Application Guidance for Laboratory Certification in the Vermont Cannabis Quality Control Program

1. Application

The certified laboratory application contains three distinct types of review.

- Pre-application Review
- New Application Full Review
- Renewal Application Review

Please be sure to choose the correct review as there are slightly different requirements. There is an explanation of each and submission requirements below.

There are additional requirements or limitations for laboratories based on accreditation and location at the end of the document. Certification will be valid for one year from the date of issuance.

a. Pre-application Review

The Agency offers a pre-application review of a laboratory's capabilities prior to a full application review. As part of the pre-application review, the Agency will evaluate potency testing qualifications, Quality Assurance/Quality Management System (QA/QMS) documentation, and Certificate of Analysis (CoA) content. This is a desk review, and the Agency will communicate its' findings in writing to the laboratory that outlines procedures that require additional work or documentation.

Any laboratory may apply for a pre-application review. There is no cost associated with this courtesy review, which should be completed within 30 days of all required submitted material. The laboratory must send:

i. a completed application with the pre-application review box checked;
ii. all documents listed on the application checklist (including all testing competencies requesting certification);
iii. once the pre-application review has been completed, this complete application can be used for the new application full review.

b. New Application Full Review

This is a full review of submitted materials towards the requirements of the Cannabis Quality Control Program (CQCP). The Agency will review accreditation status, validation /verification of referenced methods, SOPs, and proficiency studies. In addition, the Agency will review the laboratory's QA/QMS including staff qualifications, reference materials/standards traceability, data recording/storage, data quality/quality control requirements, and CoA contents.

An on-site inspection or remote interview will also be done to assess knowledge of the Hemp Rule, testing/action limit requirements, CoA data tracking, adherence to SOPs, and data quality indicators. This review should be completed within 30 days of all required submitted material. The laboratory must send:

i. a completed application, with the new application box checked;
ii. all documents listed on the application checklist for all testing competencies requesting certification; and
iii. check payment of $1500 to the Vermont Agency of Agriculture, Food and Markets (VAAFM), which must be mailed to Licensing and Registration (see application for address).

c. Renewal Application Review

The Agency may only review new documents sent since the last application. The Agency will conduct any part of the full application review it deems necessary. An on-site inspection or remote interview may also be done to assess knowledge of the Hemp Rule, testing/ action limit requirements, CoA data tracking, adherence to SOPs, and data quality indicators. This review should be completed within 30 days of all required submitted material. The lab should send:

i. a completed application with the renewal box checked;
ii. the following documents listed on the application checklist;
    1. current accreditation certificates and scope of testing;
    2. SOPs, QA manuals, or methods that have been validated since the last application, and
    3. current CoAs, organizational charts, out of State compliance documentation, latest proficiency results/audits, and a master list of all analytical and non-analytical SOPs; and
iii. check payment of $1500 to the Vermont Agency of Agriculture, Food and Markets (VAAFM), which must be mailed to Licensing and Registration (see application for address).

2. Additional requirements and limitations for laboratories

a. Out-of-State Laboratories

i. must possess accreditation that is International Organization for Standardization (ISO/IEC 17025) compliant;
ii. must send to the Agency hemp/cannabis testing compliance documentation from their respective State;
iii. on-site visits are not required by the Agency; and
iv. may apply for the pre-application, new application, or renewal application review.

b. Non-accredited Laboratories

i. may apply for certification, with a limited scope of testing (potency, moisture and pesticides);
ii. may apply for the pre-application, new application, or renewal application review; and
iii. renewal certification for laboratories which were previously non-accredited- laboratories are expected to have received accreditation or have written documentation of progression towards accreditation.

c. Accredited laboratories

i. must be ISO/IEC 17025 compliant with or without hemp/cannabis accreditation; and
ii. may apply for the pre-application, new application, or renewal application review.

d. All laboratories seeking certification

i. shall 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 (see section 4.2 of the CQCP for requirements); and
ii. CoAs for proof of compliance with the Vermont Hemp Rules will only be accepted from laboratories certified by the Cannabis Quality Control Program for each test area they are certified in; requirements for CoAs are listed in section 6 of the CQCP; reporting requirements to the Agency of harvest lot exceedances are listed in section 7 of the CQCP.