173-55 Accreditation of Cannabis Laboratories

173-55-010 Purpose

RCW 69.50.348 requires licensed cannabis producers and processors to submit representative samples of cannabis, useable cannabis, or cannabis-infused products produced or processed by the licensee to an independent, third-party testing laboratory meeting the accreditation requirements established by the state department of ecology. The purpose of this chapter is for the department of ecology to establish a state program for accreditation of cannabis laboratories.

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 laboratory standards in accordance with RCW 69.50.348.

(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.

173-55-030 Definitions

Unless a different meaning is clearly required by context, the following words and phrases as used in this chapter shall have the following meanings:

(1) Accreditation means the formal recognition by the department that a cannabis laboratory is capable of producing accurate and defensible analytical data. This recognition is signified by issuance of a written certificate accompanied by a scope of accreditation indicating the parameters for which the laboratory is accredited. The department does not, by accrediting any laboratory pursuant to these rules, vouch for or warrant the accuracy of any particular work done or report issued by that laboratory.

(2) Accreditation year means the one-year period as stated on the certificate of accreditation.

(3) Analyte means the constituent or property of a sample measured using an analytical method, such as "arsenic" or "percent moisture."

(4) Analytical data means the recorded qualitative and/or quantitative results of a chemical, physical, biological, microbiological, or other scientific determination.

(5) Analytical method means a written procedure for acquiring analytical data.

(6) Biennium means the first day of July in an odd numbered year through the 30th day of June of the next succeeding odd-numbered year. Two fiscal years equal one biennium.

(7) Cannabis flower means a type of sample matrix provided to a laboratory for testing that is a representative of a lot of cannabis flower provided to the laboratory.

(8) Laboratory means a facility:

(a) Under the ownership and technical management of a single entity in a single geographical location;

(b) That makes scientific determinations based on analytical methods performed on samples; and

(c) That submits data to the department of ecology, department of health, the Washington state liquor and cannabis board, department of agriculture, or other entity requiring the use of an accredited laboratory.

(9) Department is the state of Washington department of ecology when the term is not followed by another state designation.

(10) Fiscal year is the calendar year starting July 1st through June 30th of the following year.

(11) Matrix is the material to be analyzed. For the purposes of this chapter, this includes:

(a) Cannabis flower;

(b) Intermediate products as defined in chapter 314-55 WAC; and

(c) End products as defined in chapter 314-55 WAC.

(12) Parameter means the combination of one or more analytes determined by a specific analytical method, in a specific matrix. Example of parameters include the analyte arsenic by method EPA 6020 in cannabis flower.

(13) Procedural manual means the most recent version of the Department of Ecology's Procedural Manual for the Cannabis Laboratory Accreditation Program.

(14) Quality assurance (QA) means activities intended to assure that a quality control program is effective. A QA program is a totally integrated program for assuring reliability of measurement data.

(15) Quality control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

173-55-040 Initial Accreditation Application

(1) When a lab is applying for initial accreditation, laboratory managers or their designee must submit an application.

(2) Initial accreditation applications must include:

(a) A request for accreditation for specific parameters;

(b) Includes:

(i) The laboratory's standard operating procedures as described in WAC 173-55-075 applicable to the parameters requested;

(ii) the laboratory's quality assurance manual as described in WAC 173-55-070;

(b) proficiency test (WAC 173-55-090) results for the requested parameters;

(c) a list of all personnel and equipment the lab will use to perform analytical methods as specified in the application;

(d) method validation data such as:

(i) limit of quantitation verification data;

(ii) method detection limit studies;

(iii) valid calibrations; or

(iv) initial demonstrations of capability; and

(e) The application fee as described in WAC 173-55-180(3).

(3) Once all application requirements have been submitted to the department, the department will conduct a review of the application as described in WAC 173-055-060.

173-55-050 Accreditation Renewal Application

(1) A laboratory must apply for renewal of accreditation each year after initial accreditation to maintain the laboratory's accreditation status.

(2) Accreditation renewal applications must include:

(a) A completed accreditation renewal application;

(b) The required annual fee established in WAC 173-55-180;

(c) Any changes to the parameters for which the laboratory is seeking accreditation;

(d) A copy of the standard operating procedures (SOPs) as required in WAC 173-55-075 if changes have been made, or a statement indicating no changes have been made;

(e) A copy of the laboratory's quality assurance manual as required in WAC 173-55-070 if changes have been made, or a statement indicating no changes have been made;

(f) All proficiency testing (PT) results as required in WAC 173-55-090 since the Certificate effective date; and

(g) PT results for any new parameters requested in the renewal application.

(3) A laboratory must submit a renewal application to the department 30 days before their accreditation expires.

173-55-060 Review and Approval of Accreditation Application

(1) After receiving an application, the department will review it to determine if the:

(a) Documentation provided warrants the department accrediting the requested parameters;

(b) Personnel and equipment are adequate to support successful performance of requested parameters; and

(c) the applicant laboratory has paid the application fee.

(2) During or after this review, the department will advise the applicant if there are any required changes before continuing with the accreditation process.

(3) Once the department has reviewed the application and it will either:

(a) Approve and provide a certificate of accreditation with accompanying scope of accredited parameters, denying any requested parameters that do not warrant accreditation; or

(b) deny the laboratory accreditation.

(5) If the application is approved, the department will award a certificate of accreditation and a scope of accreditation. The accreditation types are:

(a) Full Accreditation, also referred to as Good Standing;

(b) Provisional;

(c) Interim; or

(d) Qualified.

(6) If the department denies a subset of requested parameters, the department will notify the laboratory what steps are necessary to gain accreditation for the denied parameters.

(7) If the department does not approve the application in whole, the department will notify the applicant laboratory of any missing or amended action items necessary to approve the application.

173-55-070 Quality Assurance Manual

(1) A quality assurance (QA) manual is a written record intended to assure the reliability a laboratory's measurement of data. A QA manual documents policies, organization, objectives, and specific quality control and quality assurance activities performed by the laboratory. Guidelines for contents of the QA manual are in the procedural manual.

(2) The department reviews and approves the laboratory's QA manual prior to the department's initial audit. The QA manual submitted concurrently with the application must be in detail and scope commensurate with the size of the laboratory.

173-55-075 Standard Operating Procedures

(1) A standard operating procedure (SOP) is a detailed written description of the analytical method used by the laboratory to provide data on one or more parameters. An SOP must be in detail sufficient to assure consistent and replicable results by any qualified employee at the laboratory.

(2) The department reviews and approves the laboratory's SOP for each parameter. Each SOP is submitted concurrently with the application.

(3) The laboratory must submit a revised SOP whenever the laboratory makes updates to an SOP.

(4) Guidelines for contents of a standard operating procedure are in the procedural manual.

173-55-080 Data and Record Traceability

(1) The laboratory must be able to demonstrate data and record traceability and supporting documentation.

(2) Data traceability or traceability means the ability to recreate the final result by means of records.

(a) Records 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.

(b) This unbroken trail begins upon receipt of the samples at the laboratory.

(3) To demonstrate this, a laboratory must:

(a) Be able to recreate sample results by means of records in entirety, starting at receipt of the samples by the laboratory and ending at the final report;

(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.

(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.

(4) When records are handwritten, they must be in indelible ink and comply with any relevant method requirements. This includes the date and time(s) of recording, and technician's initials.

(5) Use of electronic recordkeeping 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;

(c) It is not being used on an incubator used for analysis of samples for microbiology parameters; and

(d) must be monitored by lab personnel to verify that temperatures meet relevant method and regulatory requirements.

173-55-090 Proficiency Testing

(1) To receive initial accreditation laboratories must analyze a minimum of two PT samples per applicable parameter for which the laboratory is seeking accreditation.

(a) After an accredited laboratory submits two acceptable PT sample results and no unacceptable results in an accreditation year, the laboratory is required to submit only one acceptable PT sample result in subsequent accreditation years.

(b) If a laboratory has an unacceptable PT result when they are only required to analyze one, the lab must have an acceptable result prior to their next renewal and must return to a biannual PT schedule for the following year.

(2) 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.

(3) The department may require the laboratory to submit raw data along with the reported results of PT samples.

(4) Laboratories are responsible for obtaining PT samples from vendors meeting the following criteria:

(a) PT vendors must hold active ISO/IEC 17043 accreditation from a recognized authority.

(b) If the PT vendor is also the manufacturer of the PT material, they must also hold ISO/IEC 17034 accreditation.

(5) Proficiency tests samples must undergo the identical preparation and analytical process used for routine samples.

(6) No fee shall be charged to the department for the purchase or analysis of PT samples.

(7) The department may provide specific guidance for proficiency testing (PT) studies for applicable parameters. This could include steps outlined in the procedural manual, lists of available PT providers, or lists of parameters that require PT.

173-55-100 Audits

(1) A laboratory must undergo an audit by the department to assess critical elements and areas of standard practices. All accredited laboratories will be subject to an audit by the department on an annual basis. The laboratory must assist and accommodate department personnel during audits as required. The department will determine if the audit is held on-site.

(2) Critical elements for accreditation. Elements of a laboratory's operation 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. Critical elements include:

(a) Analytical methods. The department determines if SOPs and other documentation of analytical methods:

(i) Are present at the laboratory;

(ii) Are approved for regulatory use, if applicable;

(iii) Readily available to analysts; and

(iv) Being implemented.

(b) Equipment and supplies. The department determines if sufficient equipment and supplies as required by analytical methods are:

(i) Available at the laboratory;

(ii) Being adequately maintained; and

(iii) In a condition to allow successful performance of applicable analytical methods.

(c) QA and QC records. The department determines if QA and QC records for programs/projects within which the laboratory is generating analytical data for submission are sufficient.

(d) Sample management. The department determines if procedures for receipt, preservation, transportation, and storage of samples are sufficient. The laboratory is responsible only for those elements of sample management over which is has direct control. In addition, laboratories must demonstrate that sample management requirements of applicable regulatory programs are being met where the laboratory is submitting data.

(e) Data management. The department determines if a laboratory demonstrates that data management requirements are being met. The audit includes a review of activities necessary to assure accurate management of laboratory data including:

(i) Raw data;

(ii) Calculations;

(iii) Transcription;

(v) Computer data entry; and

(vi) Reports of analytical results.

(3) Standard practices. Standard practices are those elements of laboratory operations which might affect efficiency, safety, and other administrative functions. Typically, standard practices are not grounds for an accreditation action, but can be if a specific finding directly affects the laboratory's ability to meet a critical element for accreditation or presents a significant safety concern. Standard practices include:

(a) Personnel. The department determines if managerial, supervisory, and technical personnel have adequate training and experience to allow satisfactory completion of analytical procedures and compilation of reliable, accurate data.

(b) Facilities. The department determines if laboratory facilities allow efficient generation of reliable, accurate data in a safe environment.

(c) Safety. If the department determines the laboratory has a significant safety deficiency, the department may refer the deficiency to appropriate state or federal agencies.

(4) Documentation requests. The department requires a laboratory to submit requested documentation at least two weeks prior to the scheduled start date of an audit.

(a) Documents may be submitted electronically.

(b) The laboratory must submit analytical data for each method being audited.

(c) The department may request additional documentation if deemed necessary.

(5) After the audit is complete, the department will provide an audit report to the laboratory describing the findings and any corrective actions needed. This is typically provided within 30 days.

173-55-105 Audit Access

(1) For the purpose of conducting audits, 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 audit or inspection purposes may result in denial or revocation of accreditation by the department.

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 approve the application and provide the applicant laboratory with a certification of accreditation and a scope of accreditation listing the accredited parameters.

(2) If the department grants interim, provisional, or qualified accreditation, the department will provide the laboratory a report specifying deficiencies and/or missing information necessary to upgrade all parameters to accreditation status.

(3) The certificate and accompanying scope of accreditation 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:

(a) areas of deficiency in meeting the requirements in WAC 173-55-040 – 173-55-100.

(b) any missing information the department needs to complete the review of the laboratory's application.

(5) 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.

(a) 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 approved or denied.

(b) If the requested information is not provided within the time frame, the department will deny the application and the applicant must submit a new application to the department.

173-55-120 Qualified Accreditation

(1) A laboratory may receive qualified accreditation status from the department if the laboratory has received a waiver from the director, or their designee, of the Washington state liquor and cannabis, of the department of agriculture, or of the department of health. All accreditation requirements in WAC 173-55-040 through 173-55-100 not explicitly waived must still be met in order to gain qualified accreditation.

(2) A waiver excuses a laboratory from specific accreditation requirements explicitly outlined in the waiver from the issuing regulatory agencies.

(3) Any waiver submitted to the department must be included concurrent with the laboratory's accreditation application. A waiver can be submitted to the department by either the issuing agency or an applicant laboratory.

(4) Waivers are only valid for the accreditation year for which the lab is applying.

173-55-130 Interim Accreditation

(1) The department may approve interim accreditation to a laboratory if the department is unable to complete an audit for accreditation for a specific parameter, through no fault of the laboratory, but the department has determined that the laboratory has met all other requirements of accreditation.

(2) The department may also require the laboratory to submit analytical data as evidence of analytical capability to grant Interim accreditation.

173-55-140 Provisional Accreditation

(1) The department may approve a laboratory for provisional accreditation when the department determines that the laboratory can consistently produce valid analytical data but have deficiencies requiring corrective action.

(a) When the laboratory has corrected such deficiencies, it must provide evidence of correction to the department or request a follow-up audit, as appropriate.

(b) If the department determines the deficiencies have been corrected, it may award full accreditation as in WAC 173-55-110.

(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 Matrix Groups

(1) Laboratories are accredited within one or more matrix groups. These matrix groups are categorized as:

(a) Cannabis flower;

(b) Intermediate products as defined in chapter 314-55 WAC; and

(c) End products as defined in chapter 314-55 WAC.

(2) Within each matrix group, specific analytical methods must be used for the following:

(a) Water activity;

(b) Cannabinoid concentration analysis;

(c) Foreign matter inspection;

(d) Microbiological screening;

(e) Mycotoxin screening;

(f) Pesticide screening;

(g) Residual solvent screening; and

(h) Heavy metal testing.

(3) Within these matrix groups, laboratories are accredited for specific parameters. These may include, but are not limited to, those listed in the department's procedural manual. These parameters must use specific analytical methods chosen by the applying laboratory, including those listed in subsection (2) of this section.

(4) The scope of accreditation accompanying the accreditation certificate indicates the matrix groups and parameters for which the laboratory is accredited.

173-55-160 Denying Accreditation

(1) The department may deny accreditation if the applicant laboratory:

(a) Fails to comply with the requirements of this chapter;

(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) Refuses to permit entry for department audits (WAC 173-55-100); or

(g) Fails to pay applicable fees.

(2) The department may deny a laboratory accreditation for a specific parameter for unacceptable proficiency testing results.

(3) Laboratories denied accreditation may appeal under the provisions of WAC 173-55-190.

173-55-170 Revoking or Suspending Accreditation

The department may suspend or revoke laboratory accreditation.

(1) The department may revoke the entire accreditation and scope of accreditation or one or more individual parameters.

(2) The department may suspend the entire accreditation and scope of accreditation or one or more individual parameters.

(a) Suspension of accreditation by the department is for a specified period during which the affected laboratory must correct deficiencies that led to the suspension.

(b) If the department determines deficiencies are not corrected they may revoke the laboratory's accreditation.

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

(a) Fails to comply with standards in this chapter;

(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 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;

(g) Refuses to permit entry for department audits (WAC 173-55-100);

(h) Fails to pay applicable fees;

(i) Reports two consecutive unacceptable PT sample results.

(4) A laboratory having had its accreditation suspended or revoked may appeal under the provisions of WAC 173-55-190.

173-55-180 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, 2025, the yearly accreditation fee for a cannabis laboratory is determined using Equation 1.

Equation 1

$$Fee = 0.5*(C/N)$$

Where:

Fee	=	The fee for accreditation for the current fiscal year, rounded to the nearest whole dollar amount.
C	=	Ecology's projected costs of its accreditation program for the biennium in which the fee is applied.
N	=	Number of accredited laboratories on March 1st of the second year of the previous biennium. If there are no accredited cannabis laboratories on March 1st of the second year of the previous biennium, then "N" will be 1.

(a) The department must publish the new fee by March 1st before the biennium for which the new fee is effective. The new fee is effective from July 1st to June 30th of every biennium. This amount must be paid in full prior to the laboratory's next renewal.

(b) The fee invoiced is determined using Equation 1 for the fiscal year containing the effective date an accreditation action was rendered.

(c) Processing or application fees specified in subsections (3) and (5) of this section are deducted from the yearly accreditation fee.

(d) The department and an individual laboratory may establish a payment schedule requiring periodic installments of the annual fee.

(3) For a laboratory that is applying for initial accreditation, the laboratory must pay a nonrefundable application fee of $2,500 to the department before:

(a) Its quality assurance manual and applicable SOPs are reviewed by the department;

(b) The audit is conducted; and

(c) Interim, provisional, qualified, or full accreditation is granted for any parameters.

(4) The department will invoice the cannabis laboratory annually after granting any type of accreditation.

(5) 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) Multiple parameters may be included in one revision request.

(6) If a laboratory withdraws from the accreditation process after the audit has been completed, the department may retain any fees collected prior to the withdrawal request.

173-55-190 Appeals

A cannabis laboratory manager may appeal final accreditation actions within 30 days of notification of final action in accordance with chapter 43.21B RCW.

173-55-200 Assistance to laboratories

The department will provide assistance to laboratories to upon request.

(1) The department will schedule this assistance based on staff availability and resources.

(2) Laboratories scheduled to undergo an audit by the department may request a training session be conducted by department staff in conjunction with that audit.