Chapter 16-309 WAC
CANNABIS LABORATORY ACCREDITATION STANDARDS PROGRAM

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WAC

WAC 16-309-010 Purpose of chapter. Under the authority of chapter 15.150 RCW, the department adopts rules to establish and maintain quality standards for laboratories conducting analysis of recreational and medicinal cannabis. The standards are the elements used in the evaluation of a product's compliance with established product standards. These rules consist of method approval, method validation protocols, and performance measures and criteria applied to the testing of the product.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-010, filed 4/17/24, effective 5/18/24.]

WAC 16-309-020 Definitions. "Accessioning" means the process of receiving and organizing samples for testing in a laboratory.

"Accreditation" means the formal recognition by the accrediting authority that a cannabis laboratory is capable of producing accurate and defensible analytical data. This recognition is signified by the issuance of a written certificate, 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 certificate of accreditation.

"Accrediting authority" means the recognized agency that has the authority to perform audits and inspections to assure laboratories meet the standards established in rule and will issue, suspend, or revoke accreditation to the laboratory.

"Accuracy" means the degree to which an analytical result corresponds to the true or accepted value for the sample being tested. Accuracy is affected by bias and precision.

"Action level" means the level of concern, decision point, cut-off, or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample.

"Aliquot" means a portion of a larger whole, especially a sample taken for chemical analysis or other treatment.

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

"Analytical batch" means a group of samples, standards, and blanks which are analyzed together with the same method sequence and same lots of reagents and with the manipulations common to each sample within the same time period usually no more than 24 hours. Batch size is usually limited to instrument loading capacity.

"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.

"Autoclave" means a steam sterilizer device that is intended for use by a laboratory to sterilize biohazardous products by means of pressurized steam.

"Bias" means the difference between the expectation of the test result and the true value or accepted reference value. Bias is the total systematic error, and there may be one or more systematic error components contributing to the bias.

"Biohazardous" means products that are infectious, and sharps materials such as needles and broken glass.

"Biosafety cabinet (BSC)" means biocontainment equipment used in biological laboratories to provide personnel, environmental, and product protection.

"Blank" means a substance that does not contain the analytes of interest and is subjected to the usual measurement process. Blanks can be further classified as method blanks, matrix blanks, reagent blanks, system blanks, and field blanks. Response for target analytes must be less than 50 percent of the limit of quantitation.

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

"Calibration" means determination of the relationship between the observed analyte signal generated by the measuring/detection system and the quantity of analyte present in the sample measured. Typically, this is accomplished through the use of calibration standards containing known amounts of analyte.

"Calibration curve" means the functional relationship between instrument response and target analyte concentration determined for a series of calibration standards. The calibration curve is obtained by plotting the instrument response versus concentration and performing a regression analysis of the data.

"Calibration standard (CalS)" means a known amount or concentration of analyte used to calibrate the measuring/detection system. May be matrix matched for specific sample matrices.

"Cannabis laboratory analytical standards program (CLASP)" means the interagency coordination team for cannabis laboratory quality standards. The team consists of the department of agriculture (WSDA), the liquor and cannabis board (LCB), and the department of health (DOH). The WSDA is the designated lead agency for the team.

"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.

"Carryover" means residual analyte from a previous sample or standard which is retained in the analytical system and measured in subsequent samples. Also called memory.

"Certified reference material (CRM)" means a reference material accompanied by documentation (certificate) issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures.

Note: Standard reference material (SRM) is the trademark name of CRMs produced and distributed by the National Institute of Standards and Technology (NIST).

"Certifying scientist" means the person authorized by the scientific director to review the analytical results and issue the certificate of analysis for cannabis samples who has the education, training, and competencies to perform such duties. No certifying duties may be performed by any technical personnel directly involved with the conduct of the analytical findings or testing.

"Clean room" means an isolated environment, strictly controlled with respect to: Airborne particles of viable and nonviable nature, temperature, humidity, air pressure, air flow, air motion, and lighting.

"Continuing calibration verification standard (CCV)" means one of the primary calibration standards used to verify the acceptability of an existing calibration.

"Control" means a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

"Corrective action" means the process of identifying and eliminating the cause of a problem to prevent it from happening again.

"Cut-off concentration" means, in qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods).

"Decision point" means the level of concern, action level, cut-off, or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample.

"Department" means the state of Washington department of agriculture when the term is not followed by another state designation.

"High complexity testing" means laboratory tests that require a level of expertise to perform the test due to the complexity of the test methodology and the risk of erroneous results. These tests require a higher level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

"Initial calibration blank (ICB)" means an aliquot that consists of the same solvent used for the calibration standards, but without the analytes, analyzed following the initial calibration and prior to quantitating any samples to verify the absence of instrumental interferences.

"Initial calibration verification (ICV)" means a second source standard that is used to verify the correctness of the primary source calibration curve. This standard is initially analyzed prior to sample analysis.

"Incubation" means the act of storing microorganisms at a predetermined temperature, for a predetermined amount of time, to allow for growth of microorganism colonies.

"Inoculation" means the act of introducing microbes into a culture media to induce reproductive growth.

"Interference" means a positive or negative response or effect on response produced by a substance other than the analyte. Includes spectral, physical, and chemical interferences which result in a less certain or accurate measurement of the analyte.

"Intermediate precision" means within-laboratory precision obtained under variable conditions, e.g., different days, different analysts, and/or different instrumentation.

"Internal standard (IS)" means a chemical added to the sample, in known quantity, at a specified stage in the analysis to facilitate quantitation of the analyte. Internal standards are used to correct for matrix effects, incomplete spike recoveries, etc. Analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard must have similar physiochemical properties to those of the analyte.

"Laboratory control sample (LCS)" means a portion of respective matrix blank that is spiked with known quantities of target analytes and processed as if it were a sample. The LCS is used to evaluate the accuracy of the methodology.

"Laboratory information management system (LIMS)" means a computer software system that is used to collect information about a sample, track results through the testing process, and disseminate the final results to the customer and regulating agency.

"Limit" means a point or level beyond which something does not or may not exceed or pass. Something that bounds, restrains, or confines to the utmost extent. Limits are used to define a specific concept in analysis. Decision points and action levels are examples of limits.

"Limit of detection (LOD)" means the minimum amount or concentration of analyte that can be reliably distinguished from zero. The term is usually restricted to the response of the detection system and is often referred to as the detection limit. When applied to the instrument capability it is known as an instrument detection limit (IDL) or when applied to the complete analytical method it is often referred to as the method detection limit (MDL).

"Limit of quantitation (LOQ)" means the minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision and accuracy. Limit of quantitation (or quantification) is variously defined but must be a value greater than the MDL and applies to the complete analytical method.

"Linearity" means the ability of a method, within a certain range, to provide an instrumental response or test results proportional to the quantity of analyte to be determined in the test sample.

"Low complexity testing" means laboratory tests that require little to no expertise to perform the test due to the lack of complexity of the test methodology and the low risk of erroneous results. These tests require a low level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

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

"Matrix blank" means a substance that closely matches the samples being analyzed with regard to matrix components. Ideally, the matrix blank does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples. The matrix blank is used to determine the ab-

sence of significant interference due to matrix, reagents, and equipment used in the analysis.

"Matrix effect" means an influence of one or more components from the sample matrix on the measurement of the analyte concentration or mass. Matrix effects may be observed as increased or decreased detector responses, compared with those produced by simple solvent solutions of the analyte.

"Matrix spike (MS)" means an aliquot of a sample prepared by adding a known amount of analyte(s) to a specified amount of matrix. A matrix spike is subjected to the entire analytical procedure to establish if the method is appropriate for the analysis of a specific analyte(s) in a particular matrix. Also referred to as a laboratory fortified matrix.

"Matrix spike duplicate (MSD)" means a replicate of a sample that has known concentrations of analytes added to it. It is used to evaluate the precision and bias of a method for a specific sample matrix. A matrix spike duplicate is processed along with the same sample batch and follows the same sample preparation and analytical testing.

"Method" means a particular procedure that systematically describes how a cannabis test is performed and analyzed.

"Method validation" means the process of demonstrating or confirming that a method is suitable for its intended purpose. Validation criteria include demonstrating performance characteristics such as accuracy, precision, selectivity, limit of detection, limit of quantitation, linearity, range, ruggedness, and robustness.

"Method validation report" means documentation generated detailing the evidence which established the suitability of the method for its intended use.

"Moderate complexity testing" means laboratory tests that require a level of expertise to perform the test due to the complexity of the test methodology and the risk of erroneous results. These tests require a moderate level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

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

"Performance criteria" means defined, measurable performance characteristics of an analytical method or process-specific requirements for accuracy, precision, recovery, specificity (selectivity), sensitivity (limits of detection), inclusivity, exclusivity, linearity, range, and scope of application. Criteria may also be set by defining process (i.e., method validation protocols).

"Performance-based methods approach" means or conveys "what" needs to be accomplished, but not prescriptively "how" to do it. It is a measurement system based upon established performance criteria for accuracy and precision with use of analytical test methods. Under this measurement system, laboratories must demonstrate that a particular analytical test method is acceptable for demonstrating compliance. Performance-based method criteria may be published in regulations, technical guidance documents, permits, work plans, or enforcement orders.

"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 or confidence limit of test results. See also "random error." Precision can be further classified as repeatability, intermediate precision, and reproducibility.

"Preparation batch" means samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch consists of one to 20 samples (not including matrix blanks, LCS, matrix spikes and matrix duplicates) of the same matrix.

"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 certification that is approved by the department and provides samples for use in PT testing.

"Qualitative analysis/method" means analysis/method in which substances are identified or classified on the basis of their chemical, biological, or physical properties. The test result is either the presence or absence of the analyte(s) in question.

"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.

"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.

"Quantitative analysis/method" means analysis/method in which the amount or concentration of an analyte may be determined (or estimated) and expressed as a numerical value in appropriate units with acceptable accuracy and precision.

"Random error" means component of measurement error that in replicate measurements varies in an unpredictable manner. See also "precision."

"Range" means the interval of concentration over which the method provides suitable accuracy and precision.

"Reagent blank" means reagents used in the procedure taken through the entire method. Reagent blanks are used to determine the absence of significant interference due to reagents or equipment used in the analysis.

"Recovery" means the proportion of analyte (incurred or added) remaining at the point of the final determination from the analytical portion of the sample measured. Commonly expressed as a percentage.

"Reference material" means a material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.

"Reference standard" means a standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived.

Note: Generally, this refers to recognized national or international traceable standards provided by a standards producing body such as the National Institute of Standards and Technology (NIST).

"Relative percent difference (RPD)" means the comparison of two quantities while taking into account the size of what is being compared as calculated:

$$\text{percent RPD} = |(\text{sample} - \text{duplicate})| / ((\text{sample} + \text{duplicate})/2) * 100$$

"Repeatability (RSDr)" means precision obtained under observable conditions at a specific concentration/spike level where independent test results are obtained with the same method on identical test items in the same test facility by the same operator using the same equipment within short intervals of time.

"Representative matrix" means a cannabis matrix used to assess probable analytical performance with respect to other matrices, or for matrix-matched calibration, in the analysis of broadly similar cannabis products.

"Reproducibility (RSDR)" means precision obtained at a specific concentration/spike level under observation conditions where independent test results are obtained with the same method on identical test items in different test facilities with different operators using different equipment.

"Ruggedness/robustness" means a measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

"Sample" means 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.

"Sample package" means the sealed, tamper-resistant container (e.g., plastic bag, box, etc.) which contains the quality control sample and transportation manifest from grower or producer collection.

"Scientific director" means the individual with the proper education and training responsible for the overall laboratory operations, compliance, and training of personnel.

"Selectivity" means the extent to which a method can determine particular analyte(s) in a mixture(s) or matrix(ces) without interferences from other components of similar behavior. Also known as specificity.

"Sensitivity" means the change in instrument response which corresponds to a change in the measured quantity (e.g., analyte concentration). Sensitivity is commonly defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ.

"Shipping container" means the container (e.g., box, mailer, bag) in which the collector, or laboratory has placed one or more sample packages for transport.

"SI" means the international system of units and more commonly known as the metric system. This is the international standard for measurement. Critical laboratory measurements must be traceable to this system.

"Signal to noise ratio (SNR)" means a measure that compares the level of desired signal of an analyte to the level of background noise from the instrument thus establishing the instrument's ability to differentiate between the two.

"Specificity" means the ability of a method to measure analyte(s) in the presence of components which may be expected to be present.

"Spike recovery" means the fraction of analyte remaining at the point of final determination after it is added to a specified amount of matrix and subjected to the entire analytical procedure. Spike recovery is typically expressed as a percentage. Spike recovery must be calculated for the method as written. For example, if the method prescribes using deuterated internal standards or matrix-matched calibra-

tion standards, then the reported analyte recoveries must be calculated according to those procedures.

"Spore bioindicators" means a biological indicator that is made up of a carrier material, on which bacterial spores with a defined resistance to the sterilization process have been applied.

"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.

"Standard reference material (SRM)" means a certified reference material issued by the National Institutes of Standards and Technology (NIST) in the United States.

"Standard (solution)" means a solution containing a precisely known concentration of an element, analyte, or a substance.

"Sterilization" means a validated process used to render a product free of all forms of viable microorganisms.

"Stock standard" means a concentrated solution of method analyte(s) prepared in the laboratory from referenced and certified analyte standards, where available, or a concentrated solution of method analyte(s) purchased directly from a referenced and certified source, where available.

"Surrogate (SUR)" means a pure compound that shall not be found in any sample but is similar in nature to the compounds of interest. This compound is added to a sample in a known amount before processing to monitor method performance for each sample. It is quantified in a manner analogous to that used for the analytes. The SUR is useful in ensuring that there were no problems in sample preparation.

"Systematic error" means component of measurement error that in replicate measurements remains constant or varies in a predictable manner. This may also be referred to as bias.

"Target analytes" means those analytes required to be tested on samples by the laboratory as defined in chapter 314-55 WAC.

"Testing personnel" means those qualified on the basis of education, training, experience and demonstrated skills to perform analytical testing on cannabis, cannabis concentrates, and cannabis infused products.

"Uncertainty" means nonnegative parameter characterizing the dispersion of the values being attributed to the measured value.

"Unidirectional flow" means performing a standard operating procedure in a single direction to reduce the risk of microbiological contamination.

"Upper level of linearity (ULOL)" means the highest level at which an instrument can measure the concentration of a substance accurately within an acceptable measure of deviation.

"Validated methods" means the methods that have undergone validation.

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

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-020, filed 4/17/24, effective 5/18/24.]

WAC 16-309-030 Laboratory instructions. (1) A cannabis testing laboratory must be accredited by the accrediting authority prior to

conducting quality assurance tests on any cannabis flower or products derived under chapter 69.50 RCW.

(a) Accredited labs must conspicuously display the accreditation letter received by the accrediting authority at the lab's premises in a location where a customer may observe it unobstructed in plain sight.

(b) The laboratory must maintain a list of all tests they are currently accredited to test.

(2) The laboratory must identify potential conflicts of interest among key personnel in the organization that have involvement or influence on the testing activities of the laboratory.

(a) The laboratory conducting third-party testing must be independent of other cannabis businesses and have no financial interest in another cannabis license, excluding multiple lab accreditations.

(b) If a potential conflict of interest is identified, the laboratory must notify the accrediting authority for review, determination, and resolution of the conflict.

(3) The customer's confidential information and proprietary rights must be protected by the laboratory. The laboratory must maintain policies and procedures to protect confidential information.

(4) Cannabis labs must report certificate of analysis test results both to the customer and directly to the board in the required format(s).

(5) The department, board, and or accrediting authority may require the laboratory to submit raw data and information related to testing. The laboratory must keep and maintain all raw data and testing information for a period of five years.

(6) Laboratories must conduct an internal audit of laboratory operations to verify compliance with the accreditation checklist within 60 days of their scheduled audit. This self-audit will be reviewed by the accrediting authority at their yearly laboratory audit.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-030, filed 4/17/24, effective 5/18/24.]

WAC 16-309-040 Laboratory personnel. (1) The laboratory must have a training and retraining program for all personnel that is kept current and is documented and maintained with personnel records.

(2) The laboratory must maintain personnel files on all employees detailing their qualifications and duties for all positions that include:

(a) Resume of training and experience.

(b) Job description of current position.

(c) Copies of certificates.

(d) Copies of diploma(s).

(e) Training checklists which include what training was performed, who did the training, and when it was performed.

(f) Documentation of continuing education, if any.

(g) Documentation of demonstrated abilities and competencies.

(3) The laboratory must document the technical staff's competency for each method performed on a yearly basis demonstrating their abilities to perform their specific job functions. Completion must be signed and dated by the scientific director.

(a) Demonstration of competencies include performing instrument setup or maintenance, sample handling, extractions, testing on each instrument used, quality control acceptance, and reporting of results.

(b) Testing personnel must demonstrate acceptable performance on precision, accuracy, selectivity, reportable ranges, blanks, and unknown challenges through the use of proficiency samples or internally generated quality controls. Completion must be signed and dated by the scientific director.

(4) The laboratory must have a personnel organization chart showing the chain of command and responsibilities approved, initialed, and dated by the scientific director.

(5) The scientific director may delegate some responsibilities in their absence or for other management staff. The delegation must be in writing, indicating what functions are being delegated (i.e., quality control data review, assessment of competency, or review of proficiency testing performance), and the delegate must be qualified and approved by the scientific director.

(6) If the laboratory performs microbiological testing, at least one member of the laboratory staff must have a bachelor's degree in a biological or clinical laboratory science or medical technology from an accredited institution, or associate degree in a biological or clinical laboratory science or medical laboratory technology from an accredited institution. The scientific director may satisfy this requirement if they hold a biological or clinical laboratory science degree or medical technology from an accredited institution, as described in WAC 16-309-050.

(7) All staff must be properly trained and evaluated for proper test performance prior to starting sample testing and reporting results.

(8) The accrediting authority may waive the academic requirements listed in WAC 16-309-050 through 16-309-070, on a case-by-case basis, for highly experienced analysts. The accrediting authority may also waive the need for the specified training, on a case-by-case basis, for supervisors of laboratories associated with testing of cannabis and cannabis products.

(9) Laboratory testing personnel must be supervised by persons familiar with test methods and procedures.

(10) Supervisors of testing personnel must meet one of the qualifications for a scientific director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing. A combination of education and experience may substitute for the three years of full-time laboratory experience.

(11) The laboratory must designate a quality assurance manager or officer with defined responsibilities for ensuring the quality system is implemented and followed. The QA manager must be a separate person from the scientific director.

(12) The laboratory must report to the accrediting authority any change in the status of the scientific director. A laboratory cannot be without a scientific director for more than 30 days.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-040, filed 4/17/24, effective 5/18/24.]

WAC 16-309-050 Scientific director. (1) Each laboratory must employ a scientific director to ensure the achievement and maintenance of quality standards of practice who meets the following minimum qualifications:

(a) Must possess a doctorate in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of two years post-degree laboratory experience; or

(b) A master's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of four years of post-degree laboratory experience; or

(c) A bachelor's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of six years of post-education laboratory experience.

(2) The scientific director must have supervisory authority over all personnel involved with the accessioning, testing and storage of samples, and the reporting of results.

(3) The scientific director is not required to have direct supervisory authority over client service or IT personnel. However, they are responsible for ensuring laboratory compliance with chapters 314-55 and 246-70 WAC and this chapter, even if functions are performed by staff outside the cannabis laboratory (e.g., another department, off-site staff, corporate staff) ensuring that the confidentiality of reported results is maintained.

(4) The scientific director's responsibilities include, but are not limited to:

(a) Engaging in and responsible for the daily management of the laboratory;

(b) Establishing a training program for personnel;

(c) Ensuring that personnel are sufficiently trained;

(d) Ensuring that all personnel have demonstrated proficiency in assigned duties prior to working independently on customer cannabis samples;

(e) Ensuring that the standard operating procedures (SOP) manual is complete, current, available, signed, and followed by all personnel;

(f) Reviewing and approving any requests to modify analytical methods and documentation;

(g) Ensuring that all personnel are properly informed, and training documented when changes occur in the SOP;

(h) Ensuring that analytical methods are properly validated;

(i) Establishing a quality assurance program sufficient to legally and scientifically support results;

(j) Establishing acceptable performance limits for calibrators and controls;

(k) Ensuring that corrective action is taken in response to unacceptable QC performance or when other errors occur;

(l) Ensuring that results are not reported until after corrective actions have been taken and that the results provided are accurate and reliable;

(m) Fully understanding the function of the laboratory information management systems (LIMS) and other laboratory computer systems in sample receiving, accessioning, chain of custody, testing, and the review and reporting of results;

(n) Ensuring that the LIMS software and other software in the laboratory have been properly validated;

(o) Fully understanding the role of any external service providers and the functions of external information systems and computer

systems in the laboratory's activities associated with cannabis testing;

(p) Ensuring that external information systems and software used by the laboratory have been properly validated;

(q) Ensuring that corrective actions are taken in response to issues identified in the inspection and proficiency testing (PT) phases of the program;

(r) Demonstrating knowledge of the cannabis regulatory documents and the cannabis laboratory analysis standards program.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-050, filed 4/17/24, effective 5/18/24.]

WAC 16-309-060 Laboratory personnel performing high complexity testing. Personnel performing high complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:

(1) Have a bachelor's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(2) Must have an associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution; or

(3) Have education and training equivalents that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either:

(a) Twenty-four semester hours of medical, clinical, or chemical laboratory technology courses; or

(b) Twenty-four semester hours of science courses that include:

(i) Six semester hours of chemistry;

(ii) Six semester hours of biology; and

(iii) An additional 12 semester hours of chemistry, biology, or medical laboratory technology in any combination;

(c) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;

(d) Be approved by the scientific director to perform the test.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-060, filed 4/17/24, effective 5/18/24.]

WAC 16-309-070 Laboratory personnel performing moderate complexity testing. Personnel performing moderate complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:

(1) Have at least a high school diploma or equivalent;

(2) Have documented training to perform the test;

(3) Have the skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(4) Have the skills required to implement the quality control policies and procedures of the laboratory;

(5) Have the awareness of factors that influence test results;

(6) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;

(7) Be approved by the scientific director to perform the test.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-070, filed 4/17/24, effective 5/18/24.]

WAC 16-309-080 Laboratory personnel performing low complexity testing. Personnel performing low complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:

(1) Have at least a high school diploma or equivalent;

(2) Have training to perform the test;

(3) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;

(4) Be approved by the scientific director to perform the test.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-080, filed 4/17/24, effective 5/18/24.]

WAC 16-309-090 Standard operating procedures. (1) The laboratory must have a complete and current standard operating procedures (SOP) manual that describes in detail all laboratory operations and ensures all samples are tested in a consistent manner using the same procedures.

(2) Copies of relevant sections of the SOP must be available to all staff in their work areas.

(3) The scientific director must review and show written approval of all sections of the SOP dating when they were implemented. An itemized list of changes and versions made within the last five years must be documented on a summary of changes sheet for each section.

(4) The SOP must include a safety manual, procedure, or policy that describes specific precautionary issues throughout the lab that makes employees aware of, and know how to safely maneuver through, the issue as described in the OSHA laboratory safety guidance document.

(5) The SOP must include a procedure for decontamination and cleaning of instruments, bench space, and ventilation and microbial hoods.

(6) The SOP must include testing procedures that include pertinent information for the scope and complexity of the procedure, including:

(a) Title that identifies the activity or procedure;

(b) Scope and principle;

(c) Sample requirements;

(d) Calibration and control preparation and usage protocol;

(e) Instrumentation, equipment, materials and supplies used;

(f) Instrument settings, data acquisition, system operation, parameters and conditions for testing;

(g) Procedure for sample preparation and testing;

(h) Results review and acceptability;

(i) Additional information, notes, safety requirements, and precautions to include calculations, interferences, limitations, background corrections, and proper disposal of lab waste including biohazardous waste and cannabis waste compliant with WAC 314-55-097; and

(j) References.

(7) The SOP must include a policy for the use of personal protective equipment (PPE) when working with samples, reagents, chemicals, or potential hazards in the workplace along with a written and docu-

mented system on the competency of personnel on how to handle chemical spills and the use of chemical spill kits.

(8) The SOP must include a policy for limiting access to controlled areas of testing, storage of samples, disposal of samples, and records. Personnel must be assigned limited access according to their job responsibilities.

(9) The SOP must include a policy or procedure informing employees how to interact with law enforcement should they request information or come on-site for regulatory issues.

(10) The SOP must include a policy or procedure that informs employees and staff what tasks need to be performed and what information or documents need to be gathered prior to an audit or inspection.

(11) The SOP must include information on the proper handling and disposal of used and unused samples once testing is completed.

(12) The SOP must include information on how employees can access medical attention for chemical or other exposures, including follow-up examinations, without cost or loss of pay.

(13) The SOP must include a record or log of any deviations from the SOP detailing the reason for the deviation, the date, and approval from the scientific director.

(14) The laboratory must maintain retired procedures for at least five years beyond the retirement date and must be able to reconstruct the procedures that were in effect when a given sample was tested.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-090, filed 4/17/24, effective 5/18/24.]

WAC 16-309-100 Sampling and homogenization protocols. (1) Upon receipt, the laboratory must inspect each sample package and transportation manifest, assuring they meet the following minimum requirements:

(a) Each sample package must have a transportation manifest accompanying it to the laboratory.

(b) Each manifest must have the identifying information on it documented at the time of collection prior to sending it to the laboratory.

(c) Each manifest must have a unique sample identification number matching the label on the sample.

(d) The laboratory must reject samples when the sample ID number or label on sample container does not match the sample ID number or label on the manifest or when the container shows evidence of tampering.

(2) The laboratory must transfer samples to a secure, limited access area of the laboratory upon receipt for processing and analysis.

(3) Receipt of samples must be documented as to condition of the package, who took possession, and whether there were any unacceptable conditions.

(4) The laboratory must document all persons handling the original sample, aliquots, and extracts.

(5) The laboratory must establish the minimum volume or weight required to conduct all testing requested and any additional tests (i.e., repeat tests, differential tests, or reflex tests) that may be required.

(6) The laboratory must establish storage requirements for all sample types upon receipt at the lab.

All samples received for residual solvent testing must have an aliquot placed in an enclosed container that minimizes the evaporation of any solvents that may be present as soon as possible upon receipt.

(7) Samples that do not undergo initial testing within seven days of arrival at the laboratory must be placed in a secure temperature-controlled storage until testing.

(8) Samples must be handled in a way that avoids cross-contamination during aliquoting and handling by keeping other samples closed and out of the immediate vicinity. Analyte standards must be handled in areas separate from sample preparation areas.

(9) It is not acceptable to reuse any labware that comes into contact with samples or aliquots until after proper cleaning. Labware, equipment, and surfaces must be properly cleaned between each sample preparation or handling.

(10) All disposable pipettes/sample measuring devices can be used only once and must be discarded after use to prevent the possibility of cross-contamination.

(11) Aliquots must be labeled with a unique identifier assigned to the sample both with a barcode and in human-readable form, or just in human-readable form.

(12) When multi-well plates are used for testing, the laboratory must ensure the correct sample is aliquoted into the correct plate well and map the location of each sample on the plate.

(13) The laboratory must have a system to easily retrieve and track samples that are maintained in storage.

(14) Laboratories must ensure sample homogenization is appropriate for each test method performed.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-100, filed 4/17/24, effective 5/18/24.]

WAC 16-309-110 Security. (1) Laboratories must control and document access into operation areas (e.g., accessioning, data entry, sample handling, analytical, certification), along with sample storage areas, and records storage areas during both operating and nonworking hours.

(2) Individuals who do not have routine duties in secured areas (with the exception of auditors and emergency personnel) must be escorted, and their entries and exits must be properly documented (i.e., date, time of entry and exit, purpose of visit, and authorized escort).

(3) If a laboratory uses external service provider(s) to perform services on the laboratory's behalf (i.e., records storage, software service provider, or cloud service providers), the laboratory must show due diligence in verifying that the service provider has procedures in place to protect the confidentiality, integrity, and availability of data for the services that they will perform. The laboratory is responsible for ensuring the external service provider is in compliance with applicable requirements.

(4) Samples must be stored in a limited access, secured area.

(5) Only personnel who are assigned to the limited access, secured area can have unescorted access.

(6) Samples may be transported outside a secured area if they are in the custody of an authorized individual who is moving them to another secured location.

(7) Laboratories must maintain physical custody of samples and are not allowed to delegate sample storage to external service providers.

(8) Original hard copy records for reported samples must be maintained in a secure room, area, or file cabinet at all times suitable to prevent damage or deterioration and to prevent loss.

(9) Laboratories may use off-site record storage locations or services if they meet the limited access and security requirements listed above.

(10) The laboratory must establish a system to ensure records are protected from loss or accidental destruction. This could include backup copies of electronic records, cloud storage, or off-site secured storage of back up tapes or disks.

(11) The laboratory must establish a procedure for documenting record retrieval, removal, and disposal assuring destruction is only allowed on records held past the five-year storage requirement.

(12) The laboratory must establish a procedure for securing documents past the five-year storage requirement when specifically requested by the accrediting authority or for legal purposes.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-110, filed 4/17/24, effective 5/18/24.]

WAC 16-309-120 Quality control and assurance. (1) The laboratory must develop and maintain an extensive quality control (QC) program which involves the concurrent analysis of calibrators and controls with samples to demonstrate if the analytical system is operating within defined tolerance limits and that random and systematic errors can be identified in a timely manner.

(2) Laboratories must use controls that evaluate the performance of the sample prep and analytical instrument(s) in each preparation batch and must monitor the results of those samples within each batch and across batches for methods that include:

(a) A negative or blank control to demonstrate the assay(s) ability to perform without interference or contamination.

(b) A CCV above the cutoff or decision point but below the upper limit of linearity. Using a calibrator from the initial calibration is an acceptable CCV.

(c) A matrix spike (MS) and matrix spiked duplicate (MSD) at least every 20 samples per matrix for high complexity tests.

(d) If a matrix is not available, a representative matrix may be used and must be spiked at a concentration above the action limit with the target analytes. This is also known as a laboratory control sample (LCS).

(e) A laboratory control sample (LCS) may be used in place of a continuing calibration verification (CCV)(but not as a replacement for a failing CCV) for methods where the calibration goes through the same process as the LCS.

(f) A sample duplicate and a singular matrix spike is acceptable, when a matrix spike duplicate is not used, for each preparation batch.

(3) Positive control materials must be processed in the same manner and included with the test sample batches through the entire testing process. This does not include the ICV or CCV.

(4) Calibration curves must be verified from a second source including, but not limited to, an ICV. Laboratories must use a standard obtained from a second manufacturer if available for purchase. Labora-

tories may use a separate lot prepared independently by the same manufacturer if a standard obtained from a second manufacturer is unavailable for purchase. The ICV must include all required analytes for each analysis performed.

(5) Laboratories must use reference standards that are traceable to a primary standard through a certificate of analysis, when possible.

(6) Laboratories must use surrogate analytes or internal standards for all high complexity testing. Internal standard response must be within 50-200 percent of the response of a midpoint initial calibration standard.

(7) The use of quality control material must determine the accuracy and precision of all required analytes in each analyses performed.

(8) For any method in which quality control acceptance criteria is not defined, the criteria must not exceed 30 percent.

(9) New lots of reagents, calibrators, and control material must be validated against a currently validated calibration or method before it is put into service.

(10) All control results must be documented in a manner to allow the laboratory to detect instrument or process failure and to identify trends or bias.

(11) Quality control results must be reviewed by a qualified analyst and must meet the acceptance limits prior to reporting out sample results.

(12) Cumulative quality control records must be reviewed by the individual responsible for oversight of the laboratory's QC program on a regular basis so that they can detect assay problems, trends, shifts, and bias.

(13) The laboratory must have procedures describing corrective action to be taken and take action when cumulative control results show evidence of problems. Control records must include documentation of the specific problem noted and documented evidence of the corrective actions to resolve the problem.

(14) The laboratory must use notebooks, logbooks, or other electronic means of communicating with staff regarding issues, problems, or communications between shifts.

(15) The laboratory must have a quality assurance manual, policy, or procedure to identify operational procedures, organization objectives, functional activities, and quality control activities designed to achieve quality goals desired for operation of the lab.

(16) The laboratory must designate a quality manager who, irrespective of other duties and responsibilities, must have defined responsibility and authority for ensuring that the quality system is implemented and followed. The quality manager must have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

(17) The laboratory's quality assurance plan must measure meaningful data throughout laboratory processes that establish thresholds or limits for the indicators to trigger evaluation of the services if not met. Meaningful indicators established within the laboratory can be qualitative or quantitative and may be related to structure, processes, or outcome of the service involved.

(18) The quality assurance data must be reviewed by the scientific director on an ongoing basis that allows timely identification of problems to catch trends or issues early enough to make changes.

(19) The laboratory must maintain documentation and tracking of failed samples and batches like all other data and must make them available when requested.

(20) Instruments that use a multipoint curve must be calibrated using a minimum of a four-point curve with the first calibrator at the LOQ. No blanks can be used as a point unless required by the manufacturer. The linear correlation determination (r^2) must be ≥ 0.9950 or the correlation coefficient (r) must be ≥ 0.9975, unless otherwise specified in a CLASP-approved method. Linear regression with 1/x or no weighting must be used. Forcing the curve through zero is not allowed.

(21) To ensure the quality of data for mass spectrometry methods, the laboratory must:

(a) Perform mass spectrometric tuning at relevant frequencies or at the frequency specified by the manufacturer.

(b) Ensure method performance by comparing transitions and retention times between duplicated controls, calibrators, and samples.

(c) Use an internal or external standard to minimize errors caused by evaporation of solvents and injection errors or discrepancies.

(d) Have a detailed procedure for the manual integration of any peaks, including the review of automated integration and adjustments.

(e) Maintain all information necessary for reconstruction of the data.

(22) To ensure the quality of data for an immunoassay method, the laboratory must:

(a) Ensure functionality of new test kits and reagent lots by utilizing positive and negative controls.

(b) Ensure absorbance intensity is within the acceptable range as defined by the manufacturer.

(c) Challenge the linearity of the calibration curve by using:

(i) Different levels of positive controls to challenge the low and high end of the corresponding curve assuring results are reliable throughout the whole range of the curve;

(ii) A negative or blank control to demonstrate the assay's ability to distinguish a positive from a negative and to perform without interference or contamination.

(d) Perform second source verification by utilizing a control separate from calibration material:

(i) For multianalyte assays, calibration curves and controls must be specific for each analyte;

(ii) Control analytes with similar chemical properties as the target analyte may be used.

(23) The laboratory may verify expired neat analytical standards if the standard is recertified by the vendor and new documentation is obtained or the standard is verified by comparison to unexpired neat standard. The response factors must be within 10 percent to be considered fit for purpose. Verified expired standards must be recorded in the verification logs.

(24) The laboratory may only report quantitative results that are above the limit of quantification and below the upper limit of linearity.

(25) The laboratory must use at minimum reagent grade acids and bases, ultra-high purity grade gases, Type II water, and analytical quality materials in the preparation of standards and sample processing.

(26) Laboratory records must be legible and in ink or computerized system. Documents must be signed and dated. Changes must be initialed and dated, and there must be evidence of periodic review.

(27) When corrective action is needed, the laboratory must identify and document the issue, determine a plan for corrective actions, evaluate the results from the plan, and ensure that sample results are not reported until after the corrective actions have provide accurate and reliable results.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-120, filed 4/17/24, effective 5/18/24.]

WAC 16-309-130 Facilities, equipment, and maintenance. (1) Facilities where laboratory testing is performed must be designed for dealing with preanalytical, analytical, and postanalytical functions.

(2) The laboratory must monitor, control, and record environmental conditions as required by the relevant specifications, methods, and procedures where they influence the quality of the results. Due attention must be paid to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as necessary to the technical activities concerned.

(3) Laboratories recycling solvents by roto-evaporator or similar equipment must have a procedure for evaluating recycled solvent performance prior to use in testing. This must be applied any time the laboratory recycles solvents.

(4) The laboratory must have space for the number of personnel and separation of work areas.

(5) The arrangement of space must allow for workflow, sampling, lab space, office space, and break areas.

(6) The laboratory must have eyewash stations, safety showers, and sinks within the laboratory in areas where exposure to corrosive chemicals or substances may occur. Eyewash facilities must be no greater than 10 seconds unobstructed travel distance from the area in the laboratory where hazardous chemicals are present.

(7) The laboratory must have chemical spill kits on-site and placed in locations that are well-labeled and easily available to personnel.

(8) The laboratory must have adequate electrical outlets, unobstructed, single-use, multiplug adaptors with surge control; single-use extension cords; ground fault circuit interrupters near wet areas.

(9) The laboratory must have sufficient numbers and types of safety equipment to minimize personnel exposure to biological hazards and toxic materials. There must be vacuum traps, ventilation for fume hoods and around solvent use or storage of solvents or waste. There must be storage cabinets for flammable solvent, acids, and bases. There must be vented hoods for any microbiological analysis (i.e., Class II Type A biosafety cabinets as applicable).

(10) The laboratory must assign a unique identifier to distinguish the individual test instrument and software version used. Each test result must be traceable back to the instrument used at the time of testing.

(11) The laboratory must comply with the scheduled maintenance and function checks recommended by the manufacturer at minimum and perform preventive maintenance and check critical operating characteristics of each instrument used in the testing process. Records must be retained for all instruments and equipment.

(12) For automated liquid handling equipment performing quantitative aliquoting, the laboratory must check the accuracy and precision of each system, perform a contamination check, and monitor and detect system issues or failures (e.g., drips or leaks, short sampling, bubbles, or air gaps in reagent dispensing lines) on a regular basis.

(13) The laboratory must verify the accuracy and precision of each pipette or pipetting device prior to placing it into service. Each device must be rechecked at least every six months. If the pipette or pipetting device is used to make measurements at different volumes, accuracy and precision must be checked at each volume used. Devices that do not meet stated precision and accuracy criteria must be removed from service.

(14) The laboratory must check and record temperatures on temperature sensitive devices (e.g., water baths, heating blocks, incubators, ovens, refrigerators, freezers, and refrigerated centrifuges) on a daily or when used basis. The laboratory must establish acceptance ranges to ensure proper storage conditions for samples, calibrator and control materials, test materials, and to ensure correct analytical conditions according to manufacturer and procedure requirements. Temperature records must be complete and clearly document the date and individual performing the check, and the laboratory must document corrective actions taken to address unacceptable temperature readings.

(15) Analytical balances must be mounted in accordance with manufacturer's instructions. They must be serviced and checked periodically over the relevant weight range using ANSI/ASTM Classes 1-3 or equivalent weights.

(16) The laboratory must verify instrument and equipment performance prior to initial use, after major maintenance or service, and after relocation to ensure that they run within defined tolerance limits and according to expectations.

(17) Instrument maintenance records and function check documents must be reviewed by technical supervisory staff or the scientific director at least monthly.

(18) Instruments that do not meet performance specifications must be placed out of service and labeled as "Not in Use" until it has been repaired and shown by verification that it will perform correctly.

(19) Laboratories must demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.

(20) Laboratories must have breakrooms separate from the laboratory and ensure that food is not kept in refrigerators that have specimens, chemicals, or other laboratory related materials.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-130, filed 4/17/24, effective 5/18/24.]

WAC 16-309-140 Method performance criteria. (1) Accredited labs may reference samples for testing by subcontracting fields of testing to another accredited laboratory.

(2) Laboratories must maintain the integrity of the sample by testing samples on an "as is" or "as received" basis before sample prep unless otherwise specified in rules.

(3) Laboratories may use historical calibrations for high complexity testing as long as it is supported by analytical data through

quality control results. Historical calibrations cannot extend past 30 days.

(4) The samples fail quality control testing if the results exceed the limits indicated in chapter 314-55 WAC.

(5) Sample results are positive for the analyte being tested if their results are greater than or equal to the decision point or cut-off limits as indicated in chapter 314-55 WAC.

(6) Sample results are to be reported out in the number of digits and units of measure described in chapter 314-55 WAC.

(7) Laboratories may be accredited to conduct the following fields of testing:

Field of Testing	Level of Complexity
water activity	low
cannabinoid concentration analysis	high
foreign matter inspection	low
microbiological testing	
culture method	moderate
immunoassay method	moderate
polymerase chain reaction (PCR) method	high
residual solvent testing	high
mycotoxin testing	
enzyme-linked immunosorbent assay (ELISA) method	moderate
liquid chromatography with tandem mass spectrometry (LC-MS/MS) method	high
pesticide testing	high
heavy metals testing	high

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-140, filed 4/17/24, effective 5/18/24.]

WAC 16-309-150 Water activity testing. (1) Water activity (a_w) analysis is intended to quantitatively report out the presence of water in the sample.

The laboratory must run two continuing calibration verifications at levels bracketing the action limit concentration at the beginning of each day of testing.

(2) One sample must be run in duplicate with difference in values of 80 percent - 120 percent as a quality control specimen.

(3) The laboratory must monitor and record temperature and humidity daily or when testing is performed.

(4) The laboratory must calibrate the a_w instrument when:

(a) The instrument has been physically moved from one location to another.

(b) The instrument has been cleaned.

(c) The manufacturer's instruction manual recommends.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-150, filed 4/17/24, effective 5/18/24.]

WAC 16-309-160 Cannabinoid concentration analysis. (1) Cannabinoid concentration analysis, previously known as potency, is intended

to quantitate and accurately report cannabinoids above the lower limit of quantitation as described in chapter 314-55 WAC.

(2) Laboratories must use a method approved by the department to analyze cannabinoids.

(3) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(4) ICV, CCV, and surrogate must meet a minimum of 80-120 percent recovery for each analyte.

(5) LCS and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(6) Sample and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(7) Chromatographic performance must be described in method and must include, but is not limited to, the following criteria:

(a) Tailing factor less than 2.0;

(b) Column performance resolution greater than 1.0;

(c) Retention time shift less than two percent.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-160, filed 4/17/24, effective 5/18/24.]

WAC 16-309-170 Foreign matter inspection. (1) The laboratory must analyze not less than 30 percent of the total representative sample of cannabis and cannabis products prior to sample homogenization to determine whether foreign material is present.

(2) The laboratory must report the result of the foreign material test by indicating "pass" or "fail."

(3) The laboratory must use a microscope with photographic capabilities or a camera with magnification or resolution to document the presence of foreign matter. Magnification will only be required when something is identified and the picture without magnification does not allow identification of the foreign matter.

(4) The laboratory must document the observation with a detailed description of any foreign matter and photograph the sample supporting the report.

(5) The foreign matter inspection must be performed in a clean and sanitary location that prevents contamination or degradation prior to other testing.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-170, filed 4/17/24, effective 5/18/24.]

WAC 16-309-180 Microbiological testing. (1) Microbiological testing is intended to accurately measure qualitative, semi-quantitative, or quantitate results, and report microorganisms incurred through the production and processing of cannabis and cannabis products.

(2) The laboratory must have a microbiological testing SOP that contains a detailed description of the preparation of any material that does not come as a working stock (i.e., culture media, master mix, spiked controls).

(3) The laboratory may use either culture-based testing methods, immunoassay methods, molecular assay methods, or a combination of culture-based, immunoassay, and molecular assay methods for microbiological testing.

(4) Quality control must be performed on each new media lot, PCR reagent lot, or kit lot used. For molecular assays, DNA controls must be included with each analytical run and internal amplification controls (IACs) must be included with each individual reaction.

(a) Acceptability criteria for all calibration and QC materials such as controls, spikes, and blanks, must be defined, as well as the action to be taken when results are outside control limits. The laboratory must set controls at relevant limits around the decision points for the microbial assay(s) as defined above.

(b) Positive and negative controls must be included in all microbial assay tests. Quality controls must be analyzed in the same manner as samples.

(i) The laboratory must use control organisms that represent the target organism. Controls for the confirmation of a target, such as salmonella or Shiga toxin-producing *E. coli* (STEC), must be as similar as possible to the presumptive organism.

(ii) The laboratory must maintain documentation of quality control organisms and ensure purity of the control organism is maintained by limiting the number of cell divisions from the original culture.

(5) The laboratory must have a record of all microbial quality control and sample results. If the laboratory does not use equipment capable of recording and printing results (i.e., a PCR instrument or plate reader), then the laboratory must photograph all microbial quality control and sample results for recordkeeping.

(6) The laboratory must have a procedure in place which must specify any safety requirements or precautions unique to the microbial assay(s) used, including:

(a) Biohazard labels on equipment used to store biohazardous materials and waste such as restricted areas, refrigerators, and waste receptacles;

(b) Performing microbial assay(s) in either a Class II biosafety cabinet (BSC) or a designated clean room;

(c) Sterilization of biohazardous waste, including any materials that have come into contact with control organisms, either by autoclave or by chemical disinfectants;

(d) For safety reasons, biosafety level (BSL) 1 organisms for salmonella and STEC may be used as control organisms.

(e) Lab-prepared media must be sterilized by autoclave and undergo a quality control check for sterility before use.

Sterilization by autoclave must be documented using materials such as autoclave tape, and autoclave functionality must be tested using materials such as spore bioindicators.

(7) The laboratory must have a procedure and training for shipping and receiving bacterial enrichments, organisms, or presumptive positive samples. Biohazardous shipping and receiving training must be documented.

(8) The laboratory must perform microbial analysis in a unidirectional (i.e., one way) manner to reduce possible contamination of microbial test materials.

(a) For molecular microbial assays, the laboratory must use materials to reduce contamination such as reaction tubes that are RNAase-free and DNAase-free and use aerosol barrier pipette tips.

(b) For culture-based testing methods, all samples and controls must initiate incubation within 10 minutes of inoculation.

(9) For qualitative methods, all results must be reported as qualitative designations such as "detected," "not detected," "positive," or "negative." For quantitative methods, the laboratory may on-

ly report results that are above the limit of quantification and below the upper limit of linearity.

(10) The laboratory may not report colony-forming units (CFU) counts with greater than two significant figures.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-180, filed 4/17/24, effective 5/18/24.]

WAC 16-309-190 Residual solvent testing. (1) Residual solvent analysis is intended to accurately quantitate and report solvent residue left behind from product processing.

(2) Laboratories must use a method approved by the department to analyze residual solvents.

(3) Methanol and any other solvent listed in chapter 314-55 WAC must not be used in any preparation or analysis procedure for residual solvent testing.

(4) Upon receipt of a sample at a laboratory, the sample treatment must follow the method requirements for preservation and storage.

(5) When an extraction solvent is used in method it must be an organic solvent that is capable of accomplishing the dilution of the sample while still able to meet the quality control requirements of this method and regulatory requirements, and is NOT a required analyte per regulations. The selected solvent must be specifically cited in a lab's standard operating procedure(s).

(6) Subsampling and homogenization protocols must be specified in the approved method(s) to include:

(a) The lab must analyze at least 0.2 grams of sample per residual solvents analysis.

(b) Upon receipt of sample, the portion of the sample that is to be used for residual solvents analysis must be stored to minimize solvent evaporation.

(c) Homogenization of residual solvent samples by the lab is prohibited unless necessary due to sample composition. If homogenization is necessary, steps must be taken to minimize evaporative loss.

(7) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(8) The ICV must meet a minimum of 80 - 120 percent recovery for each analyte.

(9) CCV, surrogate, LCS and matrix spike samples must meet a minimum of 70 - 130 percent recovery for each analyte.

(10) Sample duplicates and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-190, filed 4/17/24, effective 5/18/24.]

WAC 16-309-200 Mycotoxin testing. (1) Mycotoxin testing is intended to accurately measure semi-quantitative or quantitate results, and report mycotoxins incurred through the production and processing of cannabis and cannabis products.

(2) For semi-quantitative or qualitative methods, the laboratory may report negative results. The limit of detection must be equal to or less than the analyte limit. Positive detections must be confirmed and reported using a quantitative method.

(3) For quantitative methods, the laboratory may only report numerical results that are above the limit of quantification and below the upper limit of linearity.

(4) The analytical processes for mycotoxin testing must include the following:

(a) A matrix negative and a matrix positive for each sample matrix tested per batch;

(b) Matrix positive controls at relevant levels above the decision point;

(c) The laboratory must perform a second-source calibration verification (ICV) above the decision point concentration.

(5) For high complexity testing, additional quality control is required.

(a) ICV, CCV, and surrogate must meet a minimum of 70 - 130 percent recovery for each analyte.

(b) Matrix spike samples must meet a minimum of 70 - 130 percent recovery for each analyte.

(c) Sample and matrix duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(6) Analyze matrix spike duplicates or sample duplicates at a frequency of one in 20 samples per matrix, per sample extraction or preparation method, to measure repeatability and precision of the mycotoxin assay(s).

(7) Mass spectrometry testing criteria.

(a) A minimum of three structurally significant ions (meeting the three to one signal to noise ratio) are required for confirmation. If instrument conditions or ionization techniques limit the number of ions available, the laboratory may request a deviation from the department in order to report results under these conditions.

(b) The confidence limits of the relative abundance of structurally significant ions and precursor-to-product ion transitions used for single ion monitoring and multiple reaction monitoring must be ± 30 percent (relative) when compared to the same relative abundances observed from a standard solution injection made during the same analytical run.

(8) The laboratory must have procedures that include the following:

(a) Special safety precautions required for handling mycotoxin standards;

(b) Mycotoxin standards may only be opened and used within a certified fume hood;

(c) A mycotoxin spill cleanup procedure must be included;

(d) The laboratory must ensure stability of mycotoxin standards;

(e) A detailed description of how potentially hazardous waste is disposed of.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-200, filed 4/17/24, effective 5/18/24.]

WAC 16-309-210 Pesticide testing. (1) Pesticide testing is intended to accurately quantitate and report pesticides incurred through the production and processing of cannabis and cannabis products.

(2) Pesticide standards and stock solutions must be prepared in an area separate from samples.

(3) Laboratories must use a method approved by the department to analyze pesticides.

(4) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(5) ICV, CCV, and surrogate must meet a minimum of 70 - 130 percent recovery for each analyte.

(6) LCS and matrix spike samples must meet a minimum of 70 - 130 percent recovery for each analyte.

(7) Sample and matrix duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(8) Mass spectrometry confirmation criteria.

(a) A minimum of three structurally significant ions (meeting the three to one signal to noise ratio) are required for confirmation. If instrument conditions or ionization techniques limit the number of ions available, the laboratory may request a deviation from the department in order to report results under these conditions.

(b) The confidence limits of the relative abundance of structurally significant ions and precursor-to-product ion transitions used for single ion monitoring and multiple reaction monitoring must be ± 30 percent (relative) when compared to the same relative abundances observed from a standard solution injection made during the same analytical run.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-210, filed 4/17/24, effective 5/18/24.]

WAC 16-309-220 Heavy metals testing. (1) Heavy metals testing is intended to accurately quantitate and report metals incurred through the production and processing of cannabis and cannabis products.

(2) Analytical standards and solutions must be National Institutes of Standards (NIST) traceable or equivalent.

(3) The ICP-MS must be tuned each day of analysis using a tuning solution containing elements representing all of the mass regions of interest.

(4) Instruments must be calibrated every day of testing using a minimum of a four-point curve (no blanks can be used as a point).

(5) Laboratories must use a method approved by the department to analyze heavy metals.

(6) A stabilizer must be added during sample preparation to stabilize mercury through the acid digestion and analysis. The stabilizer must be at the same level in the calibration standards as the samples.

(7) An internal standard (IS) must be added and analyzed in all calibration standards and samples.

(8) Spectral interference checks (SIC) must be used to verify that the interference levels are corrected by the instrument's data system. The SIC must contain known amounts of interfering elements that will demonstrate the magnitude of interference and test for any corrections.

(9) An initial calibration verification (ICV) and initial calibration blank (ICB) must be analyzed each day of testing.

(a) The ICB is analyzed after the ICV and must not contain target analytes.

(b) The ICV must meet a minimum of 70 - 130 percent recovery for each analyte.

(10) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(11) CCV, surrogate, LCS, and matrix spike samples must meet a minimum of 70 - 130 percent recovery for each analyte.

(12) Sample duplicates and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(13) Sample concentrations that exceed the highest calibration standard must be diluted and reanalyzed to fall within the linear calibration range.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-220, filed 4/17/24, effective 5/18/24.]

WAC 16-309-230 Other analytes. Should a laboratory test for analytes beyond the analytes required in chapter 314-55 or 246-70 WAC, they must adhere to the following guidelines:

(1) Additional test results must be identified as analytes outside the scope of accreditation on the certificate of analysis.

(2) Additional analytes that are tested using methods that also include required analytes for compliance must meet similar requirements for testing and reporting.

(3) Additional analytes that are tested using methods that do not include required analytes for compliance must be validated and tested using standards established in this chapter.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-230, filed 4/17/24, effective 5/18/24.]

WAC 16-309-240 Laboratory computers and information systems. (1) The laboratory must have computer systems and software for sample tracking throughout the laboratory's possession from receipt of the samples through testing, reporting, and disposal.

(2) The laboratory must maintain a system security plan (SSP) for each information system used, including corporate systems and external service provider systems.

(3) The laboratory must have security controls (i.e., management, operations, and technical controls) in place to protect the confidentiality, integrity, and availability of the system and its information.

(4) If the laboratory contracts with an external service provider such as a cloud service provider, the laboratory must show due diligence in verifying that the service provider has procedures in place to protect the confidentiality, integrity, and availability of data for the services that they will perform on behalf of the laboratory.

(5) The laboratory must protect any internal computer systems (e.g., desktops, servers, instrument computers) against electrical power interruptions and surges that can contribute to data loss.

(6) The laboratory must protect any internal computer systems from spyware, viruses, malware, and other attacks through the use of firewalls and by maintaining software security updates.

(7) The laboratory must validate and document changes made to computer systems, software, interfaces, calculations, and security measures prior to implementing for use on samples.

(8) Software testing must include performing manual calculations or checking against another software product that has been previously tested, or by analysis of standards.

(9) The laboratory must have a signed contract or agreement with any external service providers that includes the priority elements of physical, technical, and administrative safeguards to protect their systems and data.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-240, filed 4/17/24, effective 5/18/24.]

WAC 16-309-250 Method approvals. (1) Laboratories must use an agency approved method for cannabinoid concentration, pesticides, residual solvents, and heavy metals testing. A list of approved analytical and preparative methods are available on the agency's website (https://agr.wa.gov/departments/cannabis/cannabis-lab-analysis-program). If a laboratory wants to use a method not currently on the approved agency list of methods, the lab can submit a method for approval.

(2) Laboratories must, at a minimum, do the following for a new method approval:

(a) Laboratories must submit a method approval form with their required method documentation and method validation data emailed to the department at cannabis@agr.wa.gov.

(b) Receive written approval from the department of the validated method for use on customer samples.

(3) The initial method review and approval may take 30 days. The department may request revisions, clarifications, and/or additional data to review the method.

(4) Laboratories will receive notification via email about the status of the method. Approved methods will be added to the agency website for public access.

(5) Laboratories with denied methods will be provided with a detailed synopsis of why the method was insufficient.

(6) Methods submitted to the WSDA for approval must include a standard operating procedure that documents the following:

(a) A title that indicates the type of procedure being conducted (i.e., pesticides, residual solvents, cannabinoid concentration, or heavy metals).

(b) A document control number, date, and revision number.

(c) Approval signatory and date.

(d) A table of contents and page numbering.

(e) A section that documents the revision history for the method.

(f) A definitions section that includes a definition of terms, acronyms, and abbreviations used in the methods.

(g) A section that outlines the purpose, range, limitations (including limit of quantitation and limit of detection), intended use of the method, and target analytes.

(h) A summary section that includes an overview of the method procedure and quality assurance.

(i) An interference section that identifies known or potential interferences that may occur during use of the method and describes ways to reduce or eliminate these interferences.

(j) A safety section that describes special precautions needed to ensure personnel safety during the performance of the method.

(k) A section for equipment, supplies, reagents, and standards that are required to perform the method.

(l) A section that provides requirements and instructions for collecting, preserving, and storing samples.

(m) A quality control section that cites the procedures and analyses required to document the quality of data generated by the method and includes corrective actions for out-of-control data. This section must also describe how to assess data for acceptance based on quality control measures.

(n) A calibration and standardization section that describes the method or instrument calibration and standardization process and the required calibration verification.

(o) A procedure section that describes the sample processing and instrumental analysis steps of the method and provides detailed instructions to analysts.

(p) A section that provides instructions for analyzing data, equations, and definitions of constants used to calculate final sample analysis results.

(q) A method performance section that provides method performance criteria, including precision or bias statements regarding detection limits and sources or limitations of data produced using the method.

(r) A pollution prevention and waste management section that describes aspects of the method that minimizes or prevents pollution and the minimization and proper disposal of waste and samples.

(s) A section for references that lists source documents and publications that contain ancillary information.

(t) A section that contains all the tables, figures, diagrams, example forms for data recording, and flowcharts. This section may also contain validation data references in the body of the method.

(7) Methods must be validated and laboratories must submit method validation documentation as detailed in WAC 16-309-260.

(8) Should the department determine a method has become obsolete or invalid, it may retire the approved method after providing six months notice.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-250, filed 4/17/24, effective 5/18/24.]

WAC 16-309-260 Method validations. (1) Laboratories must perform method validation studies prior to implementing a new or original test method, implementing an approved method, implementing a new instrument, or modifying an existing method or instrument for each matrices tested.

(2) The records must include sufficient information to allow for a comprehensive review of the studies performed. Laboratories must have criteria for acceptance of study data, for agreement of replicate study samples, and for defining true outlier values. Study samples for quantitative methods must meet the same qualitative criteria (e.g., the same retention time, mass ratio, internal standard abundance, and chromatography criteria) used for samples. The laboratory's acceptance criteria must be described in the SOP and in the study summary.

(3) Laboratories must perform reverification studies on an annual basis at minimum on high complexity nonreagent methods. Reverification studies are designed to verify that the existing LOD, LOQ, and ULOL values are still valid and do not require laboratories to analyze the same number of samples that are required for full validation studies.

(4) If the laboratory modifies an existing test method or instrument parameter that affects the performance of the method, the revised method must be re-validated prior to use. If the modification is rela-

tively minor, the validation studies may be focused on those parameters that have been affected.

(5) Validations must include linearity, precision, accuracy, LOD, LOQ, ULOL, carryover, selectivity/interference, and matrix effects. unless defined specifically below.

(6) The laboratory must characterize the linearity of a method based on replicate analysis (i.e., a minimum of three replicates at each concentration) of samples of at least six concentrations. The concentrations must be distributed above and below the cutoff for the test.

(7) The laboratory must characterize the precision of a method based on replicate analysis, at least 20 results total. Analysis must be at significant concentrations around the cutoff/decision point and expected range. At least three replicates at each concentration must be analyzed. Precision studies must be performed on multiple days and in multiple batches in order to assess intra-batch and inter-batch variability.

(8) The laboratory must characterize the accuracy (expressed as bias) of a method by calculating the percent difference between the analyzed sample results and the target concentrations. Accuracy studies must be performed on multiple days and in multiple batches to assess intra-batch and inter-batch variability.

(9) The laboratory must characterize the LOD of a method by a series of replicates with decreasing concentrations (i.e., a minimum of three replicates at each concentration). The LOD must be experimentally determined and supported by analytical data. The laboratory can choose to artificially set the LOD at the established LOQ if the LOQ is at least 25 percent below the decision point limit.

(10) The laboratory must characterize the LOQ of a method by a series of replicates with decreasing concentrations (i.e., a minimum of three replicates at each concentration). The LOQ of a method must be determined and supported by analytical data and must be at least 25 percent below the decision point limit.

(11) The laboratory must characterize the ULOL of a method by a series of replicates with increasing concentrations (i.e., a minimum of three replicates at each concentration). Laboratories may select a value at the upper end of the dynamic range for a method, but it must be determined and supported by analytical data.

(12) The laboratory must investigate the potential of carryover of a method from one sample to another during testing by analyzing highly concentrated samples followed by negative samples (i.e., without the analyte of interest) and evaluate the negative samples for carryover. Positive samples that follow a sample at carryover concentrations must be reinjected or reextracted to eliminate carryover concerns.

(13) The laboratory must investigate the day-to-day precision using positive and negative samples assuring the ruggedness of the testing method provides good reproducibility over a period of at least five days.

(14) The laboratory must investigate the selectivity and interferences of a method by testing commonly encountered compounds and compounds that are structurally similar that could potentially interfere with the method at higher concentrations. Laboratories may accept manufacturer studies of immunoassay products if the study was performed using cannabis-focused compounds.

(15) The laboratory must investigate any possible matrix effect by evaluating the potential for components of the sample matrix to ei-

ther suppress or enhance the ionization of the analytes of the compound(s) of interest and internal standard(s). Studies must include the evaluation of at least five different lots of products (i.e., flower from five different plants or from five different plant lots).

(16) When dilution of a sample is necessary to keep the result concentration within the range of linearity, the laboratory must conduct dilution integrity studies to document that the dilution does not affect the method's performance. These consist of precision/accuracy studies using samples at the dilution specified in the procedure.

(17) The laboratory must perform a parallel study when a new instrument or a new/revised procedure is implemented where results from the revised/new method or new instrument are compared to results from the existing method/instrument.

(18) The laboratory must perform a positive/negative differentiation study when validating a qualitative test by analyzing positive and negative samples that have been verified by a quantitative method to assess the assay's ability to differentiate positive and negative samples. The laboratory may analyze a combination of positive and negative controls, proficiency test (PT) samples or previously tested samples. The laboratory must analyze a minimum of five positive samples at differing concentrations and five negative samples (i.e., 10 results total).

(19) The laboratory must verify extraction efficiency assuring their method can sufficiently extract out the analyte of interest from the sample matrix.

(20) Records for validation and periodic reverification studies must be organized in a format to facilitate a comprehensive review and, at a minimum, the records must include:

(a) A stated purpose;

(b) Description of test method(s);

(c) Identity of the instrument(s) used for the study;

(d) A listing of the instrument parameters used for the study;

(e) A description of the study samples;

(f) A summary of the statistical data collected to characterize the assay;

(g) A discussion;

(h) A summary with conclusions; and

(i) All raw analytical data from the samples analyzed in the study.

(21) The laboratory must use the same criteria for acceptance of study data (e.g., the same retention time, mass ratio, internal standard abundance, and chromatography criteria) as used for the daily samples.

(22) The laboratory must maintain the original assay validation study records for methods in production for an indefinite period. Validation and reverification study records must be made available at the time of inspection or upon request. Labs are required to maintain records for retired methods for five years.

(23) All immunoassay and qualitative assay methods must be properly validated prior to use with samples and supported with the following studies:

(a) Linearity;

(b) Precision and accuracy around the cutoff;

(c) Selectivity;

(d) Carryover;

(e) A parallel study using the existing and new/revised procedures;

(f) Positive/negative sample differentiation studies.

(24) All quantitative assays must be properly validated prior to use with samples and supported with the following studies:

(a) Determination of LOQ, LOD, and ULOL;

(b) Precision/accuracy around the cutoff;

(c) Carryover;

(d) Selectivity/interference;

(e) For an assay validation: Method parameters including ion selection;

(f) For full instrument validation: Instrument parameter optimization;

(g) For LC-MS, and LC-MS/MS methods: Matrix effects;

(h) For assays using a new technology: Parallel studies of PT samples and customer samples (e.g., when validating a technology different from the existing method);

(i) For assays using an extraction: Extraction efficiency must be determined; and

(j) Hydrolysis efficiency (if sample preparation includes a hydrolysis step).

(25) An abbreviated instrument validation must be performed prior to implementing an additional instrument of an exact model that has been validated by the laboratory. The laboratory must perform the following studies:

(a) Determination of the LOQ, LOD, and ULOL;

(b) Carryover evaluation;

(c) Instrument parameter optimization; and

(d) For LC, LC-MS, and LC-MS/MS methods: Evaluation of matrix effects.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-260, filed 4/17/24, effective 5/18/24.]

WAC 16-309-270 Proficiency testing. The laboratory must participate in an approved proficiency testing (PT) program that reflects the best available science as determined by the accrediting authority.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-270, filed 4/17/24, effective 5/18/24.]

WAC 16-309-280 Reports. (1) All sample test results must be supported by analytical data and all analytical data must have a documented review, once reviewed by an analyst, and once reviewed by a certifying scientist prior to being reported.

(2) Laboratories must report results as either "negative," "none detected," "pass/fail," or the numeric concentration equal to or above the decision point or cutoff of the required analytes tested as indicated in rules.

(3) For the purpose of reporting, decision points or cutoff limits have been written in chapter 314-55 WAC to the number or significant digits that laboratories are expected to use when reporting results.

(4) If the result is above the established ULOL, the laboratory must dilute the sample and retest to bring the results within the linear range of the test, unless allowed differently in the guidelines.

(5) The concentration of a diluted primary sample prior to applying the dilution factor must be above the concentration of the lowest calibrator or control in the batch.

(6) At a minimum, the computer generated COA reports for samples going to the customer must contain:

(a) A title: "Certificate of Analysis" or "Test Report";

(b) Laboratory name, lab ID number, and address;

(c) Unique identification of the test report certificate and on each page an identification in order to ensure that the page is recognized as a part of the COA, and a clear identification of the end of the report;

(d) The name, address, and license number of the customer;

(e) Date of sample collection;

(f) Sample identification number from transportation manifest;

(g) Sample/matrix type (flower, concentrate etc.);

(h) Product/sample name and category;

(i) Amount of sample received;

(j) Date received by laboratory;

(k) Name of certifying scientist;

(l) Date reported by the laboratory;

(m) Results of each test performed to include name of test, results, measurands (i.e., mg/g), cutoffs, and instrument/method of testing used;

(n) A statement to the effect that the results relate only to the items tested.

(7) Laboratories must use the analyte terminology and abbreviations specified by rules to ensure consistency in reporting and interpretation of test results.

(8) Laboratories must not release any cumulative or individual test result prior to the completion of all analysis by the lab for that sample.

(9) Any amendments to a COA after the original issuance must include a statement for the reason issued like "Corrected Report," "Supplement to COA (to include COA number)," or an equivalent form of wording.

(10) When it is necessary to issue a completely new COA, it must be uniquely identified and contain a reference to the original that it replaces (i.e., reprint).

(11) All records must include the identity of personnel performing the aliquoting, sample preparation, calibration, testing of samples and controls, and review of results.

(12) Observations, data, and calculations must be recorded at the time they are made and must be identifiable to the specific task.

(13) When mistakes occur in records, each mistake must be lined out, not erased, or made illegible or deleted, and the correct value entered alongside. All such alterations or corrections to records must be signed or initialed and dated by the person making the correction.

(14) All entries to hard copy laboratory records must be made using indelible ink. No correction fluid or tape may be used on laboratory data records.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-280, filed 4/17/24, effective 5/18/24.]

WAC 16-309-290 Procurement controls. (1) The laboratory must have procedure(s) for the selection and purchasing of services and

supplies it uses that affect the quality of the tests and/or calibrations. Procedures covering reagents and laboratory consumables must exist for the purchase, receipt, storage, and disposition of expired materials.

(2) The laboratory must ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned.

(3) New lots or materials received outside of expected environmental conditions must be documented and validated before use.

(4) Reagents and standards must be inspected, dated, and initialed upon receipt, and upon opening.

(5) Calibration standards and analytical reagents must have an expiration or reevaluation date assigned.

(6) Standards and solutions must be identified with lot number or other assigned unique identifier to trace back to preparation documentation.

(7) Prospective suppliers must be evaluated and selected on the basis of specified criteria.

(8) Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-290, filed 4/17/24, effective 5/18/24.]

WAC 16-309-300 Subcontracting. (1) The laboratory must notify the customer of the subcontract arrangement in writing, including the subcontractors' accreditation credentials under chapters 69.50 RCW and 314-55 WAC.

(2) The laboratory must maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with chapter 314-55 WAC for the work in question.

(3) When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information must be forwarded to laboratory management for corrective action.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-300, filed 4/17/24, effective 5/18/24.]