspension is the temporary removal of a laboratory's certification for a defined period, allowing the laboratory time to correct deficiencies.
- 9.3. A laboratory's certification shall be revoked for the following reasons:
- a. Failure to correct deficiencies within the defined period of time as part of a suspension;
 - b. Submittal and/or representation of another laboratory's proficiency test results as its own results;
 - c. Misrepresentation of any material fact and/or falsification of any document or record pertinent to receiving or maintaining certification;
 - d. Denial of entry to Agency personnel during normal business hours for an on-site assessment as the Agency requires; and
 - e. Falsification of any CoA report relating to a laboratory analysis.
10. **Laboratory Certification: Changes in Ownership, Location, or Name**
- 10.1. Laboratories are required to inform the Agency of changes in ownership, location, or name within 30 days.
- 10.2. A change in the location of a laboratory may necessitate the Agency to conduct an on-site assessment or review of changes in laboratory operations.
- 10.3. Certification may be transferred when laboratory ownership changes without significant changes to laboratory operations including staff, equipment, methodologies, and organization. If there are non-significant changes to laboratory operations due to change in ownership the Agency may conduct an on-site assessment or review of changes in practices and procedures that accompanied the certification application.

- 10.4. If there are significant changes in laboratory operations and/or organizational structure, or proper notice has not been given to the Agency, the laboratory may be required to reapply and pay applicable fees and shall be considered a new laboratory (even if the name remains the same).
- 10.5. Traceability of a laboratory sample ID# on a previously issued CoA is required for three years from date of issuance of CoA.

11. Suggested References

- 11.1. Additional guidance and resources for laboratories developing protocols and methods to supplement ISO/IEC 17025:
 - a. Food and Drug Administration, FDA 21 CFR 58 Good Lab Practices (GLP).
 - b. American Herbal Pharmacopoeia (AHP), “Cannabis Inflorescence, Standards of Identity, Analysis and Quality Control” 2014.
 - c. Association of Public Health Laboratories (APHL), “How to Write a Laboratory Quality Manual” May 2017.
 - d. Hemp proficiency testing and reference samples, University of Kentucky, <http://www.rs.uky.edu/regulatory/hpt/index.php>
 - e. AOAC International, Appendix K: Guidelines for Dietary Supplements and Botanicals, Part 1 guideline on single laboratory validation, 2012.
 - f. AOAC International, Official Method 2018.11, Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils, revised first action 2020 with the Determination of Plant Material Dry Weight.
 - g. Association of Public Health Laboratories, Guidance for State Medical Cannabis Testing Programs, May 2016.
 - h. AOAC International, SMPR 2019.003, Quantitation of Cannabinoids in Plant Materials of Hemp.
 - i. U.S. Pharmacopeia (USP), Chapter 467, Residual Solvents, July 2007.
 - j. United Nations Office on Drugs and Crime (UNODC), Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products, revised and updated, New York, 2009.

12. Tables of Requirements

12.1 Table 1. Sampling guidance for laboratories

Sample type	Representative sampling scheme	Recommended quantity for lab testing (AOAC reference is method 2018.11)
Harvest Lot	Labs develop a comprehensive sampling plan for submitted samples, which followed the Hemp Pre-Harvest Sampling Protocol.	AOAC recommends a minimum of 5g for grinding (homogenization), then 0.5g for potency extraction.
Liquids, including concentrates,	AOAC recommends thorough homogenization.	AOAC recommends a dilution using 0.05g for concentrates and tinctures, or

tinctures, and oils		0.5g of oil, with a final volume of 25ml of solvent for all products.
Solids, including salves, pressed material, dried trim flower, etc	Mix uniform material in a product container; otherwise representative sampling.	Several references recommend 2g for 95% confidence level; for dried trim flower AOAC recommends 5g (see harvest lot above).
Infused products	Follow FDA GLP guidelines or other guidelines from recognized sources in section 4.2.	Develop lab SOPs from guidelines from recognized sources in section 4.2.

NOTE: Hemp registration for personal use only requires potency and moisture testing from the harvest lot requirements.

12.2 Table 2. Testing requirements for hemp (N/A = not applicable)

	Potency	Moisture or Water Activity	Microbiological (mycotoxins, total aerobic microbial, total combined yeast & mold)	Heavy Metals	Pesticides	Residual solvents
Harvest lot						
	Each lot	Each lot	N/A	Note 5	Each Lot Note 6	N/A
Plant material						
Trim flower	Note 1	Each process lot	Each process lot	Note 1	Note 1	N/A
Concentrates						
Liquids	Each process lot	N/A	Each process lot	Each process lot	Each process lot	Note 3
Solids	Each process lot	N/A	Each process lot	Each process lot	Each process lot	Note 3
Products and Infused products						
Liquids, including infused products (tinctures, and water based)	Note 4	N/A	Note 2	Note 1 or Note 2	Note 2	Note 2 or Note 3
Solids, including infused edibles, tablets	Note 4	N/A	Note 2	Note 1 or Note 2	Note 2	Note 2 or Note 3

Note 1: Harvest lot testing is sufficient to show compliance.

Note 2: Trim flower or hemp concentrate testing is sufficient to show compliance.

Note 3: Residual solvents are tested whenever solvent based extraction techniques are used.

Note 4: Please apply the standards articulated in Vermont Hemp Program Rule Section 8.3 (a) for potency compliance. (Summarized, a hemp product or hemp-infused product process lot complies when a CoA demonstrates that the product meets the acceptable potency level or the processor’s formulation demonstrates compliance with the acceptable potency level.) Please apply the standards articulated in Vermont Hemp Program Rule Section 6 for processors. (Summarized: all claims of a specific quantity of any cannabinoid must be analyzed at least once to confirm formulation).

Note 5: Testing for heavy metals is required whenever the hemp crop land was used for orchard crops or any land use other than farming as defined in the Required Agricultural Practices Rule, unless a recent soils test demonstrates that the heavy metals are within the authorized action limits for soils.

Note 6: No pesticide testing required if crop is certified organic.

Note 7: Testing for other contaminants is necessary when the Agency of Natural Resources has approved biosolids applications to the hemp crop land.

12.3 Table 3. Potency parameters and limits for hemp: crops, trim flower, products and infused-products

Parameter	Action limits (%)
d9-THC	0.3
Total THC	1.0

12.4 Table 4 Moisture parameters and limits (either analysis) for hemp and cannabis

Parameter	Action limits for trim flower
Moisture content	13 %
Water activity	0.65

12.5 Table 5. Microbiological parameters and limits for hemp and cannabis

Parameter	Action limits for trim flower	Action limits for concentrates	Action limits for products and infused-products
Total Aerobic Microbial Count (CFU per gram or ml) *	100,000	10,000	1000

Total Combined Yeast and Mold Count (CFU per gram or ml) *	10,000	1000	100
Mycotoxin: the total of Aflatoxin B1, B2, G1, and G2	20 ppb	20ppb	20ppb
Mycotoxin- Ochratoxin A	20 ppb	20ppb	20ppb

*CFU = Colony Forming Unit per gram or milliliter (CFU/g or CFU/ml)

12.6 Table 6. Metal parameters and limits for hemp and cannabis

Parameter	Action limits for harvest lot and trim flower (ppm, mg/kg)	Action limits for concentrates, products and infused-products (ppm, mg/kg, mg/l)	Action limits for soil (ppm, mg/kg) for agricultural use (additional levels for Cr, Cu, Ni, and Zn, see Note 1)
Arsenic	0.200	1.500	---
Cadmium	0.200	0.500	0.43
Lead	0.500	1.000	200
Mercury	0.100	1.500	---

Note 1: Soil action limits for Agricultural use, (NYSDEC) as referenced in UVM table 2 :

http://www.uvm.edu/vtvegandberry/factsheets/interpreting_heavy_metals_soil_tests.pdf

Additional levels must also be met for Chromium (11 ppm), Copper (270), Nickel (72 ppm) and Zinc (1100 ppm).

12.7 Table 7. Pesticide parameters and limits for hemp and cannabis

Parameter	Action limits for harvest lots, trim flower, concentrates, products and infused-products (ppm, mg/kg, mg/l)
Acephate	0.1
Acequinocyl	0.1
Abamectin (each isomer)	0.1
Azoxystrobin	0.1
Bifenazate	0.1
Bifenthrin	3.0
Carbaryl	0.5
Chlorpyrifos	0.04
Cypermethrin (zeta) sum of isomers	1.0
Etoxazole	0.1
Imazalil	0.04

Imidacloprid	5.0
Myclobutanil	0.1
Pyrethrins I and II (sum of isomers)	0.5
Spinosyn (each for Spinosad A & D)	0.1

12.8 Table 8. Residual solvent parameters and limits for hemp and cannabis

Parameter	Action limits for concentrates, products and infused-products (ppm, mg/kg, mg/l)
Acetone	5000
Acetonitrile	410
Benzene	2
Chloroform	60
Ethanol	5000
Heptanes (total)	5000
Hexanes (total)	290
Isopropyl alcohol	5000
Methanol	3000
Methylene Chloride	600
Toluene	890
Xylenes (total)	2170
Any solvent not permitted for extraction in the hemp rule (butane, propane, or other hydrocarbons) each	5000

12.9 Table 9. Cannabinoid labeling requirements for hemp and cannabis

Parameter	Hemp: trim flower, products and infused products	Hemp concentrate	Cannabis and cannabis products
Cannabinoids	Within 20% of label value	Within 10% of label value	Within 10% of label value

END RJS