



EXPEDITED RULE MAKING

CR-105 (December 2017) (Implements RCW 34.05.353)

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STATE OF WASHINGTON
FILED

DATE: April 17, 2024

TIME: 8:48 AM

WSR 24-09-074

Agency: Department of Agriculture

Title of rule and other identifying information: (describe subject) Chapter 16-310 WAC, Accreditation of Cannabis Laboratories. The Department is proposing to establish a new chapter in the Washington Administrative Code for the accreditation of cannabis laboratories in accordance with the standards set forth in chapter 16-309 WAC. The purpose of this rule is to ensure that laboratory standards described in chapter 16-309 WAC are followed when testing cannabis and cannabis products in Washington State.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Under 2019 House Bill 2052, the Department of Ecology was to take over the accreditation of cannabis laboratories, and began creating a fee-based program to audit and accredit the laboratories. In the process of writing cannabis laboratory standards, the Department identified an opportunity to save costs to laboratories and streamline the hiring and work process related to laboratory standards and accreditation by taking on the task of laboratory audits and accreditation. The Department wrote an agency request bill replacing the Department of Ecology with the Department of Agriculture as the accrediting agency and requesting continuous funding and expedited rulemaking authority to do this work. The bill, Second Substitute House Bill (SSHB) 2151, passed in 2024 and was signed by the governor. The bill authorized the creation of a new rule chapter to implement auditing and accrediting laboratories by the Department's Cannabis Lab Accreditation Standards Program. The bill also changes some components of the audit program, as audit fees will remain at a similar level to their current state. Laboratories will no longer be accredited by a third-party consultant and will instead be audited and accredited by a team at WSDA.

Reasons supporting proposal: The Department has a statutory obligation to write rules that establish a cannabis laboratory accreditation program by July 1, 2024, and an obligation to audit and accredit the labs under the authority of RCW 69.50.348.

Statutory authority for adoption: RCW 69.50.348.

Statute being implemented: RCW 69.50.348.

Is rule necessary because of a:

- | | | |
|-------------------------|------------------------------|--|
| Federal Law? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Federal Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| State Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |

If yes, CITATION:

Name of proponent: (person or organization) Washington State Department of Agriculture

Private
 Public
 Governmental

Name of agency personnel responsible for:

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Drafting:	Trecia Ehrlich	1111 Washington Street, Olympia, WA 98504	360-584-3711
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Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

- Relates only to internal governmental operations that are not subject to violation by a person;
- Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;
- Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;
- Content is explicitly and specifically dictated by statute;
- Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or
- Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

- The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;
- The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;
- The rule is no longer necessary because of changed circumstances; or
- Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): Expedited Rulemaking was explicitly required as stated in SSHB -2151 and the associated session law.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

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AND RECEIVED BY (date) June 17th, 2024

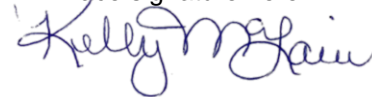
Date: 04/17/2024

Name: Kelly McLain

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Signature:

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Chapter 16-310 WAC
ACCREDITATION OF CANNABIS LABORATORIES

NEW SECTION

WAC 16-310-010 Purpose of chapter. Under the authority of RCW 69.50.348, the department adopts rules to establish a state program for the accreditation of cannabis laboratories in accordance with chapter 16-309 WAC. The purpose of this program is to ensure the laboratory standards described in chapter 16-309 WAC are followed when testing cannabis and cannabis products under chapter 314-55 WAC.

NEW SECTION

WAC 16-310-020 Scope. (1) This chapter applies to cannabis laboratories that conduct tests for or prepare analytical data on cannabis in Washington state.

(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.

NEW SECTION

WAC 16-310-030 Definitions. "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 the issuance of a written accreditation letter, accompanied by a scope of accreditation indicating the parameters for which the laboratory is accredited.

"Accreditation year" means the one-year period as stated on the letter of accreditation.

"Analyte" means the constituent or property of a sample measured using an analytical method.

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

"Analytical method" means a written procedure for acquiring analytical data.

"Audit" means an inspection and evaluation of laboratory methods, instrumentation, facilities, equipment, records, and staff.

"Board" means the Washington state liquor and cannabis board.

"Cannabis laboratory" or "laboratory" means a facility:

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

(b) Where scientific determinations are performed on samples taken from cannabis plants and products; and

(c) Where data is submitted to the customer or regulatory agency, or other entity requiring the use of an accredited laboratory under provisions of a regulation, permit, or contractual agreement.

"Data pack" means documentation created that supports each sample collected and sent to the laboratory for testing to include, but not limited to, any and all chain of custodies, manifests, worksheets, testing data including repeat testing, calibration data, quality control data, final report to customer, and any document created or received for that sample from time of receipt to disposal of sample.

"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, certificates of analysis, and the values of a standard.

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

"Department" means the state of Washington department of agriculture.

"Good standing" means the laboratory has met all its obligations to the state to remain certified by the board such as passing proficiency testing, current with any and all payments required, current with all accreditation requirements, and has no outstanding obligations to the board.

"Interlaboratory comparison" means a method used in quality control to evaluate the consistency and accuracy of test results across multiple laboratories. It involves sending sample replicates to different labs and comparing the results to identify discrepancies or variations.

"Matrix" means the material to be analyzed including, but not limited to, flower, trim, leaves, other plant matter, cannabis concentrate, cannabis infused, and edibles.

"Parameter" means the combination of one or more analytes determined by a specific analytical method.

"Precision" means the closeness of agreement between independent test results obtained under specified conditions. This is described by statistical methods such as a standard deviation (SD), coefficient of variation (CV), or confidence limit of test results.

"Proficiency testing (PT)" means evaluation of the results from the analysis of samples, the true values of which are known to the supplier of the samples but unknown to the laboratory conducting the analyses.

"Proficiency testing provider" means a third-party company, organization, or entity not associated with certified laboratories or a laboratory seeking accreditation that is approved by the department and provides samples for use in PT testing.

"Quality assurance (QA) manual" means a written record intended to assure the reliability of measurement data. A QA manual documents policies, organization, objectives, and specific QC and QA activities.

"Quality control (QC)" means the routine application of statistically based procedures to evaluate and control the accuracy of analytical results.

"Regular business hours" means the time frame during which the laboratory conducts testing or normal business. Should a laboratory have multiple shifts to conduct testing, normal business hours would include these shifts.

"Sample" means a representative portion of material taken from a larger quantity of homogenate for the purpose of examination or analysis, which can be used for judging the quality of a larger quantity for the purpose of compliance.

"Standard operating procedures (SOP)" means a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

"Validation" means the process of demonstrating or confirming the performance characteristics through assessments of data quality indicators for a method of analysis.

NEW SECTION

WAC 16-310-040 Accreditation during transition period. (1) Laboratory accreditations issued by the board in 2023 will remain valid through their expiration date in 2024.

(2) Accreditation issued by the department prior to December 31, 2024, will be based on the laboratory standard set forth in chapter 314-55 WAC and be considered accreditation renewal. Accreditation will expire in one calendar year after issuance.

(3) After December 31, 2024, all laboratories must comply with the standard set forth in chapter 16-309 WAC in order to maintain accreditation.

(4) Laboratories must submit validation studies for their cannabinoid concentration analysis, residual solvent testing, pesticide testing, and heavy metals testing to the department for their methods prior to November 1, 2024.

(5) Laboratories that have not received approval for a validation study by January 1, 2025, will not be able to test for that parameter until the parameter is approved.

(6) Laboratories that have been accredited in 2024 to the standard identified in chapter 314-55 WAC must fill out an initial accreditation application in order to transfer to the department's accreditation program beginning January 1, 2025.

NEW SECTION

WAC 16-310-050 Laboratory initial accreditation application.

(1) A laboratory that has yet to become accredited must complete an initial application provided by the department to apply for accreditation to perform cannabis and cannabis product testing.

(2) The applying laboratory must submit an initial application fee with the application to the department before an initial inspection can be scheduled.

(3) Prior to the first audit, the laboratory must successfully complete a round of proficiency testing for each parameter the laboratory intends to be accredited for. Proficiency testing must come from a vendor approved by the department and graded results must be sent to the department for review.

(4) The laboratory must include the following pre-audit materials with the application:

(a) Current information on its testing operation to include a list of analytes tested with method and instrument(s) used.

(b) A schedule of its operations listing the days and hours for various processes of operations.

(c) A list of staff along with their qualifications and job function(s).

(d) A map of the facilities and description detailing security of the premises along with the location of the lab and locations where different types of testing are performed.

(e) A description of the laboratory computer systems describing any hardware, software, firewalls, both internal and external to the laboratory, that are used in the testing or reporting of cannabis. Sufficient information must be available to allow inspectors to verify compliance with program requirements.

(f) A copy of the current quality assurance manual.

(g) Validation studies for each method for which the laboratory is seeking accreditation.

(h) The department may request additional documents as necessary.

(5) Once all required conditions and documents are reviewed and accepted by the department, an audit will be scheduled to occur within 30 days.

NEW SECTION

WAC 16-310-060 Laboratory continued accreditation. (1) Laboratories must apply for accreditation renewal each year after initial accreditation to maintain their accreditation status.

(2) Renewal application documents must be submitted to the department at least 60 days prior to their accreditation expiration date. Documents may be submitted electronically.

(3) The laboratory must include the following pre-audit materials with the application:

(a) Current information on its testing operation to include a list of analytes tested with method and instrument(s) used.

(b) A schedule of its operations listing the days and hours for various processes of operations.

(c) A list of staff along with their qualifications and job function(s).

(d) A map of the facilities and description detailing security of the premises along with the location of the lab and locations where different types of testing are performed.

(e) A description of the laboratory computer systems describing any hardware, software, firewalls, both internal and external to the laboratory, that are used in the testing or reporting of cannabis. Sufficient information must be available to allow inspectors to verify compliance with program requirements.

(f) A copy of the current quality assurance manual.

(g) A complete data pack containing all testing performed on designated samples as determined by the department during the accreditation period.

(h) Notification of any major changes to methods or procedures from the previous audit such as changes in instrumentation, new ex-

traction method, software changes, or updates to quality assurance procedures.

- (i) The department may request additional documents as necessary.

NEW SECTION

WAC 16-310-070 Application review and approval process. Upon review of the accreditation application and required documents, the department will either:

- (1) Notify the applicant laboratory of any missing items or amendments necessary to approve the application.

- (2) Approve the application, schedule an audit, and accredit the laboratory for initial, or renewed status upon successful completion of the audit.

- (3) Extend a laboratory's current accreditation by a maximum of 60 days for the purpose of scheduling.

- (4) Deny the application and deny accreditation. If the department denies accreditation or denies a subset of requested parameters, the department will notify the laboratory of the deficiencies.

NEW SECTION

WAC 16-310-080 Quality assurance manual. (1) The department will review and approve the laboratory's quality assurance (QA) manual prior to the department's initial and continued accreditation on-site audit of the lab.

- (2) The QA manual submitted concurrently with the application must be in detail and scope commensurate with the size and mission of the laboratory. Instructions for contents of the QA manual are in WAC 16-309-120.

NEW SECTION

WAC 16-310-090 Standard operating procedures. (1) The department will review the laboratory's standard operating procedures (SOP) on-site during each audit.

- (2) The SOP must be in detail sufficient to assure consistent and replicable results by any qualified employee at the laboratory.

- (3) Guidelines for contents of a standard operating procedure are in WAC 16-309-090, the cannabis testing laboratory standards manual, and other guidance documents that may be published by the department.

NEW SECTION

WAC 16-310-100 Data and record traceability. (1) During audits and when necessary, the department will ask the lab to demonstrate data and record traceability with documentation. To demonstrate this, a cannabis 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 or certificate of analysis, known as a data pack;

(b) Document validation of any chemical, reagent, and/or media used by an analytical method;

(c) Document storage of samples as required by the specific analytical method and regulations;

(d) Document that all temperature-based equipment such as a refrigerator, oven, or incubator is within control at the time of testing. When electronic recordkeeping equipment is used, these records must be 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 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, technician's initials, and temperature when relevant. Any changes to handwritten records should be single line crossed out, initialed, and dated.

(3) Unmonitored use of continuous data-loggers is not an acceptable substitute when methods and regulations require temperature checks. Use of electronic recordkeeping equipment is allowed when:

(a) The equipment can demonstrate the accuracy and precision required by the applicable method and regulations;

(b) It includes the date and time the record was captured, using a fully traceable and secure format; and

(c) It is reviewed for failure each day instrument or equipment is used.

(4)(a) Certificates of analysis must be consistent with laboratory data.

(b) Reference labs must be named on the certificate of analysis when used.

NEW SECTION

WAC 16-310-110 Proficiency testing. (1) The laboratory must participate in an approved proficiency testing (PT) program on an ongoing basis and achieve a passing score for each field of testing parameter for which the lab will be or is accredited.

(2) The cost of obtaining and testing PT samples is the sole responsibility of the laboratory.

(3) The department will maintain a list of approved proficiency tests and proficiency test providers that laboratories can use.

(4) A laboratory must successfully complete a minimum of one round of PT for each field of testing the lab seeks to be accredited for and provide proof of the successful PT results to the accrediting authority prior to initial accreditation.

(5) Accredited laboratories must successfully analyze a minimum of two PT samples for each parameter per year.

(6) The closing dates of a PT study for a particular field of accreditation can be no more than seven months apart, and the opening date of a PT study for a particular parameter must be at least seven calendar days after the closing date of the previous PT study for the same parameter or field of testing.

(7) At least one of the scores must be from a round of PT that occurs within six months prior to the laboratory's accreditation renewal date.

(8) To maintain accreditation, the laboratory must continue to pass each PT and parameter for which the lab is accredited.

(9) If the laboratory fails to achieve a pass for a parameter, the laboratory must investigate the root cause of the laboratory's performance and establish a corrective action plan for each unsatisfactory analytical result within five business days and report its finding and resolution to the department.

(10) If the corrective action has not resolved the analytical deficiency, the laboratory must suspend testing of that parameter, even if they have not yet been contacted by the department to do so first. The laboratory must then work with the department to resolve the issue and must receive authorization from the department before they can re-start testing for that parameter.

(11) The department may require the laboratory to submit raw data along with the report of analysis of PT samples.

(12) If the PT provider does not provide individual acceptance criteria for each analyte, the following criteria will be applied to determine whether the lab achieves a passing score for the round of PT:

(a) +/- 30 percent recovery from the reference value for residual solvent testing; or

(b) +/- 3 z or 3 standard deviations from the reference value for all other fields of testing.

(13) The department may waive proficiency tests for certain parameters if approved PT samples are not readily available or for other valid reasons.

(a) If a proficiency test is not available for any parameter for which the laboratory is accredited or applying for accreditation, the laboratory must implement an alternative assessment procedure for the affected analyte(s) approved by the department.

(b) An alternative assessment requirement can be fulfilled via a split-sample analysis sent to testing staff as a blind or potential customer sample unknown to the analyst.

(14) (a) PTs must undergo the identical preparation and analytical processes that are used for customer samples including, but not limited to, adhering to the same sample tracking, sample preparation, analysis methods, standard operating procedures, calibrations, quality control, and acceptance criteria used in testing customer samples.

(b) Should a PT provider require a sample preparation step such as spiking a standard onto a matrix or hydrating a sample, the laboratory must prepare the sample according to their instructions. Testing a spiking solution independently is not allowed.

(15) The laboratory is responsible for ensuring the department receives all PT results directly from the PT provider.

(16) The laboratory must ensure that the information provided to the PT provider reflects accurate information about the laboratory that corresponds to the information in the laboratory's accreditation or application for accreditation including, but not limited to:

- (a) The laboratory's name and address;
- (b) The laboratory's ID number; and
- (c) The method and analyte codes.

(17) For pesticide and cannabinoid concentration analyses, a laboratory must use PT samples made with a useable cannabis matrix.

(a) If a useable cannabis matrix is unavailable, then a PT sample made with useable hemp matrix may be used.

(b) If a PT sample made with a useable hemp matrix is used for accreditation of cannabinoid concentration analysis, then the PT vendor must prepare the sample in useable hemp material itself and may not provide a separate spiking solution with the sample.

(18) Presence-absence microbiology parameters must correctly detect the presence or absence of target organisms on all replicates in their PTs to be considered acceptable.

(19) It is strictly prohibited for laboratories to communicate with other laboratories about proficiency testing samples prior to the final results reported back to the laboratory by the proficiency testing provider.

(20) It is strictly prohibited for laboratories to send PT samples to another laboratory for testing.

(21) Laboratories must participate in interlaboratory comparison testing when the department provides samples.

(a) Testing and reporting of interlaboratory comparison sample results to the department must be conducted within five business days of receipt of samples.

(b) The cost of performing interlaboratory comparison testing is the sole responsibility of the laboratory.

(c) To be considered acceptable, results from interlaboratory comparison testing must be within:

(i) +/- 30 percent recovery from the reference value for residual solvent testing; or

(ii) +/- 3 z or 3 standard deviations from the reference value for all other fields of testing.

(d) If a laboratory fails an interlaboratory comparison test, they must investigate the root cause of the laboratory's performance and establish a corrective action plan for each unsatisfactory analytical result within five business days and report its finding and resolution to the department.

(e) Failure to correct deficiencies or findings of misconduct identified from interlaboratory comparison testing could lead to suspension of accreditation.

(f) Laboratories will not be required to perform interlaboratory comparison testing on more than five samples per year per parameter being investigated.

NEW SECTION

WAC 16-310-120 Audits. (1) A laboratory must undergo an audit by the department to assess critical elements and areas of required standard practices.

(a) All accredited laboratories will be audited on an annual basis. The laboratory must assist or accommodate department personnel and auditors during audits as necessary.

(b) Audits will be performed on-site.

(c) Off-site audits will only be available at the discretion of the department.

(2) The laboratory must successfully show that they meet the minimum standards for each of the critical elements. Critical elements of accreditation are components of a cannabis laboratory's operations which are critical to the consistent generation of accurate and defensible data and keep the laboratory compliant with regulations.

(3) Critical elements include:

(a) Analytical methods. The laboratory must demonstrate that documentation of analytical methods the laboratory employs:

(i) Are present at the laboratory;

(ii) Are approved by the scientific director;

(iii) Are readily available to analysts; and

(iv) Have been validated and implemented before testing customer samples.

(b) Equipment and supplies. The laboratory must demonstrate that sufficient equipment and supplies as required by analytical methods are:

(i) Available at the laboratory;

(ii) Being adequately maintained;

(iii) Have been validated before placing into service; and

(iv) In a condition to allow successful performance of applicable analytical procedures.

(c) QA and QC records. The laboratory must maintain and make available QA and QC records. QA and QC records must monitor laboratory testing and functions to demonstrate analytical performance and compliance requirements.

(d) Sample management. The laboratory must demonstrate that its procedures for sample receipt, analysis, storage, and disposal are sufficient to meet regulatory requirements.

(e) Data management. The laboratory must demonstrate 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;

(iv) Computer data entry; and

(v) Reports of analytical results.

The department may deny, revoke, or suspend accreditation for deficiencies in critical elements.

(4) The laboratory must successfully show that they meet the minimal requirements of required standard practices. Standard practices are those elements of laboratory operations which might affect efficiency, safety, and other administrative functions, but may not affect quality of analytical data. Typically, deficiencies to standard practices are not grounds for significant accreditation actions 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 laboratory must demonstrate 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. The laboratory must demonstrate that it allows for the efficient generation of reliable, accurate data in a safe environment.

(c) Safety. The laboratory must demonstrate that it has met the minimum safety requirements as stipulated in chapter 16-309 WAC. If the department determines the laboratory has a significant safety deficiency, the department may refer the deficiencies to appropriate state or federal agencies.

NEW SECTION

WAC 16-310-130 Audit access. (1) For the purpose of conducting audits, the department may, during regular business hours, enter business premises in which analytical data relevant 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.

NEW SECTION

WAC 16-310-140 Evaluation and issuance of accreditation. (1) After the department's determination that an applicant laboratory has met the requirements in chapter 16-309 WAC and this chapter, the department will grant approval of the application and provide the applicant laboratory with proof of accreditation and a scope of accreditation listing the accredited parameters.

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

(3) 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 chapter 16-309 WAC or this chapter; and

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

(4) The laboratory shall have 30 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 or will be corrected. Initial accreditation will not be issued until deficiencies have been corrected.

(a) Based on its review of documentation provided by the applicant laboratory, the department will issue a written decision that states whether the laboratory's application is granted or denied.

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

NEW SECTION

WAC 16-310-150 Interim accreditation. (1) The department may grant interim accreditation if the laboratory is unable to complete an audit for accreditation for a specific parameter, but all other requirements of accreditation have been satisfied.

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

NEW SECTION

WAC 16-310-160 Provisional accreditation. (1) The department may approve an existing laboratory with prior accreditation for provisional accreditation when the department determines that the laboratory can consistently produce valid analytical data but has deficiencies requiring corrective action.

(a) When the laboratory has corrected such deficiencies, it must provide documented 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 approve full accreditation as in WAC 16-310-140.

(2) The department may extend a provisional accreditation in 30-day intervals for up to one year.

NEW SECTION

WAC 16-310-170 Denying accreditation. (1) The department may deny accreditation for reasons including, but not limited to, the following laboratory actions:

(a) Failure to comply with standards of this chapter;
(b) Misrepresenting itself to the department;
(c) Failure to disclose pertinent information in the application;
(d) Falsifying reports of analysis including proficiency testing results;

(e) Engaging in unethical or fraudulent practices concerning generation of analytical data;

(f) Refusing to permit entry for department audits as required by WAC 16-310-130;

(g) Failure to pay applicable fees; or

(h) Is determined by the department or the board to be criminally negligent or not in compliance with chapter 69.50 RCW.

(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 16-310-210.

(4) The department will notify the board of any laboratories that are denied accreditation.

NEW SECTION

WAC 16-310-180 Revoking or suspending accreditation. The department may suspend or revoke laboratory accreditation.

(1) The department may revoke or 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.

(2) The department may suspend or revoke accreditation for reasons including, but not limited to, the following laboratory actions:

(a) Failure to comply with standards in chapter 16-309 WAC and this chapter;

(b) Violating a state rule relative to the analytical procedures for which it is accredited;

(c) Misrepresenting itself to the department;

(d) Falsifying reports of analysis including PT results;

(e) Engaging in unethical or deceitful practices concerning generation of analytical data;

(f) Is deficient in its ability to provide accurate and defensible analytical data;

(g) Refusing to permit entry for department audits as required by WAC 16-310-130;

(h) Failing to pay applicable fees; or

(i) Reporting two consecutive unacceptable PT sample results for the same analyte.

(3) A laboratory may appeal the suspension or revocation of its accreditation under the provisions of WAC 16-310-210.

NEW SECTION

WAC 16-310-190 Withdrawal of accreditation. (1) The laboratory may withdraw from the accreditation program by sending a letter to the department signed by the laboratory director containing the last date they will perform testing under this program.

(2) The laboratory will remain responsible for any storage of data acquired during regulated testing for five years from the date the testing was performed.

(3) The laboratory must properly dispose of any cannabis or cannabis product remaining in the laboratory.

(4) The department may verify compliance with these rules even after withdrawal, suspension, or revocation of accreditation.

NEW SECTION

WAC 16-310-200 Fee structure. (1) The laboratory must pay a nonrefundable initial or transfer application fee in the amount of \$3,200 to the department before the application will be reviewed and an audit will be conducted.

(2) Audit fees must be paid at least 30 days prior to the initial accreditation audit or any continued accreditation audits.

(a) A fee of \$7,200 must be paid for on-site audits.

(b) A fee of \$2,100 must be paid for off-site surveillance audits.

(3) (a) 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 laboratory must include a processing fee of \$1,000 with the request.

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

(4) 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.

(5) Processing and application fees are nonrefundable.

NEW SECTION

WAC 16-310-210 Appeals. A laboratory's scientific director may appeal final accreditation actions within 25 days of notification of final action in accordance with chapters 34.05 RCW and 16-08 WAC.