What is the purpose of this 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 with THC levels greater than 0.3 percent. The standards provided are the elements used in the evaluation of a products compliance with established product standards. They consist of approved methods, method validation protocols, and performance measures and criteria applied to the testing of the product. These standards help ensure the data that laboratories generate are credible and can be used to provide consumer protections.

Definitions

1. "Accreditation" means the formal recognition by the department of ecology 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.
2. "Accreditation year" means the one-year period as stated on the certificate of accreditation.
3. "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.
4. "Aliquot" means a portion of a larger whole, especially a sample taken for chemical analysis or other treatment.
5. "Analyte" means the constituent or property of a sample measured using an analytical method.
6. "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 within one day) or in continuous sequential time periods.
7. "Analytical data" means the recorded qualitative and/or quantitative results of a chemical, physical, biological, microbiological, radiochemical, or other scientific determination.
8. "Analytical method" means a written procedure for acquiring analytical data.
9. "Autoclave" means a steam sterilizer device that is intended for use by a laboratory to sterilize biohazardous products by means of pressurized steam.
10. "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.
11. "Biohazardous" means products that are infectious, and sharps materials such as needles and broken glass.
12. "Biosafety Cabinet (BSC)" means biocontainment equipment used in biological laboratories to provide personnel, environmental, and product protection.
13. "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.

14. "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.
15. "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.
16. "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.
17. "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, accrediting agency or other entity requiring the use of an accredited laboratory under provisions of a regulation, permit, or contractual agreement.
18. "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.
19. "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).
20. "Clean room" means an isolated environment, strictly controlled with respect to: Airborne particles of viable and non-viable nature, Temperature, Humidity, Air pressure, Air flow, Air motion, and Lighting.
21. "Continuing Calibration Verification Standard (CCV)" means one of the primary calibration standards used to verify the acceptability of an existing calibration.
22. "Cross Check Reference Standard (CCR)" means a solution of method standards prepared from a stock standard solution that is obtained from a source that is independent of that used to prepare the calibration standards (i.e. independent vendor, independent lot, or independent preparation). The CCR is used to verify that the original calibration source is acceptable.
23. "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). See also Threshold Value.
24. “Decision point” means the level of concern, cutoff or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample.

25. "Demonstration of Capability (DOC)" means a procedure to establish the ability of the analyst to generate acceptable accuracy and precision using the method.
26. "Department " means the state of Washington Department of Agriculture when the term is not followed by another state designation.
27. “ECY” means the Washington State Department of Ecology.
28. "End Product" means a cannabis product that requires no further processing prior to retail sale.
29. "False Negative Rate" means in qualitative analysis, a measure of how often a test result indicates that an analyte is not present, when, in fact, it is present or, is present in an amount greater than a threshold or designated cut-off concentration.
30. "Field Blank" means an aliquot of reagent water exposed to the environment during field sample collection and processed in the laboratory as an environmental sample. A field blank is used to document that contamination is not introduced during sample collection.
31. "Incubation" means the act of storing microorganisms at a pre-determined temperature, for a pre-determined amount of time, to allow for growth of microorganism colonies.
32. "Inoculation" means the act of storing microorganisms at a pre-determined temperature, for a pre-determined amount of time, to allow for growth of microorganism colonies.
33. "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.
34. "Intermediate Precision" means within-laboratory precision obtained under variable conditions, e.g., different days, different analysts, and/or different instrumentation.
35. "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 should have similar physio-chemical properties to those of the analyte.
36. "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.
37. "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).
38. "Limit of Quantitation (LOQ)" means the minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision. Limit of quantitation (or quantification) is variously defined but must be a value greater than the MDL and should apply to the complete analytical method.

39. "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.
40. "Matrix " means the material to be analyzed, including, but not limited to, flower, trim, leaves, other plant matter, cannabis concentrate, cannabis infused, and edibles.
41. "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 absence of significant interference due to matrix, reagents and equipment used in the analysis.
42. "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.
43. "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.
44. "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.
45. "Parameter" means the combination of one or more analytes determined by a specific analytical method.
46. "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).
47. "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.
48. "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.
49. "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.

50. "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.
51. "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.
52. "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.
53. "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.
54. "Quality control (QC)" means the routine application of statistically based procedures to evaluate and control the accuracy of analytical results.
55. "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.
56. "Random error" means component of measurement error that in replicate measurements varies in an unpredictable manner. See also Precision.
57. "Range" means the interval of concentration over which the method provides suitable accuracy and precision.
58. "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.
59. "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.
60. "Reference Material" means a material, sufficiently homogenous 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.
61. "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).
62. "Relative Percent Difference (RPD)" means the comparison of two quantities while taking into account the size of what is being compared as calculated:
    %RPD=|(sample–duplicate)|/((sample+duplicate)/2) * 100
63. "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. Should be included in all quantitative MLV reports.

64. "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.
65. "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. Should be included in all quantitative MLV reports.
66. "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.
67. "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.
68. "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.
69. "Scientific Director" means the individual with the proper education and training responsible for the overall laboratory operations, compliance and training of personnel.
70. "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. Selectivity is generally preferred in analytical chemistry over the term Specificity.
71. "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.
72. "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.
73. "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.
74. "Specificity" means in quantitative analysis, specificity is the ability of a method to measure analyte in the presence of components which may be expected to be present. The term Selectivity is generally preferred over Specificity.
75. "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 should be calculated for the method as written. For example, if the method prescribes using deuterated internal standards or matrix-matched calibration standards, then the reported analyte recoveries should be calculated according to those procedures.
76. "Spore bioindicators" means a biological indicator is made up of a carrier material, on which bacterial spores with a defined resistance to the sterilization process have been applied.

77. "Standard operating procedure (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.
78. "Standard Reference Material (SRM)" means a certified reference material issued by the National Institutes of Standards and Technology (NIST) in the United States.
79. "Sterilization" means a validated process used to render a product free of all forms of viable microorganisms.
80. "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.
81. "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.
82. "Testing Personnel" means those qualified on the basis of appropriate education, training, experience and demonstrated skills to perform analytical testing on cannabis, cannabis concentrates, and cannabis infused products.
83. "Uncertainty" means non-negative parameter characterizing the dispersion of the values being attributed to the measured value.
84. "Unidirectional flow" means performing a standard operating procedure in a single direction to reduce the risk of microbiological contamination.
85. "Validated methods" means the methods that have undergone validation.
86. "Validation (method)" means the process of demonstrating or confirming the performance characteristics through assessments of data quality indicators for a method of analysis.

Instructions for the Laboratory

(1) A cannabis testing laboratory must be accredited by the Department of Ecology prior to conducting quality assurance tests on any cannabis flower or products derived under RCW 69.50.
    a. Accredited labs must conspicuously display the certification letter received by the Department of Ecology at the lab's premises in a conspicuous location where a customer may observe it unobstructed in plain sight.
    b. The laboratory must maintain a list of all tests they are currently certified 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 shall be independent of other cannabis businesses and have no financial interest in another cannabis license, excluding multiple lab accreditations.
(3) The customer's confidential information and proprietary rights must be protected by the laboratory.
    a. The laboratory shall maintain policies and procedures to protect confidential information.

(4) Cannabis labs must report quality control test results directly to the board in the required format.
(5) The department 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 (5) years.

Personnel

(1) Each laboratory must employ a Scientific Director to ensure the achievement and maintenance of quality standards of practice that 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 program requirements 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. Engagement in and responsible for the daily management of the laboratory.
    b. Establishment of a training program for personnel.
    c. Ensure that personnel are sufficiently trained.
    d. Ensure that all personnel have demonstrated proficiency in assigned duties prior to working independently on customer cannabis samples.
    e. Ensure that the Standard of Practice (SOP) manual is complete, current, available, signed, and followed by all personnel.
    f. Ensure that all personnel are properly informed, and training documented when changes occur in the SOP.
    g. Ensure that analytical methods are properly validated.
    h. Establish a Quality Assurance program sufficient to legally and scientifically support results.
    i. Establish acceptable performance limits for calibrators and controls.
    j. Ensure that corrective action is taken in response to unacceptable QC performance or when other errors occur.

k. Ensure that results are not reported until after corrective actions have been taken and that the results provided are accurate and reliable.
l. Fully understand 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.
m. Ensure that the LIMS and other software in the laboratory have been properly validated.
n. Fully understand 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.
o. Ensure that external information systems and software used by the laboratory have been properly validated.
p. Ensure that appropriate corrective action is taken in response to issues identified in the inspection and Proficiency Testing (PT) phases of the program.
q. Demonstrate knowledge of the cannabis regulatory documents and the Cannabis Laboratory Analysis Standards Program.

(5) The laboratory must have a training and retraining program for all personnel that is kept current and is adequately documented and maintained with personnel records.

(6) 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 transcripts.
e. Training checklists which include what training was performed, who did the training, and when it was performed.
f. Documentation of continuing education.
g. Documentation of demonstrated abilities and competencies.

(7) The laboratory must document the technical staff's competency on a yearly basis demonstrating their abilities to perform their specific job functions. Completion must be signed and dated by the Scientific Director.
a. 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.

(8) The laboratory must have a personnel organization chart showing the chain of command and responsibilities approved by the Scientific Director.

(9) The Scientific Director may delegate some responsibilities in their absence or for other management staff but it must be in writing indicating what functions that are being delegated (i.e., quality control data review, assessment of competency, or review of

proficiency testing performance) and the person must be qualified and approved by the Scientific Director.

(10) If the laboratory performs microbiological testing then at least one member of 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 or medical technology from an accredited institution as described in [first point in Personnel section].

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

(12) Testing personnel must be qualified on the basis of appropriate education, training, experience and demonstrated skills and must meet the following minimum requirements

a. Have a Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; or
b. Associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution; or
c. Have education and training equivalents that includes.
    1. At least 60 semester hours, or equivalent, from an accredited institution that at a minimum include either.
        a. 24 semester hours of medical, clinical or chemical laboratory technology courses; or
        b. 24 semester hours of science courses that include
            i. Six semester hours of chemistry;
            ii. Six semester hours of biology; and an additional
            iii. Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination.

(13) Laboratory testing personnel must have adequate supervision by persons familiar with test methods and procedures.

(14) 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.

(15) The laboratory must designate a quality assurance manager/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.

(16) The laboratory must report to the department of Ecology any change in the status of the Scientific Director. A laboratory cannot be without a Scientific Director for more than thirty (30) days.

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 the SOP, or at least appropriate sections 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 all changes/versions must be documented on a Summary of Changes sheet for each section.
(4) The laboratory must have 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 testing SOPs must include pertinent information for the scope and complexity of the procedure:
    a. Scope and principle
    b. Sample requirements
    c. Calibration and control preparation and usage protocol
    d. Equipment, materials and supplies used
    e. Instrument settings, parameters and conditions for testing
    f. Procedure for sample preparation and testing
    g. Results review and acceptability
    h. Additional information, notes, safety requirements and precautions to include calculations, interferences, limitations, background corrections, assignment of uncertainty, and proper disposal of lab waste including biohazardous waste.
    i. References
(6) The laboratory must have a policy for the use of appropriate personal protective equipment (PPE) when working with samples, reagents, chemicals or potential hazards in the workplace.
(7) The laboratory must have a policy or procedure informing employees how to interact with law enforcement should they request information or come on-site for regulatory issues.
(8) The laboratory must have a policy or procedure that informs employees and staff about what tasks need to be performed and what information or documents need to be gathered prior to the audit or inspection.
(9) The laboratory must keep a record/log of any deviations from the SOP detailing the reason for the deviation, the date, and approval from the laboratory director.
(10) The laboratory must maintain retired procedures for at least five (5) years beyond the retirement date and should be able to reconstruct the procedures that were in effect when a given sample was tested.

Sampling and Homogenization Protocols

(1) Upon receipt, the laboratory must inspect each sample package and transportation manifest, assuring they meet the minimum requirements.
    a. Each sample package must have a transportation manifest accompanying it to the laboratory.
    b. Each manifest must have the appropriate 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 COC 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 package, who took possession and are there 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/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.

(7) Samples that do not undergo initial testing within 7 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.

(9) It is not acceptable to reuse any labware that comes into contact with samples or aliquots until after proper cleaning.

(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 either with a barcode and in human-readable form or just human-readable form.

(12) When multi-well plates are used, the laboratory must use automated liquid handling equipment that ensures the correct sample is aliquoted into the correct plate well and maps 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.

(15) Laboratories must use no less than the minimum sample size, use no more than the homogenization size, store the samples at the appropriate conditions, and analyze the samples within the appropriate hold times for each testing procedure listed below.

Cannabis Flower	Minimum Sample Size (g)	Homogenization Size (particles in mm)	Storage Requirements (C)	Hold Times
Cannabinoid Concentration	0.5	3	8	14 days
Foreign matter	Full Sample	No Homogenization	N/A	30 days
Microbiological	1.0	No Homogenization	0 > < 8	7 days
Mycotoxins	0.5	3	8	14 days
Pesticides	0.5	3	-30	3 days
Water Activity	0.5	3	8	30 days

Hydrocarbon, CO2, & Ethanol Concentrate	Minimum Sample Size	Homogenization Size (particles in mm)	Storage Requirements (C)	Hold Times
Cannabinoid Concentration	0.5	No Homogenization	8	14 days
Mycotoxins	0.5	No Homogenization	8	14 days
Pesticides	0.5	No Homogenization	-30	3 days
Residual Solvent	0.25	No Homogenization	0	14 days

Non-solvent Concentrate	Minimum Sample Size	Homogenization Size (particles in mm)	Storage Requirements (C)	Hold Times
Cannabinoid Concentration	0.5	No Homogenization	8	14 days
Microbiological	1.0	No Homogenization	0 > < 8	7 days
Mycotoxins	0.5	No Homogenization	8	14 days
Pesticides	0.5	No Homogenization	-30	3 days

Food Grade Solvent Concentrate	Minimum Sample Size	Homogenization Size (particles in mm)	Storage Requirements (C)	Hold Times
Cannabinoid Concentration	0.5	No Homogenization	8	14 days
Microbiological	1.0	No Homogenization	0 > < 8	7 days
Mycotoxins	0.5	No Homogenization	8	14 days
Pesticides	0.5	No Homogenization	-30	3 days
Residual Solvents	0.25	No Homogenization	0	14 days

Infused Oils	Minimum Sample Size	Homogenization Size (particles in mm)	Storage Requirements (C)	Hold Times
Cannabinoid Concentration	0.5	No Homogenization	8	14 days
Microbiological	1.0	No Homogenization	0 > < 8	7 days
Mycotoxins	0.5	No Homogenization	8	14 days
Pesticides	0.5	No Homogenization	-30	3 days

High Purity Concentrates (Distillates & Isolates)	Minimum Sample Size	Homogenization Size (particles in mm)	Storage Requirements (C)	Hold Times
Cannabinoid Concentration	0.5	No Homogenization	8	14 days
Microbiological	0.5	No Homogenization	0 > < 8	7 days
Mycotoxins	0.25	No Homogenization	8	14 days
Pesticides	0.5	No Homogenization	-30	3 days

Security

(1) Laboratories must control and document access into operation areas (e.g., accessioning, data entry, sample handling, analytical, certification), along with sample storge areas, and records storage areas.
(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 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. 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) Hardcopy records for reported samples must be maintained in a secure room, area, or file cabinet at all times.
(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 adequately 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 (5) year storage requirement.

Quality Control & Assurance

(1) The laboratory must develop and maintain an extensive Quality Control Program which involves the concurrent analysis of calibrators and controls with samples to demonstrate

whether or not 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 appropriate calibrators and controls in each analytical batch and must monitor the results of those samples within each batch and across batches.

(3) The laboratory must use controls that evaluate the performance of the sample prep and analytical instrument(s) each day of testing that include:

   a. A negative or blank control to demonstrate the assay(s) ability to perform without interference or contamination.
   b. A positive or spiked control below the cutoff or decision point but above the limit of quantitation for each matrix of sample.
   c. A positive or spiked control above the cutoff or decision point but below the upper limit of linearity for each matrix of sample.
   d. A matrix spiked duplicate at least every 20 samples per matrix.

(4) Control materials must be processed in the same manner and included with the test sample batches through the entire testing process.

(5) Controls must be prepared from a source different from the calibration standard source and contain all target analytes. The different source can be with a standard obtained from a second manufacturer or a separate lot prepared independently by the same manufacturer.

(6) Laboratories must establish acceptance limits for each method based on statistical evaluation of the data generated by the analysis of quality control check samples.

(7) The use of quality control material must determine, where feasible, the accuracy and precision of all analyses performed.

(8) Quality control acceptance criteria for analysis must be within ± 20% of established value unless specific acceptance limits are established by rule.

(9) New lots of reagents, calibrators and control material must be validated against a currently validated calibration or method before putting 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 the analyst performing the test 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 that would adequately 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 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.

(15) The laboratory must designate a quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed.
(16) 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.
(17) 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 appropriate changes.

Facilities, Equipment, and Maintenance

(1) Facilities where laboratory testing is performed must be appropriate for dealing with pre-analytical, analytical, and post-analytical 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 shall be paid to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.
(3) The laboratory must have adequate space for the number of personnel and appropriate separation of work areas.
(4) The arrangement of space must allow for appropriate workflow, sampling, lab space, office space and break areas.
(5) The laboratory must have adequate 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 ten (10) seconds unobstructed travel distance from the area in the laboratory where hazardous chemicals are present.
(6) 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.
(7) The laboratory must have sufficient numbers and types of safety equipment to minimize personnel exposure to biological hazards and toxic materials. There must be appropriate ventilation for fume hoods and around solvent use or storage of solvents or waste. There must be appropriate vented hoods for any microbiological analysis (i.e., Class II Type A biosafety cabinets as applicable.)
(8) The laboratory must assign a unique identifier to distinguish the individual test instrument and software version used. Each result must be traceable back to the instrument used at the time of testing.
(9) The laboratory must comply with the scheduled maintenance and function checks recommended by the manufacturer 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.

(10) 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.
(11) 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 6 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.
(12) 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.
(13) Analytical balances must be mounted in accordance with manufacturer's instructions. They must be serviced and checked periodically over the appropriate weight range using ANSI/ASTM Classes 1-3 or equivalent weights.
(14) 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.
(15) Instrument maintenance records and function check documents must be reviewed by technical supervisory staff or the Scientific Director at least monthly.
(16) Instruments that don't 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.
(17) Laboratories shall 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.

Method Performance Criteria

(1) Laboratories may be accredited to conduct the following fields of testing:
    a. Water activity
    b. Cannabinoid concentration analysis
    c. Foreign matter inspection
    d. Microbiological screening
    e. Mycotoxin screening
    f. Pesticide screening; and
    g. Residual solvent screening
    h. Heavy metal testing

(2) Certified labs may reference samples for testing by subcontracting fields of testing to another accredited laboratory.
(3) Laboratories must test samples on an "as is" or "as received" basis.

Water Activity Testing

(1) The sample fails quality control testing for water activity if the results exceed the following limits:
    a. Water activity rate of more than 0.65 a_w for useable cannabis;
    b. Water activity rate of more than 0.85 a_w for solid edible products.
(2) One sample must be run in duplicate with difference in values of 20% or less per batch of up to 20 samples 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 run two continuing calibration verifications at levels bracketing the target concentration at the beginning of each day of testing.
(5) The laboratory must calibrate the a_w instrument when:
    a. The instrument hasn't been calibrated in the last seven days.
    b. The instrument has been physically moved from one location to another.
    c. The instrument has been cleaned.
    d. The manufacturer's instruction manual recommends.

Cannabinoid Concentration Analysis

(1) Cannabinoid concentration analysis, previously known as potency, is intended to quantitate and accurately report the cannabinoids described herein:

Cannabinoid	Lower Limit of Quantitation (mg/g)	CAS #
CBD	1.0	13956-29-1
CBDA	1.0	1244-58-2
Δ9-THC	1.0	1972-08-3
Δ9-THCA	1.0	23978-85-0

    a. Regardless of analytical equipment or methodology, laboratories must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.
(2) Laboratories must use the standard methods approved by the WSDA to analyze cannabinoids.
    a. CLASP Method CCSP – Cannabinoid Concentration Sample Preparation
    b. CLASP Method CCA – Cannabinoid Concentration Analysis
(3) Laboratories that would like to use another method or make modifications to the methods provided must seek approval from the WSDA. Laboratories must, at a minimum, do the following for a new method validation:
    a. Communicate the intended method changes to the WSDA.

b. Receive written approval from the WSDA regarding the appropriate validation criteria.
c. Produce all data required from the validation.
d. Receive written approval from the WSDA of the validated method for use on customer samples.

Foreign Matter Inspection

(1) The laboratory must analyze not less than 30% of the total representative sample of cannabis and cannabis products prior to sample homogenization to determine whether foreign material is present.
(2) The laboratory shall report the result of the foreign material test by indicating "pass" or "fail" to the LCB and on the COA.
(3) The laboratory must use a microscope with both low and high-power magnification with photographic capabilities to assess foreign matter.
(4) The laboratory must document a detailed description of the foreign matter inspection 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.
(6) The sample fails quality control testing for foreign matter inspection if the results exceed the following limits:
    a. Five percent of stems 3 mm or more in diameter; or
    b. Two percent of seeds or other foreign matter; or
    c. One insect fragment, one hair, or one mammalian excreta in sample.

Microbiological Screening

(1) The sample fails quality control testing for microbiological screen if results exceed the following limits:

Unprocessed Plant Material	**Colony Forming Unit per Gram (CFU/g)**
Bile Tolerant Gram Negative bacteria (BTGN)	$1.0 * 10^4$
Shiga toxin-producing Escherichia coli (STEC)	<1
Salmonella spp.	<1
Processed Plant Material	**Colony Forming Unit per Gram (CFU/g)**
Bile Tolerant Gram Negative bacteria (BTGN)	$1.0 * 10^3$
Shiga toxin-producing Escherichia coli (STEC)	<1
Salmonella spp.	<1

(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) 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 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.

(4) 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, 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.

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

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

(6) 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 screening methods, all samples and controls must initiate incubation within 10 minutes of inoculation.

(7) For qualitative methods, all results must be reported as qualitative designations such as “detected”, “not detected”, “positive”, or “negative”. The laboratory may only report

quantitative results that are above the limit of quantification and below the upper limit of quantification.

a. The laboratory may not report CFU counts with greater than two significant figures.

Residual Solvent Screening

1. Residual solvent analysis is intended to accurately quantitate, and report solvent residue left behind from product processing. A sample fails quality control testing for residual solvents if the results exceed the limits in the table below:

Solvent	µg/g	ppm (simplified)	CAS #
Acetone	$5.0 * 10^3$	5000	67-64-1
Benzene	2	2	71-43-2
Butanes (Sum of Isomers)	$5.0 * 10^3$	5000	
• n-butane			106-97-8
• 2-methylpropane (isobutane)			75-28-5
Cyclohexane	$3.9 * 10^3$	3880	110-82-7
Chloroform	2	2	67-66-3
Dichloromethane	$6.0 * 10^2$	600	75-09-2
Ethanol	$5.0 * 10^3$	5000	64-17-5
Ethyl acetate	$5.0 * 10^3$	5000	141-78-6
Heptanes (Single Isomer)	$5.0 * 10^3$	5000	
• n-heptane			142-82-5
Hexanes (Sum of Isomers)	$2.9 * 10^2$	290	
• n-hexane			110-54-3
• 2-methylpentane			107-83-5
• 3-methylpentane			96-14-0
• 2,2-dimethylbutane			75-83-2
• 2,3-dimethylbutane			79-29-8
Isopropanol (2-propanol)	$5.0 * 10^3$	5000	67-63-0
Methanol	$3.0 * 10^3$	3000	67-56-1
Pentanes (Sum of Isomers)	$5.0 * 10^3$	5000	
• n-pentane			109-66-0
• methylbutane (isopentane)			78-78-4
• dimethylpropane (neopentane)			463-82-1
Propane	$5.0 * 10^3$	5000	74-98-6
Toluene	$8.9 * 10^2$	890	108-88-3
Xylenes (Sum of Isomers)	$2.2 * 10^3$	2170	
• 1,2-dimethylbenzene (ortho-)			95-47-6
• 1,3-dimethylbenzene (meta-)			108-38-3
• 1,4-dimethylbenzene (para-)			106-42-3

2. Laboratories must use the standard EPA methods adapted for cannabis to analyze residual solvents.
    a. METHOD 8015D (SW-846): Nonhalogenated Organics Using GC/FID
    b. METHOD 8260D (SW-846): Volatile Organic Compounds By Gas Chromatography/Mass Spectrometry
    c. METHOD 3585 (SW-846): Waste Dilution For Volatile Organics
    d. METHOD 5021A: Volatile Organic Compounds In Various Sample Matrices Using Equilibrium Headspace Analysis
3. Method validation protocols are as established within each approved method.
4. Performance criteria are as established within each approved method. The following additional performance measures and adaptations must supersede or be used in conjunction with the minimum method requirements, as appropriate.
    a. Laboratories must follow the method-specified quality control (QC) as a minimum. Additional QC criteria at the project level may be set by the department as long as the minimum QC requirements written in the methods are followed.
    b. Methanol and any other solvent listed in subsection (1) must not be used in any preparation or analysis procedure.
    c. Sections describing fuel (gasoline/diesel) specific analysis procedures, such as section 7.4 in Method 8015D, should not be followed.
    d. All WSLCB rules for field and product sampling should be followed. Upon receipt of a sample at a lab, the sample treatment should follow the method requirements for preservation and storage that is cited within 8260D, 8015D, or approved companion preparation method.
    e. In Method 3585, the term “Appropriate Solvent” must be defined and understood as, “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, the proceeding analytical method, and regulatory requirements, and is NOT a required analyte per WAC 314-55-102.” The selected solvent must be specifically cited in a lab’s standard operating procedure(s).
5. Sub-sampling and homogenization protocols are as specified in the approved method(s), except as noted for sample receipt and handling protocols:
    a. Each sample must individually meet the WSLCB sampling requirements.
    b. The container must contain a minimum of 2 grams of sample for residual solvents analysis. The total sample amount may contain more product but must allow for the sample size required for residual solvents.
    c. The lab must analyze 0.25 grams of sample per residual solvents analysis.
    d. Samples must be submitted in a hard sealable container or syringe. When headspace is encountered, laboratories must either reject the sample, or flag the data as having biased results due to headspace.
    e. Samples must be stored at < 8°C and must be analyzed within 14 days of receipt.
    f. 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.

g. If any field QC is submitted (e.g., field blanks, trip blanks), the lab must follow the applicable steps in the approved methods for these samples.

Mycotoxin Screening

1. The laboratory must fail quality control testing for mycotoxins if the results exceed the following limits:

Mycotoxin	µg/kg	CAS #
Aflatoxins (Sum of Isomers)	20.	
• Aflatoxin B1		1162-65-8
• Aflatoxin B2		7220-81-7
• Aflatoxin G1		1165-39-5
• Aflatoxin G2		7241-98-7
Ochratoxin A	20.	303-47-9

2. The laboratory must have procedures that includes the following:
    a. Any special safety precautions required for handling mycotoxin standards;
        i. Mycotoxin standards may only be opened and used within a certified fume hood.
        ii. A mycotoxin spill cleanup procedure must be included.
        iii. The laboratory must ensure stability of mycotoxin standards.
    b. A detailed description of how potentially hazardous waste is disposed of;
3. 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. Laboratories recycling solvents by roto-evaporator or similar equipment must have a procedure for evaluating recycled solvent performance prior to use in testing;
    d. Records of mass spectrometric tuning, performed at relevant frequencies or at the frequency specified by the manufacturer when utilizing a mass spectrometer;
    e. Ensuring method performance by comparing transitions and retention times between duplicated controls, calibrators, and samples.
4. To ensure the quality of data for an immunoassay method, the laboratory must:
    a. Ensure functionality of new test kits and reagent lots for by utilizing positive and negative controls;
        i. Absorbance intensity must be within the acceptable range as defined by the manufacturer.
    b. Challenge the linearity of the calibration curve;
        i. Different levels of positive controls must challenge the low and high end of the corresponding curve to assure that results are reliable throughout the whole range of the curve.

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

c. Perform second source verification by utilizing a control separate from calibration material;
d. For multi-analyte assays, calibration curves must be performed and documented, and controls implemented that are specific to each analyte;
    i. Control analytes with similar chemical properties as the target analyte may be used.
e. Include matrix spike controls in each batch of samples, performed at a minimum frequency of 1 in 20 samples per matrix;
f. Analyze matrix spike duplicates or laboratory duplicates at a frequency of 1 in 20 samples per matrix, per sample extraction or preparation method, to measure repeatability and precision of the mycotoxin assay(s);
g. Use an internal standard to minimize errors caused by evaporation of solvents and injection errors or discrepancies;
h. Have a detailed procedure for the manual integration of peaks, including the review of automated integration and adjustments;
    i. All information necessary for reconstruction of the data must be maintained.
i. Report only quantitative results that are above the lower limit of quantification and below the upper limit of quantification;
j. Report results below the limit of detection with a qualitative indicator such as "trace" or "not detected".

Pesticide Screening

(1) Pesticide screening is intended to accurately quantitate and report pesticides incurred through the production and processing of cannabis and cannabis products. A sample fails quality control testing for pesticides if the results exceed the limits in the table below:

Analyte	µg/g (ppm)	CAS#
Abamectin (Sum of Isomers)	0.50	71751-41-2
• Avermectin B1a		65195-55-3
• Avermectin B1b		65195-56-4
Acephate	0.40	30560-19-1
Acequinocyl	2.0	57960-19-7
Acetamiprid	0.20	135410-20-7
Aldicarb	0.40	116-06-3
Azoxystrobin	0.20	131860-33-8
Bifenazate	0.20	149877-41-8
Bifenthrin	0.20	82657-04-3
Boscalid	0.40	188425-85-6
Carbaryl	0.20	63-25-2

Carbofuran	0.20	1563-66-2
Chlorantraniliprole	0.20	500008-45-7
Chlorfenapyr	1.0	122453-73-0
Chlorpyrifos	0.20	2921-88-2
Clofentezine	0.20	74115-24-5
Cyfluthrin	1.0	68359-37-5
Cypermethrin	1.0	52315-07-8
Daminozide	1.0	1596-84-5
DDVP (Dichlorvos)	0.10	62-73-7
Diazinon	0.20	333-41-5
Dimethoate	0.20	60-51-5
Ethoprophos	0.20	13194-48-4
Etofenprox	0.40	80844-07-1
Etoxazole	0.20	153233-91-1
Fenoxycarb	0.20	72490-01-8
Fenpyroximate	0.40	134098-61-6
Fipronil	0.40	120068-37-3
Flonicamid	1.0	158062-67-0
Fludioxonil	0.40	131341-86-1
Hexythiazox	1.0	78587-05-0
Imazalil	0.20	35554-44-0
Imidacloprid	0.40	138261-41-3
Kresoxim-methyl	0.40	143390-89-0
Malathion	0.20	121-75-5
Metalaxyl	0.20	57837-19-1
Methiocarb	0.20	2032-65-7
Methomyl	0.40	16752-77-5
Methyl parathion	0.20	298-00-0
MGK-264	0.20	113-48-4
Myclobutanil	0.20	88671-89-0
Naled	0.50	300-76-5
Oxamyl	1.0	23135-22-0
Paclobutrazol	0.40	76738-62-0
Permethrins (Sum of Isomers)	0.20	52645-53-1
• cis-Permethrin		54774-45-7
• trans-Permethrin		51877-74-8
Phosmet	0.20	732-11-6
Piperonyl butoxide	2.0	51-03-6
Prallethrin	0.20	23031-36-9
Propiconazole	0.40	60207-90-1
Propoxur	0.20	114-26-1
Pyrethrins (Sum of Isomers)	1.0	8003-34-7
• Pyrethrin I		121-21-1
• Pyrethrin II		121-29-9
Pyridaben	0.20	96489-71-3

Spinosad (Sum of Isomers)	0.20	168316-95-8
• Spinosyn A		131929-60-7
• Spinosyn D		131929-63-0
Spiromesifen	0.20	283594-90-1
Spirotetramat	0.20	203313-25-1
Spiroxamine	0.40	118134-30-8
Tebuconazole	0.40	80443-41-0
Thiacloprid	0.20	111988-49-9
Thiamethoxam	0.20	153719-23-4
Trifloxystrobin	0.20	141517-21-7

(2) For the purposes of this section, limits have been written to the number of significant digits that laboratories are expected to use when reporting to the board and on associated certificates of analysis.

(3) Laboratories must maintain a valid manufacturer COA for each pesticide standard used that contains the source of the analyte, purity, lot number, traceability and expiration date. The COA must be kept for at least five (5) years from the expiration date of use.

a. Certified standards compliant with ISO Guide 34 should be used when available.

(4) Custody of a standard begins when the standard is received in the laboratory. Each standard shall be given a code that uniquely identifies the standard from neat material to final dilutions. Receipt of standards shall be documented, and each standard shall be traceable. Records shall include name, unique code, purity, lot number, date received, and expiration date.

(5) Storage of analytical standards:

a. Neat standards shall be kept in a separate standards freezer at < -20°C unless degradation occurs at such temperatures. In these cases, neat standards shall be stored at the manufacture's recommended storage temperature.

b. Stock standards and dilutions including mixed standards shall be kept in refrigerators or freezers separate from those used for samples. Stock standards and dilutions shall be stored in teflon-lined, screw-capped, glass bottles or sealed glass ampules.

c. Access to the freezers and refrigerators shall be controlled and standards usage documented through the use of appropriate records (e.g., log books). These records shall contain at a minimum: standard name and/or unique code, date and time removed, initials of person removing standard, date and time returned, initials of person returning standard.

d. When a neat standard is removed from freezer storage, it is best practice that the standard be stored in a desiccator while it is brought to room temperature to minimize the potential for hydrolysis.

(6) Stock standard solutions and intermediate dilutions should be prepared in a separate standard preparation area to avoid contamination of samples with pesticide standards.

(7) Standard Checking:

a. Stock solutions of neat pesticide standards not previously prepared or not currently in use in the laboratory shall be prepared in duplicate and the two standards compared to each other. Responses for standards of comparable concentrations must match within 15% relative percent difference (RPD).

i. If standards do not match, potential sources of variation should be reviewed, and a third standard shall be made and compared. This process shall be continued until two matching standards are prepared.

b. New stock solutions that are prepared from neat pesticides currently used in the laboratory shall be compared to the old stock solution. The two standards must match within 15% RPD. If the two standards do not match, the problem must be identified and solved before the standard is used for quantitation.

c. Documentation of the standard checking process shall be kept through appropriate records (i.e. logs). Chromatograms of all standards shall be kept indicating the standard comparisons of old and new standards and the calculated difference.

(8) Working dilutions and mixed standards shall be checked to ensure integrity of the solutions. These solutions should be made as frequently as necessary to ensure that concentrations do not change and/or individual pesticides do not degrade. Each laboratory shall determine the frequency of remaking dilutions/mixed standards. Documentation supporting this decision shall be maintained;

a. An archive file of all old mixed standards shall be kept and the dates the standards were used shall be indicated. The archive file shall be maintained for a minimum of five years.

b. All working/mixed standards shall be identified by a unique and traceable code. Working/mixed standard records shall contain a minimum of pesticide name, solvent, date of preparation, expiration date, and preparer.

(9) Each laboratory shall establish the proper procedures for disposal (e.g., disposal by a licensed contractor) of expired analytical standards (both neat standards and dilutions). Disposal shall be in accordance with the laboratory's Chemical Hygiene Plan and shall be documented.

(10) Multi-residue Screening

a. A laboratory may choose to rotate spike mixtures between analytical sets or spike all compounds analyzed, as long as each extraction/detection system is adequately represented within each set.

b. If the laboratory chooses to rotate spike mixtures they must spike no less than 50% of the analytes and all analytes must be spiked between two concurrent sets.

(11) Samples analyzed by each extraction/detection system shall include the analysis of a process control compound. More than one process control may be required. The laboratory shall make every effort to choose a compound that is not expected to be an incurred residue.

a. Each sample set component, except the reagent and matrix blanks, shall be spiked with a process control at approximately 5x the Limit of Quantitation (LOQ) prior to the extraction step of the analytical procedure.

i. However, if the intent of the process control is to monitor the percent recovery of a clean-up step, or of a derivatization, then the process control shall be added to the extract before the clean-up or derivatization step.

b. All process controls shall have recoveries between 70 and 130%.

(12) Sample set

a. A sample set is a group of samples, which are spiked individually with the designated process control(s), extracted with the required QC samples, and analyzed with the applicable required QC samples. Each set shall not exceed 35

samples. Required QC samples per set consist of a reagent blank, matrix blank, and matrix spike(s).

i. A reagent blank is intended to demonstrate glassware cleanliness and total system integrity. It shall be prepared by subjecting an amount of distilled water equivalent to that contained in an average sample to the entire analytical process.

ii. A matrix blank is intended to demonstrate the behavior of a substrate within an analytical system. Ideally, a matrix blank should be void of any compounds of interest. A matrix blank may be a previously characterized sample of the same commodity. If a suitable sample is not available, a portion of one of the samples may be randomly selected and used as a matrix blank. If an incurred residue is found in the matrix blank, which has been chosen from the sample set, determine if the same residue is incurred in the actual sample and is not present in other samples in the same set. If this condition cannot be met, appropriate action must be taken, such as reviewing reagent blank information.

iii. A matrix spike is intended to reflect the behavior of a chemical in a substrate within an analytical system. The matrix spike indicates the behavior of the chemical for the entire sample set. Analysis of a matrix spike provides valuable information on matrix interference effects as a result of the co-eluted matrix components, affecting the accuracy or detection capability for the analytes of interest.

1. A second portion of the same material used for the matrix blank shall be used for the matrix spike(s).
2. The spike shall be added prior to extraction at approximately 2x LOQ (or less).
3. All spiked compounds shall have recoveries between 70 and 130%.

(13) Extracts shall be stored in appropriate containers (e.g., bottles, tubes, injection vials, etc.) and at appropriate temperature (approximately 4 °C or lower) for a period(s) as specified in the laboratory's internal SOP to protect them from degradation and solvent evaporation.

a. Vials held in active autosampler trays during instrumental analysis do not require refrigeration.

(14) Calibration

a. Standard response drift greater than 20% RPD, %D, or RSD indicate that additional standards within the run may be injected in order to attempt to meet the 20% calibration integrity requirement. Each laboratory shall document exceptions in internal SOPs and shall determine the number of intermediate standards required throughout the run to maintain calibration integrity.

b. For cases where no residues were detected in samples and only the spike recovery is being quantified, the requirement for calibration integrity shall be 30%.

c. Incurred residue(s) may be subtracted from matrix matched standards prior to generating the calibration curve. A laboratory may elect to subtract incurred residue(s) if the following conditions are met:

i. Blank matrix cannot be obtained. The laboratory shall make every effort to obtain blank matrix such as purchasing organic produce, saving analyzed samples that are pesticide free, etc.

ii. The incurred residue is less than 2xLOQ (Limit of Quantitation).

d. For any analyte that is quantitated using a calibration curve, the fitness of curve, shall be demonstrated in the same injection sequence used to report the data by the following:
   i. Linear calibration curve with a minimum of four points
   ii. Correlation coefficient (where $R > 0.995$ / $R^2 > 0.990$)
   iii. No weighting, 1/x, or 1/C weighting

e. Results obtained using a calibration curve shall lay within the range of the calibration curve. If results fall outside the calibration curve, the sample must be diluted or the calibration curve extended.
   i. If method range has been extended beyond the highest validated level, then samples may be diluted for quantitation purposes. However, dilutions must be done proportionally with matrix so that the matrix concentration of the sample is similar to that of the analytical standards used to prepare the calibration curve.

(15) Quantification of multi-peak compounds may be based on the largest peak or the sum of all the peaks. Summation using the instrument's peak integration software is preferred and, when used, must be applied to the multi-peak compound with consistent parameters across all samples.

(16) Injection sequence description

a. Each laboratory shall develop an SOP detailing an appropriate injection sequence to ensure data integrity and uniform response across the sample set. "Uniform response" shall be construed as no greater than 20% RPD, %D, or RSD between calibration or 30% if a residue was not detected and only the spike is being quantitated.

b. Standards shall be run at a minimum of the beginning and end of the data run to demonstrate calibration integrity. This may be accomplished via a single standard or a full set of calibration curve standards.

c. Each initial analytical run shall include the reagent blank, matrix blank, spikes, and samples. For additional runs (i.e., reinjects/dilutions) QC samples shall be run as necessary (i.e. reagent or matrix interference).

d. A non-extracted LOD standard for each compound analyzed shall be run with each data set as a diagnostic tool (i.e., the laboratory is not required to calculate signal-to-noise ratio (s/n), but the peak must be observable). If the peak is not observable, the laboratory shall take the appropriate action (e.g., raise the LOD, re-inject the standard, etc.).
   i. For laboratories that use in-matrix calibration standards, the LOD standard shall also be in-matrix.
   ii. For laboratories that do not use in-matrix calibration standards, the LOD standard shall be in the same solution as the calibration standards.

(17) GC and LC Retention Time

a. If an external standard is used, the retention time (RT) of the compound of interest in the standard and the RT of the same compound in the sample shall be within 0.1 minutes.

b. If an internal standard is used, the relative retention time (RRT) of the compound of interest to the internal standard within the reference standard and the RRT of

the compound of interest to the internal standard within the sample shall be within 0.01 minutes.

(18) GC/MS and LC/MS Confirmation Criteria

a. A minimum of three structurally significant ions (meeting the 3:1 s/n ratio) are required for confirmation. For GC/MS, because the molecular ion is the most structurally significant ion in a mass spectrum, if it is present and meets the 3:1 s/n ratio, it is preferable that it be included as one of the three ions.
    i. Note: If instrument conditions and/or ionization techniques limit the number of ions available, the laboratory shall request a deviation from the depratment in order to report results under these conditions.
b. A pair of isotopic cluster ions may be used as two of the three structurally significant ions required for confirmation.
c. Use of fragment ions resulting from water loss to meet the three structurally significant ions requirement is discouraged.
d. The confidence limits of the relative abundance of structurally significant ions used for SIM and/or full scan identification shall be ± 30% (relative) when compared to the same relative abundances observed from a standard solution injection made during the same analytical run.
e. MS spectra produced by "soft" ionization techniques (e.g., GC/MS - chemical ionization and for LC/MS – APCI, APPI, ESI, etc.) may require additional evidence for confirmation. If the isotope ratio of the ion(s) or the chromatographic profile of isomers of the analyte is highly characteristic, there may be sufficient information for confirmation. Additional evidence may consist of MS/MS data, use of a different ionization technique, use of a different chromatographic separation system, and for LC/MS systems, altering fragmentation by changing ionization conditions.
f. GC/MS: Fragmentation that results from "soft" ionization techniques is highly dependent on instrument design and the conditions applied (i.e., the obtained spectra can widely differ). Commercially available spectral libraries bundled with GC/MS instruments may contain spectra generated under standard 70eV EI conditions; therefore, the use of library search software for spectra from "soft" ionization techniques could result in identification errors and is discouraged.

(19) GC/MS/MS and LC/MS/MS Confirmation Criteria

a. Target analyte confirmation shall be performed by either (1) monitoring the transition of one precursor ion to at least two product ions, OR (2) monitoring at least two precursor-to-product ion transitions.
b. Multipeak compound confirmation may be based on the largest peak or the sum of all the peaks. If it is based on the sum of all the peaks, one or two of the constituents can be used for both transitions.
    i. Note: If instrument conditions and/or ionization techniques limit the number of transitions available, the laboratory shall request a deviation from the department in order to report results under these conditions.
c. The abundance of the signal from the precursor-to-product ion transition shall meet the 3:1 s/n ratio requirement.
d. The relative abundances of ion transitions used for compound identification in the sample shall be ± 30% (relative) when compared to the same relative abundances

observed from a standard solution analyzed during the same analytical run if more than one precursor-to-product ion transition is monitored.

i. The ion ratio tolerance shall be calculated using the following example: If the ion ratio (qualifier area count/target area count) is 15%, the acceptable range will be 15%+/-4.5 or 10.5% to 19.5%.

e. Use of product ions resulting from water loss for identification is discouraged.

(20) Structurally significant ions and/or precursor-to-product ion transitions used for confirmation shall be documented.

(21) Raw data handling

a. Hardcopy raw data are defined as any laboratory worksheets, logbooks, records, notes, chromatograms, calculations, instrument printouts, and any other data, which are the result of original observations and activities. Electronic raw data are the files generated by the instrument system.

b. For manual entry, hardcopy raw data shall be recorded directly, promptly, and legibly in permanent ink. Pencil or erasable pen is not acceptable. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Each individual error shall be corrected using a single-line cross out (no white-out). It is recommended, but not required, that the reason for the correction be indicated. Each correction shall be dated and initialed. Documented error codes may be used to explain errors.

c. Each participating laboratory shall ensure sample and data traceability for raw and electronic data collection and processing. Chromatograms that have been reprocessed through the data system shall be clearly labeled.

d. Each participating laboratory shall maintain a log of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record.

Heavy Metals Testing

(1) Heavy metal screening is required for all DOH compliant products and is optional for no-DOH compliant products; however, heavy metal limits provided below apply to all products. A sample and related quantity of product fail quality control testing for heavy metals if the results exceed the limits provided in the table below.

Total Metal	µg/g
Arsenic	2.0
Cadmium	0.82
Lead	1.2
Mercury	0.40

(3) The laboratory must use ultra high-purity grade acids, gasses, water, and materials in the preparation of standards and sample processing.

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

(5) Instruments must be calibrated using a minimum of a four-point curve (no blanks can be used as a point). The correlation determination (r^2) should be ≥ 0.990 or the correlation coefficient ® should be ≥ 0.995. Linear Regression with 1/x or no weighting must be used. Forcing the curve through zero is not allowed.

(6) Laboratories must adapt their testing protocol from EPA approved methods to perform heavy metals testing:

   a. EPA SW-846 Method 6020B: Inductively Coupled Plasma Mass Spectrometry.

(7) The laboratory must properly prepare samples using a digestion method that provides total sample decomposition for metal analysis. Appropriate preparation methods include:

   a. SW-846 Method 3050B Rev 2: Acid Digestion of Sediments, Sludges, and Soils.
   b. SW-846 Method 3052: Microwave Assisted Acid Digestion of Siliceous and Organically Based matrices.
   c. SW-846 Method 3031: Acid Digestion of Oils for Metals Analysis by Atomic Absorption or Inductively Coupled Plasma (ICP) Spectrometry.

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

(9) An Internal Standard (IS) must be added and analyzed in all calibration standards and samples.

(10) An Initial Calibration Verification (ICV) and Initial Calibration Blank (ICB) must be analyzed after the initial calibration.

(11) The ICB is analyzed after the ICV and must not contain target analytes above half the lower limit of quantitation (LLOQ).

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

(13) For the purposes of this section, limits have been written to the number of significant digits that laboratories are expected to use when reporting to the board and on associated certificates of analysis.

(14) Results for solids should be reported on a dry-weight basis.

Other Analytes

1. Non-regulated testing.
   a. A laboratory that conducts quality control testing or a research and development test for a licensees may use methods not approved by the department, but the laboratory may not identify those test results as accredited results. Non-regulated tests may not be used for any labeling or marketing purposes.
   b. The certificate of analysis must clearly indicate that the testing performed was for research and development testing and is not considered a compliance test.
2. If a laboratory would like to be accredited for an analyte or test method that is not included in recreational or medical cannabis regulatory testing, they must seek approval from the department prior to implementation.

a. The department will determine if an analyte extension is acceptable or if a new method validation will be required.
b. The laboratory must validate any new analytes or methods per Method Validation (WAC xx-xx).
c. The validated SOP must be made available to the department for review.

3. When testing a sample for non-compliance chemistry tests, a laboratory must comply with the following quality control:
    a. At a minimum, run a method blank, matrix blank, and reagent blank with each batch to demonstrate the procedure is free of contaminants at or above the limit of quantitation.
    b. Run a laboratory control standard (LCS) with each batch to demonstrate acceptable performance of the procedure. Acceptable performance of the LCS means percent recovery for all additional analytes are within 80% to 120%.
    c. Analyze a duplicate sample with each batch. Each duplicate sample must pass the precision limit of 10% relative percent difference (RPD).
    d. Perform an initial calibration with no less than 4 points on a linear regression with an r^2>0.99.
    e. Run a cross check reference standard (CCR) with each new calibration curve that must be within 85% to 115% of the expected concentration.
    f. Run a continuing calibration verification (CCV) with each batch that must be within 90% to 110% of the expected concentration.
4. Each analyst must perform a demonstration of capability using the lab's new SOP, whether an analyte extension or new method, for each target analyte.
5. Document all troubleshooting and corrective actions performed.
6. Report quantitative results that are only within the applicable quantitation range of the method.

Laboratory Computers and Information Systems

(1) The laboratory must have computer systems and software adequate 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 adequately 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 adequately 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 shall 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/agreement with external service providers that includes the priority elements of physical, technical, and administrative safeguards to protect their systems and data.

Method Validations

(1) Laboratories must perform method validation studies prior to implementing a new or original test method, implementing a standardized method, implementing a new instrument, or modifying an existing method or instrument for each matrices tested.
(2) When modifying a Standardized Method, a laboratory must consider the "Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products" written by the USFDA for full validation requirements.
(3) The following describes the four standard levels of performance defined for method validation of analytical regulatory standardized methods for chemical analytes:
    a. Level One: This is a single laboratory validation level with the lowest level of validation requirements and is appropriate for emergency/limited use.
    b. Level Two: This is a single laboratory validation level. The originating lab has conducted a comprehensive validation study, with performance criteria similar to an AOAC Single Laboratory Validation study. If appropriate, a comparison with an existing reference method has been performed.
    c. Level Three: This is a multi-laboratory validation level. Level Three validation employs a minimum of one collaborating laboratory in addition to the originating laboratory.
    d. Level Four: This validation level has criteria equivalent to a full AOAC or ISO Collaborative Study. The method must be followed as closely as practicable, and any deviations by participants from the method described, no matter how trivial they may seem, must be noted.
(4) 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.

(5) Laboratories must perform re-verification studies on an annual basis at minimum on non-reagent methods. Re-verification 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.

(6) 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 relatively minor, the validation studies may be focused on those parameters that have been affected.

(7) Validations must include Linearity, Precision, Accuracy, Limit of Detection (LOD), Limit of Quantitation (LOQ), Upper Limit of Linearity (ULOL), Carryover, Selectivity/Interference, and Matrix Effects unless defined specifically below.

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

(9) The laboratory must characterize the precision of a method based on replicate analysis, at least 25 results total. Analysis must be at significant concentrations around the cutoff/decision point and expected range. At least five 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.

(10) 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 in order to assess intra-batch and inter-batch variability.

(11) The laboratory must characterize the limit of detection (LOD) of a method by a series of replicates with decreasing concentrations (i.e., a minimum of five replicates at each concentration) until the results can no longer be used to identify an analyte. The LOD must be experimentally determined and supported by data.

(12) The laboratory must characterize the limit of quantitation of a method by a series of replicates with decreasing concentrations (i.e., a minimum of five replicates at each concentration) until the results can no longer accurately quantify the analyte.

(13) The laboratory must characterize the upper limit of linearity of a method by a series of replicates with increasing concentrations (i.e., a minimum of five replicates at each concentration) until the results can no longer accurately quantify the analyte.

(14) 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. Concentrations evaluated should be realistic (i.e., high concentrations that may be found in the testing population) and at least as high as the established ULOL.

(15) 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 (5) days.
(16) 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.
(17) The laboratory must investigate any possible matrix effect by evaluating the potential for components of the sample matrix to either 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 10 different lots of products (i.e., flower from 10 different plants for from 10 different plant lots.)
(18) 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 assay performance. These consist of precision/accuracy studies using samples at the dilution specified in the procedure.
(19) 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.
(20) 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 should analyze a minimum of 10 positive samples at differing concentrations and 10 negative samples, in duplicate (i.e., 40 results total).
(21) The laboratory must verify extraction efficiency assuring their method can sufficiently extract out the analyte of interest from the sample matrix.
(22) Records for validation and periodic re-verification studies must be organized in a format to facilitate a comprehensive review and at a minimum, the records must include:
    a. A state 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.
(23) 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.

(24) The laboratory must maintain assay validation study records for an indefinite period. Validation and reverification study records must be made available at the time of inspection or upon request.
(25) 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.
(26) All quantitative assays must be properly validated prior to use with samples and supported with the following studies:
    a. Determination of LOQ, LOD, ULOL,
    b. Precision/accuracy around the cutoff,
    c. Carryover,
    d. Selectivity/Interference,
    e. For an assay validation: method parameters including appropriate ion selection,
    f. For full instrument validation; instrument parameter optimization,
    g. For LC, 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).
(27) 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. Interference studies,
    d. Instrument parameter optimization, and
    e. For LC, LC-MS, and LC-MS/MS methods: evaluation of matrix effects.

Proficiency Testing

(1) The laboratory must participate in an approved Proficiency Testing (PT) program on an ongoing basis and achieve a passing score for each field of testing parameter for which the lab will be or is certified.
(2) The cost of obtaining and testing PT samples is the sole responsibility of the laboratory.
(3) WSDA will maintain a list of approved proficiency tests and proficiency test providers that laboratories can use.

(4) A laboratory must successfully complete a minimum of one round of PT for each field of testing the lab seeks to be certified for and provide proof of the successful PT results to ECY prior to initial certification.
(5) Accredited laboratories must analyze a minimum of two PT samples for each field of testing per year.
(6) After an accredited laboratory submits two satisfactory PT sample results for each field of testing with no unsatisfactory results in an accreditation year, the laboratory will only be required to submit one satisfactory PT sample result for each field of testing in subsequent accreditation years. This applies only if there are no intervening unsatisfactory PT sample results.
    (a) The closing dates of a PT study for a particular field of accreditation can be no more than seven months apart, when two are required in a year.
    (b) The opening date of a PT study for a particular parameter must be at least seven calendar days after the closing date of the previous PT study for the same parameter.
(7) The WSDA and/or ECY may require the laboratory to submit raw data along with the report of analysis of PT samples.
(8) The WSDA may waive proficiency tests for certain parameters if approved PT samples are not readily available or for other valid reasons.
    (a) If a proficiency test is not available for any analyte, the laboratory must implement an alternative assessment procedure for the affected analyte(s).
    (b) An alternative assessment requirement can be fulfilled via a split-sample analysis sent to testing staff as a blind or potential customer sample unknown to the analyst.
(9) PTs must undergo the identical preparation and analytical processes that are used for customer samples including, but not limited to, adhering to the same sample tracking, sample preparation, analysis methods, standard operating procedures, calibrations, quality control, and acceptance criteria used in testing customer samples.
(10) The laboratory is responsible for assuring ECY receives all PT results directly from the PT provider.
(11) The laboratory must ensure that the information provided to the PT provider reflects accurate information about the laboratory that corresponds to the information in the laboratory's accreditation or application for accreditation, including but not limited to:
    (a) The laboratory's name and address;
    (b) The laboratory's ID number; and
    (c) The method and analyte codes.
(12) For pesticide and cannabinoid concentration analyses, a laboratory must use PT samples made with a usable cannabis matrix.
    (a) If a usable cannabis matrix is unavailable, then a PT sample made with usable hemp matrix may be used.
    (b) If a PT sample made with a usable hemp matrix is used for accreditation of potency analysis, then the PT vendor must prepare the sample in usable hemp material itself and may not provide a separate spiking solution with the sample.
(13) Presence-absence microbiology parameters must correctly detect the presence or absence of target organisms on all replicates in their PTs to be considered acceptable.

(14) The laboratory may not report test results for any parameter once they are deemed as "unacceptable", "questionable", "unsatisfactory", or otherwise deficient by the Proficiency Testing program until satisfactorily resolved and the corrective actions are approved by the ECY.
   (a) If the laboratory fails to achieve a passing score for a parameter, the laboratory must investigate the root cause of the laboratory's performance and establish a corrective action report for each unsatisfactory analytical result.
   (b) If the corrective action has not resolved the analytical deficiency, the laboratory must suspend testing of that parameter until the issue has been resolved and a supplemental PT has been successfully performed.

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

(16) It is strictly prohibited for laboratories to send PT samples to another laboratory for testing. Testing that normally would reflex to another laboratory (i.e. heavy metals) will not be reflexed on a PT Set sample.

Reports

(1) All sample test results must be supported by data and reported in accordance with WSDA guidelines.

(2) Laboratories must report the numeric concentration of the required analytes tested.

(3) For the purpose of reporting, limits have been written to the number or significant digits that laboratories are expected to use when reporting to the Liquor and Cannabis Board (LCB) and on associated certificates of analysis (COA).

(4) If the result is above the established ULOL, the laboratory may report that the "quantitative result exceeds the linear range of the test" or may report the result as "> [the ULOL value]" when allowed in the guidelines.

(5) It is not acceptable for a laboratory to report a sample as greater than a value other than the established ULOL, and it is not acceptable to multiply the validated ULOL by a dilution factor for reporting.

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

(7) At a minimum, the computer generated COA reports for samples going to the customer must contain:
   a. Laboratory Name and Address
   b. Date of Collection
   c. Sample Identification Number from transportation manifest
   d. Collector name and contact information
   e. Matrix Type (flower, concentrate etc.)
   f. Date received by Laboratory
   g. Name of Certifying Scientist
   h. Date reported by the Laboratory
   i. Results of each test performed to include measurands (i.e., mg/g) and cutoffs

(8) Laboratories must use the analyte terminology and abbreviations specified by WSDA to ensure consistency in reporting and interpretation of test results.
(9) Laboratories must not release any cumulative or individual test result prior to the completion of all analysis by the lab.

Procurement Controls

(1) The laboratory shall 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 shall exist for the purchase, receipt, storage, and disposition of expired materials.
(2) The laboratory shall 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) Reagents and standards shall be inspected, dated and initialed upon receipt, and upon opening.
(4) Calibration standards and analytical reagents shall have an expiration or reevaluation date assigned.
(5) Solutions hall be adequately identified to trace back to preparation documentation.
(6) Prospective suppliers shall be evaluated and selected on the basis of specified criteria.
(7) Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.

Subcontracting.

(1) The laboratory shall advise 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 shall 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 shall be forwarded to appropriate management for action.