

173-55 Accreditation of Cannabis Laboratories

173-55-010 Purpose

Liquor and cannabis board, Department of health, and other entities require persons and organizations submitting analytical data under the purview of their programs to use cannabis laboratories which are accredited. The purpose of this chapter is for the Department of ecology to establish a state program for accreditation of cannabis laboratories which conduct tests and submit data to the Liquor and cannabis board, the Department of health, and other entities which require the use of accredited laboratories. The accreditation program under this chapter is designed to satisfy the intent of **RCW 69.50.348**.

173-55-020 Scope

- 1) The Washington state cannabis laboratory accreditation program applies to cannabis laboratories which conduct tests for or prepare analytical data on cannabis following procedures designated in **WSDA Chapter 16-309 WAC**.
- 2) Accreditation does not guarantee validity of all analytical data submitted by the accredited laboratory but rather assures that the laboratory has demonstrated its capability to generate and report the analytical data (**WAC 173-55-030**, definition of "accreditation").

173-55-030 Definitions

- Accreditation year – The 365 (366 days if a leap year) day length of time for which accreditation is valid; starting the effective date initial accreditation is granted.
- Data traceability or traceability - The ability to recreate the final result by means of records. This must be an unbroken trail of accountability for verifying or validating the chain of custody of samples, the data, the documentation of a procedure, or the values of a standard.
- Registration – Participation of a laboratory in a process to prepare the laboratory for accreditation, signified by issuance of a written certificate accompanied by a scope of registration indicating those parameters for which the laboratory has achieved registration status.
- Registered – A status designating a laboratory is, or a subset of the laboratory's parameters are, engaged in the process of gaining accreditation from Ecology after July 1, 2024.

173-55-040 Accreditation Approval Requirements

- 1) When applying for initial or renewal of accreditation (see **WAC 173-55-170** for maintaining an existing accreditation), managers of cannabis laboratories must:
 - a) Submit a cannabis laboratory accreditation application (**WAC 173-55-050**) and required fees (**WAC 173-55-190**) to the department fiscal officer;
 - b) Follow the approved methods and/or validation procedures from **Chapter 16-309 WAC** by submitting Standard Operating Procedures (SOP's) for all methods for which the laboratory is seeking accreditation;

- i. In instances where a method modification is being utilized by the laboratory, the laboratory must be able to provide the WSDA's approval documentation at the department's request.
- c) Submit a copy of the laboratory's Quality Assurance Manual (**WAC 173-55-070**);
- d) Follow the data traceability requirements outlined in **WAC 173-55-080**;
- e) Submit the most recent set of Proficiency Testing (PT) sample results (**WAC 173-55-090**); and
- f) Undergo an audit (**WAC 173-55-090**).

173-55-050 Application for Accreditation or Registration

- 1) Through the application, laboratory managers:
 - a) Must request accreditation for specific parameters;
 - b) Provide evidence that sufficient personnel and equipment are available to successfully perform analytical methods as specified in the application; and
 - c) Pay the application fee.
- 2) Through review of the application submitted by the applicant laboratory, the department determines if:
 - a) Requested parameters are eligible for accreditation; and
 - b) Personnel and equipment are adequate to support successful performance of requested parameters.
- 3) Laboratories accredited with WSLCB prior to July 1, 2024 will be granted registration status upon receipt of their application of accreditation.
- 4) Following the review, the department will either approve the application (granting full, interim, provisional, or qualified accreditation) or notify the applicant laboratory of any missing or amended action items necessary to approve the application.

173-55-060 Registered status

- 1) This category is for parameters that:
 - a) Were accredited by the WSLCB on June 30, 2024, and;
 - b) Have applied for accreditation with Ecology, but have not completed Ecology's accreditation process.
- 2) The department does not, by registering parameters pursuant to these rules, vouch for or warrant the accuracy of any particular work done or report issued by the laboratory.
- 3) Laboratories with this status can continue to operate and conduct business, unless otherwise specified by the WSLCB.
- 4) Laboratory's parameters cannot remain in "Registered" status after June 30, 2025, unless explicitly notified by the department.

173-55-070 Quality Assurance Manual

- 1) The department reviews and approves the laboratory's Quality Assurance (QA) manual prior to the department's initial on-site audit. The QA manual submitted concurrently with the application must be in detail and scope commensurate with the size and mission of the laboratory. Guidelines for contents of the QA manual are in the procedural manual.

2) The QA manual must address QA and QC requirements set forth by **Chapter 16-309 WAC**.

173-55-080 Data and record Traceability

1) In order to demonstrate data traceability, a cannabis laboratory must:

- a) Be able to recreate final sample results by means of records in entirety;
- b) Document proper storage of any chemical, reagent, and/or media used by an analytical method;
- c) Document proper storage of samples as required by the specific analytical method and/or regulation;
- d) Document that all temperature-based equipment such as a refrigerator, oven, or incubator is within control. When electronic record keeping equipment is used, these records must be appropriately monitored by lab personnel to verify that temperatures meet relevant method and regulatory requirements;
- e) Keep a log for all instruments, including documentation of installation, setup, maintenance, and removal from service; and
- f) Document proper preparation and quality control (QC) of chemicals, reagents, and media used in support of the analyses.

2) When records are handwritten, they must be in indelible ink and comply with the relevant method requirements and include the date and time(s) of reading, temperature(s), and technician's initials .

3) Un-monitored use of continuous data-loggers is not an acceptable substitute when methods and/or regulations require temperature checks. Use of electronic record keeping equipment is allowed when:

- (a) The equipment can demonstrate the accuracy and precision required by the applicable method and/or regulations;
- (b) it includes the date and time the record was captured, using a fully traceable and secure format, and;
- (c) it is not being used on an incubator used for analysis of samples for microbiology parameters

173-55-090 Proficiency Testing

1) The department will communicate to applying laboratories of specific requirements for participation in proficiency testing (PT) studies for applicable parameters. This communication could include steps outlined in the procedural manual and any waived items. The department determines the sufficiency of such proficiency tests.

2) Accredited cannabis laboratories must analyze a minimum of two PT sample per applicable parameter per year for which the laboratory holds accreditation. After an accredited laboratory submits two satisfactory PT sample results and no unsatisfactory results in an accreditation year, the laboratory is required to submit only one satisfactory PT sample result in subsequent accreditation years. This applies as long as there are no intervening unsatisfactory PT sample results.

3) For full accreditation, proficiency tests for Potency, Pesticides, and Residual Solvents must be in cannabis material containing concentrations of cannabinoids representative of products available to consumers.

- 4) The department may require the laboratory to submit raw data along with the report of analysis of PT samples.
- 5) Applying laboratories are responsible for obtaining PT samples from vendors approved by the department. No fee shall be charged to the department for the purchase or analysis of PT samples.
- 6) PTs must undergo the identical preparation and analytical process that are used for samples.

173-55-100 Audits

A cannabis laboratory must undergo an audit by the department to assess critical elements and areas of recommended practices. All accredited laboratories will be audited on an annual basis. The laboratory must assist/accommodate department of ecology personnel during audits as required. The department will determine if the audit will be on-site. The department's audit will establish if a cannabis laboratory or accreditation applicant satisfies the critical elements for full accreditation or reaccreditation.

1) Critical elements for accreditation. Components of a cannabis laboratory's operations which are critical to the consistent generation of accurate and defensible data are critical elements for accreditation. The department may deny, revoke, or suspend accreditation for deficiencies in critical elements. To gain and maintain accreditation, laboratories must demonstrate to the department's satisfaction that the laboratories meet requirements set forth below for the following critical elements:

a) **Analytical methods.** A cannabis laboratory must demonstrate that documentation of analytical methods that the laboratory employs:

- i) Are present at the laboratory;
- ii) Are approved for regulatory use, if applicable;
- iii) Readily available to analysts; and
- iv) Being implemented. In instances where the laboratory is using a locally developed method, the audit may include an evaluation of the adequacy of that method and review of the validation documents. In instances where a method modification is being utilized by the laboratory, the laboratory must be able to provide to the department the WSDA's approval documentation for the modification.

b) **Equipment and supplies.** A cannabis laboratory must demonstrate that sufficient equipment and supplies as required by analytical methods employed by the laboratory are:

- i) Available at the laboratory;
- ii) Being adequately maintained; and
- iii) In a condition to allow successful performance of applicable analytical procedures.

c) **QA and QC records.** A cannabis laboratory must maintain and make available for department inspection QA and QC records. A department audit includes a review of QA and QC records the laboratory is generating analytical data for submission to the WSLCB or other relevant and applicable regulatory bodies.

d) **Sample management.** A cannabis laboratory must demonstrate to the department's satisfaction that sample management requirements of applicable regulatory programs are being met. The audit includes a review of applicable procedures for receipt, preservation, transportation, and storage of samples. The laboratory is responsible only for those elements of sample management over which it has direct control.

e) **Data management.** A cannabis laboratory must demonstrate to the department's satisfaction that data management requirements of applicable regulatory programs are being met. A department audit includes a review of activities necessary to assure accurate management of laboratory data including:

- i) Raw data;
- ii) Calculations; and
- iii) Transcription, computer data entry, reports of analytical results.

2) **Recommended practices.** Recommended practices are those elements of laboratory operations which might affect efficiency, safety, and other administrative functions, but do not normally affect quality of analytical data. Failure to follow these practices may result in the department's denial, suspension, or revocation of accreditation status.

a) **Personnel.** A cannabis laboratory must ensure that its managerial, supervisory, and technical personnel have adequate training and experience to allow satisfactory completion of analytical procedures and compilation of reliable, accurate data. Minimum personnel requirements are set forth in **Chapter 16-309 WAC**.

b) **Facilities.** A cannabis laboratory must ensure that it allows for the efficient generation of reliable, accurate data in a safe environment.

c) **Safety.** The department may refer serious safety deficiencies to appropriate state or federal agencies.

3) **Documentation requests.** Laboratories must submit requested documentation to the department at least two weeks prior to the scheduled start date of an audit. At a minimum the documents submitted must include:

- a) Standard operating procedures for all methods being audited;
- b) Analytical data for each method being audited; and
- c) Additional documentation deemed necessary by the department to conduct the audit.

173-55-110 Evaluation and issuance of certificate

1) After the department's determination that an applicant laboratory has met the requirements in WAC 173-55-040 through 173-55-100, the department will grant approval of the application and provide the applicant laboratory with a certification of accreditation.

2) If the department grants the application for accreditation in full, the parameters are granted "Good Standing" status, and the department will issue a certificate and accompanying scope of accreditation to the applicant laboratory. The certificate remains the property of the department and must be surrendered to the department upon revocation or voluntary termination of accreditation status.

3) If the department grants accreditation in part, the parameters will be placed into the appropriate statuses, the department will issue a certificate and accompanying scope of accreditation to the applicant laboratory, and a report specifying steps necessary to upgrade all parameters to Good Standing. The certificate remains the property of the department and must be surrendered to the department upon revocation or voluntary termination of accreditation status.

4) If the department denies the application for accreditation in whole, it will provide written notification to the applicant laboratory specifying areas of deficiency in the application steps necessary to upgrade the laboratory to accredited status. If the deficiency is a lack of requested information required in WAC 173-55-040 through 173-55-100, the laboratory shall have 180 calendar days from the receipt of the notification to provide the requested information to the department or provide documentation to the department that describes how the specified deficiencies have been corrected. Based on its review of such documentation provided by the applicant laboratory, the department will issue a written decision that states whether the laboratory's application is granted or denied. If the requested information is not provided within the timeframe, the department will deny approval and the applicant must submit a new application to the department.

173-55-120 Qualified Accreditation

This category of accreditation applies to parameters that have received an approved waiver from the director, or their designee, of WSLCB, WSDA, and Department of Health.

- 1) A waiver excuses a laboratory from a specific accreditation requirement (or requirements) explicitly outlined in the waiver from the issuing regulatory agencies. Laboratories with qualified accreditation can continue to operate and conduct business.
- 2) Any waiver submitted to Ecology will be included with the laboratory's accreditation documents along with a description of the impact(s) of the waiver on accreditation.
- 3) Waivers are only valid for the accreditation year for which they are granted.

173-55-130 Interim Accreditation

When a laboratory is seeking initial accreditation for a specific parameter, if the department is unable to complete an audit through no fault of the laboratory, but all other requirements of accreditation have been satisfied, the department may grant interim accreditation. To be considered for interim accreditation, the laboratory must:

- a) Submit an application and applicable fees;
- b) Successfully complete applicable proficiency tests; and
- c) Submit a QA manual that meets the requirements of **WAC 173-55-070**.

The department may also require the laboratory to submit an analytical data package as evidence of analytical capability.

173-55-140 Provisional accreditation

1) The department may grant provisional accreditation to cannabis laboratories which can consistently produce valid analytical data but have deficiencies requiring corrective action. When the laboratory has corrected such deficiencies, it must provide evidence of correction to the department, or request a follow-up on-site audit, as appropriate. If the department determines the deficiencies have been corrected, it may award full accreditation as in **WAC 173-55-100**.

2) The department may renew a provisional accreditation for a subsequent accreditation year if the applicant laboratory has demonstrated to the department that all reasonable measures to correct deficiencies have been exhausted.

173-55-150 Accreditation categories

1) Cannabis laboratories are accredited within one or more of the matrix groups defined in 3) below. Within each matrix group, accreditation is granted within the following broad categories:

- Water activity;
- Cannabinoid concentration analysis;
- Foreign matter inspection;
- Microbiological screening;
- Mycotoxin screening;
- Pesticide screening;
- Residual Solvent screening
- Heavy metal testing;

Within these categories, laboratories are specifically accredited for well-defined parameters, such as, but not limited to, those suggested in the procedural manual, using specific analytical methods or sampling techniques chosen by the applying laboratory.

2) The scope of accreditation accompanying the accreditation certificate indicates the parameters for which the laboratory is accredited, and footnoting any applicable conditional qualifications, such as registered, interim, provisional, or qualified accreditation.

3) The scope of accreditation also indicates the matrix groups within which each parameter applies. Those matrix groups may include, but are not limited to:

- Cannabis Flower;
- Intermediate Products as defined in chapter **314-55 WAC**;
- End Products as defined in chapter **314-55 WAC**.

173-55-160 Requirements for maintaining accreditation status

- 1) Accreditation is granted for a one-year period (the accreditation year) and expires one year after the effective date of accreditation.
- 2) A cannabis laboratory accredited by the department must renew its accreditation annually each year following its initial accreditation. The annual renewal materials outlined in this section are due 30 days prior to expiration of accreditation to be considered timely. Renewal requires the laboratory to submit:
 - a) An application and appropriate fees;
 - b) An update of the laboratory's QA manual if applicable;
 - c) Successful completion of proficiency testing requirements.

173-55-170 Denying accreditation

- 1) The department may deny accreditation if the applicant laboratory:
 - a) Fails to comply with standards for critical elements of the on-site audit;
 - b) Misrepresents itself to the department;
 - c) Fails to disclose pertinent information in the application;
 - d) Falsifies reports of analysis including proficiency testing results;
 - e) Engages in unethical or fraudulent practices concerning generation of analytical data;
 - f) Is deficient in its ability to provide accurate and defensible analytical data; or
 - g) Fails to render applicable fees.
- 2) The department may deny a laboratory accreditation for a specific parameter for unsatisfactory proficiency testing results.
- 3) Laboratories denied accreditation may appeal under the provisions of **WAC 173-55-200**. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, laboratories denied accreditation may reapply to the accreditation for accreditation by submitting an application accompanied by the applicable fee indicated in **WAC 173-55-190**.

173-55-180 Revoking or suspending accreditation

The department may suspend or revoke laboratory cannabis accreditation previously granted by the department.

1) Revocation of a previously department granted cannabis accreditation may involve the departments revocation of the entire laboratory or one or more individual parameters.

2) Suspension of accreditation by the department is for a specified period during which the affected laboratory corrects deficiencies that led to the suspension. Suspension may involve the entire laboratory, or one or more individual parameters.

3) The department may suspend or revoke accreditation if the accredited laboratory:

- a) Fails to comply with standards for critical elements of an on-site audit;
- b) Violates a state rule relative to the analytical procedures for which it is accredited;
- c) Misrepresents itself to the department;
- d) Falsifies reports of analysis including PT results;
- e) Engages in unethical or fraudulent practices concerning generation of analytical data;
- f) Is deficient in its ability to provide accurate and defensible analytical data;
- g) Refuses to permit entry for department compliance inspections (**WAC 173-55-210**);
- h) Fails to pay applicable fees;
- i) Fails to maintain third-party accreditation; or
- j) Reports two consecutive unsatisfactory PT sample results.

4) A laboratory having had its accreditation suspended or revoked may appeal under the provisions of **WAC 173-55-210**. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, a laboratory having had its accreditation revoked or suspended may reapply to the department for accreditation by submitting an application accompanied by the applicable fee indicated in **WAC 173-55-190**

173-55-190 Fee structure

1) Fees in this chapter are in U.S. dollars and are established to cover costs of administering the cannabis accreditation program.

2) Effective July 1, 2024, the yearly accreditation fee for a cannabis laboratory is \$62,500. Biennially, upon a finding by the department that a fee change is necessary, the department may increase the accreditation fee by the fiscal growth factor for the next biennium. The fiscal growth factor is calculated by the office of financial management under RCW 43.135.025. The department must publish the new fee by March 1st before the year for which the new fee is effective. The new fee is effective from July 1st to June 30th of every year. This amount must be paid in full prior to issuance of initial accreditation, or yearly renewal.

- a) Processing or application fees specified in sections 3) and 6) of this chapter are deducted from the yearly accreditation fee.

- b) The department and an individual laboratory may establish a payment schedule requiring periodic installments of the annual fee.
- 3) For a cannabis laboratory that has not been accredited for any parameter by the department in the previous 12 months or the WSLB on June 30, 2024, the laboratory must pay a non-refundable application fee of \$1500 to the department before:
- a) Its quality assurance manual and applicable SOP's are reviewed by the department;
 - b) The audit is conducted; and
 - c) Interim, Provisional, Qualified, or full accreditation is granted for any parameters.
- 4) For a cannabis laboratory accredited by the WSLCB on June 30, 2024, they will be granted registered status without needing to pay the application fee mentioned in section 3 of this chapter.
- 5) The department will invoice the cannabis laboratory annually after renewal of their accreditation is complete.
- 6) If a laboratory requests to revise their scope of accreditation to add or reinstate a parameter, or parameters, outside of their initial application or renewal process, the department will invoice the cannabis laboratory a processing fee of \$500 for that request.
- a) The processing fee will be invoiced after the department has issued the revised accreditation documents.
 - b) The processing fee will be deducted from the yearly accreditation fee for the laboratory outlined in section 1).
 - c) Multiple parameters may be included in one revision request.
- 7) If a laboratory withdraws from the accreditation process after the audit has been completed, the department may retain the entire fee.

173-55-200 Appeals

A Cannabis laboratory manager may appeal final accreditation actions within thirty days of notification of final action in accordance with chapter **43.21B RCW**.

173-55-210 Compliance inspections and access

- 1) For the purpose of conducting on-site audits or inspections to ensure compliance with this chapter, the department may, during regular business hours, enter business premises in which analytical data pertaining to accreditation under the provisions of this chapter are generated or stored.
- 2) A laboratory's refusal to permit the department entry for such inspection purposes may result in denial or revocation of accreditation by the department.

173-55-220 Assistance to laboratories

Laboratories scheduled to undergo an audit by the department may request a training session be conducted by department staff in conjunction with that audit. Accredited laboratories may also request on-site or virtual assistance at times other than the audit. Whether requested as part of the on-site audit or otherwise, the department will provide such assistance to the extent allowed by staff resources available at the time.

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