NEW SECTION

WAC 314-55-103 Good laboratory practice checklist. A third-party testing lab must be certified by the WSLCB or its vendor as meeting the board's accreditation and other requirements prior to conducting required quality assurance tests. The following checklist will be used by the board or its vendor to certify third-party testing labs:

ORGANIZATION	Document Reference	Y	N	NA	Comments
1. The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.					
2. The laboratory conducting third-party testing shall have no financial interest in a licensed producer or processor for which testing is being conducted.					
a. If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.					
3. The laboratory shall have policies and procedures to ensure the protection of its client's confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.					
4. The laboratory is responsible for all costs of initial certification and ongoing site assessments.					
5. The laboratory must agree to site assessments every two years to maintain certification.					
6. The laboratory must allow WSLCB staff or their representative to conduct physical visits and check I-502 related laboratory activities at any time.					
7. The laboratory must report all test results directly into WSLCB's traceability system within twenty-four hours of completion. Labs must also record in the traceability system an acknowledgment of the receipt of samples from producers or processors and verify if any unused portion of the sample was destroyed or returned to the customer.					

HUMAN RESOURCES	Document Reference	Y	N	NA	Comments
8. Job descriptions for owners and all employees: Key staff.					
9. Qualifications of owners and staff: CVs for staff on file.					
a. Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.					
b. Documentation that the scientific director meets the requirements of WSLCB rules.					

HUMAN RESOURCES	Document Reference	Y	N	NA	Comments
c. Chain of command, personnel organization/flow chart, dated and signed by the laboratory director.					
d. Written documentation of delegation of responsibilities (assigned under chapter 314-55 WAC as related to quality assurance testing) to qualified personnel, signed and dated by the laboratory director.					
e. Documentation of employee competency: Prior to independently analyzing samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls). Dated and signed by the laboratory director.					
f. 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; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.					
10. Written and documented system detailing the qualifications of each member of the staff.					
a. The need to require formal qualification or certification of personnel performing certain specialized activities shall be evaluated and implemented where necessary.					
11. Standard operating procedure manual that details records of internal training provided by facility for staff. Laboratory director must approve, sign and date each procedure.					
a. Instructions on regulatory inspection and preparedness.					
b. Instruction on law enforcement interactions.					
c. Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.					
d. Written and documented system of employee training on hazards (physical and health) of chemicals in the workplace, including prominent location of MSDS sheets and the use of appropriate PPE.					
e. Written and documented system on the competency of personnel on how to handle chemical spills and appropriate action; spill kit on-site and well-labeled, all personnel know the location and procedure.					
f. Information on how employees can access medical attention for chemical or other exposures, including follow-up examinations without cost or loss of pay.					
g. Biosafety and sterile technique training.					

STANDARD OPERATING PROCEDURES	Document Reference	Y	N	NA	Comments
12. As appropriate, laboratory operations covered by procedures shall include but not be limited to the following: a. Environmental, safety and health activities; b. Sample shipping and receipt; c. Laboratory sample chain of custody and material control; d. Notebooks/logbooks; e. Sample storage; f. Sample preparation; g. Sample analysis; h. Standard preparation and handling; i. Post-analysis sample handling; j. Control of standards, reagents and water quality; k. Cleaning of glassware; l. Waste minimization and disposition.					
13. The following information is required for procedures as appropriate to the scope and complexity of the procedures or work requested: a. Scope (e.g., parameters measured, range, matrix, expected precision, and accuracy); b. Unique terminology used; c. Summary of method; d. Interferences/limitations; e. Approaches to address background corrections; f. Apparatus and instrumentation; g. Reagents and materials; h. Hazards and precautions; i. Sample preparation; j. Apparatus and instrumentation setup; k. Data acquisition system operation; l. Calibration and standardization; m. Procedural steps; n. QC parameters and criteria; o. Statistical methods used; p. Calculations; q. Assignment of uncertainty; r. Forms used in the context of the procedure.					

FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
14. Allocation of space: Adequate for number of personnel and appropriate separation of work areas.					
15. Arrangement of space.					
a. Allows for appropriate work flow, sampling, lab space separate from office and break areas.					
b. Employee bathroom is separate from any laboratory area.					
16. Adequate eyewash/safety showers/sink.					

FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
17. Procurement controls.					
a. 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 shall exist for the purchase, receipt and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.					
b. 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.					
c. Prospective suppliers shall be evaluated and selected on the basis of specified criteria.					
d. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.					
e. When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.					
18. Utilities.					
a. Electrical: i. Outlets: Adequate, unobstructed, single use, no multi-plug adaptors; ii. No extension cords; iii. Ground fault circuit interrupters near wet areas.					
b. Plumbing: i. Appropriateness of sink usage: Separate for work/personal use; ii. Adequate drainage from sinks or floor drains; iii. Hot and cold running water.					
c. Ventilation: i. Areas around solvent use or storage of waste solvent; ii. Vented hood for any microbiological analysis - Class II Type A biosafety cabinet.					
d. Vacuum: i. Appropriate utilities/traps for prevention of contamination.					
e. Shut-off controls: Located outside of the laboratory.					
19. Waste disposal: Appropriate for the type of waste and compliant with WAC 314-55-097, Marijuana waste disposal—Liquids and solids.					
20. Equipment list.					
a. Equipment and/or systems requiring periodic maintenance shall be identified and records of major equipment shall include: i. Name; ii. Serial number or unique identification;					

FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
iii. Date received and placed in service; iv. Current location; v. Condition at receipt; vi. Manufacturer's instructions; vii. Date of calibration or date of next calibration; viii. Maintenance; ix. History of malfunction.					
21. Maintenance.					
a. Regular preventive maintenance of equipment demonstration in logbook including, but not limited to: Thermometer calibration, pipette calibrations, analytical balances, and analytical equipment. Documentation of a schedule and reviewed by the laboratory director.					
b. Documentation of curative maintenance in logbook, signed and dated by laboratory director.					
c. Temperature maintenance log book for refrigerators.					
d. Decontamination and cleaning procedures for: i. Instruments; ii. Bench space; iii. Ventilation hood.					
e. Documentation of adequacy of training of personnel and responsibility for each maintenance task.					
f. The organization shall describe or reference how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems.					
22. Computer systems.					
a. Adequate for sample tracking.					
b. Adequate for analytical equipment software.					
c. Software control requirements applicable to both commercial and laboratory developed software shall be developed, documented, and implemented.					
d. In addition, procedures for software control shall address the security systems for the protection of applicable software.					
e. For laboratory-developed software, a copy of the original program code shall be: i. Maintained; ii. All changes shall include a description of the change, authorization for the change; iii. Test data that validates the change.					
f. Software shall be acceptance tested when installed, after changes, and periodically during use, as appropriate.					
g. Testing may consist of performing manual calculations or checking against another software product that has been previously tested, or by analysis of standards.					

FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
h. The version and manufacturer of the software shall be documented.					
i. Commercially-available software may be accepted as supplied by the vendor. For vendor supplied instrument control/data analysis software, acceptance testing may be performed by the laboratory.					
23. Security.					
a. Written facility security procedures during operating and nonworking hours.					
b. Roles of personnel in security.					
c. SOP for controlled access areas and personnel who can access.					
d. Secured areas for log-in of sample, and for short and long-term storage of samples.					
24. Storage.					
a. Appropriate and adequate for sample storage over time. The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.					
b. Adequate storage of chemical reference standards.					
c. Appropriate storage of any reagents: Fireproof cabinet, separate cabinet for storage of any acids.					
d. Appropriate safe and secure storage of documents etc., archiving, retrieval of, maintenance of and security of data for a period of three years.					

QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
25. Sampling/sample protocols: Written and approved by the laboratory director.					
a. Demonstrate adequacy of the chain-of-custody tracking upon receipt of sample including all personnel handling the sample.					
b. Sampling method (representative of an entire batch) including, but not limited to, homogenization, weighing, labeling, sample identifier (source, lot), date and tracking.					
c. Condition of the sample: Macroscopic and foreign matter inspection - Fit for purpose test. Scientifically valid testing methodology: Either AHP monograph compliant, other third-party validation.					
d. Failed inspection of product: Tracking and reporting.					
e. Return of failed product documentation and tracking.					
f. Disposal of used/unused samples documentation.					

QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
g. Sample preparation, extraction and dilution SOP.					
h. Demonstration of recovery for samples in various matrices (SOPs): i. Plant material - Flower; ii. Edibles (solid and liquid meant to be consumed orally); iii. Topical; iv. Concentrates.					
26. Data protocols.					
a. Calculations for quantification of cannabinoid content in various matrices - SOPs.					
b. Determination of the range for reporting the quantity (LOD/LOQ) data review or generation.					
c. Reporting of data: Certificates of analysis (CA) - Clear and standardized format for consumer reporting.					
d. Documentation that the value reported in the CA is within the range and limitations of the analytical method.					
e. Documentation that qualitative results (those below the LOQ but above the LOD) are reported as "trace," or with a nonspecific (numerical) designation.					
f. Documentation that the methodology has the specificity for the degree of quantitation reported. Final reports are not quantitative to any tenths or hundredths of a percent.					
g. Use of appropriate "controls": Documentation of daily use of positive and negative controls that challenge the linearity of the curve; and/or an appropriate "matrix blank" and control with documentation of the performance for each calibration run.					
27. Chemical assay procedure/methodology.					
28. Proficiency:					
a. Documentation of use of an appropriate internal standard for any quantitative measurements as applicable to the method.					
b. Appropriate reference standards for quantification of analytes, performing and documenting a calibration curve with each analysis.					
c. Demonstration of calibration curve r^2 value of no less than 0.995 with a minimum of four points within the range.					
d. Documentation of any proficiency testing as it becomes available. Laboratory director must review, evaluate and report to the WSLCB any result that is outside the stated acceptable margin of error.					
29. Method validation: Scientifically valid testing methodology: Either AHP monograph compliant, other third-party validation; **or**					

QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
30. Level II validation of methodology used for quantification of THC, THCA and CBD for total cannabinoid content (if reporting other cannabinoids, the method must also be validated for those compounds):					
a. Single lab validation parameters are demonstrated for GC, HPLC data review: i. Linearity of reference standards; ii. Use of daily standard curve; iii. Accuracy; iv. Precision; v. Recovery (5 determinations not less than 90%); vi. Reproducibility over time within a relative standard deviation of 5%.					
b. Dynamic range of the instrumentation: Limits of quantification (LOQ) and limits of detection (LOD).					
c. Matrix extensions for each type of product tested, data review of recovery for: i. Solvent-based extract; ii. CO_2 extraction or other "hash oil"; iii. Extract made with food grade ethanol; iv. Extract made with food grade glycerin or propylene glycol; v. Infused liquids; vi. Infused solids; vii. Infused topical preparations; viii. Other oils, butter or fats.					
d. Presence of QC samples and recording of daily testing.					
e. Appropriate use of an internal reference standard.					
f. Daily monitoring of the response of the instrument detection system.					
31. Other methods.					
a. Microbiological methods fit for purpose.					
b. Microbial contaminants within limits of those listed in the most recent AHP monograph and otherwise directed by WSLCB.					
c. Moisture content testing fit for purpose. Scientifically valid testing methodology: Either AHP monograph compliant, other third-party validation.					
d. Solvent residuals testing fit for purpose; solvent extracted products made with class 3 or other solvents used are not to exceed 0.5% residual solvent by weight or 500 parts per million (PPM) per one gram of solvent based product and are to be tested.					
e. Any other QA/QC methods is proven to be fit for purpose.					
32. Laboratory notebooks.					
a. Legible and in ink (or computerized system).					

QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
b. Signed and dated.					
c. Changes initialed and dated.					
d. Periodically reviewed and signed by a management representative.					
33. Preventive/corrective action.					
a. The laboratory shall have a process in place to document quality affecting preventive/corrective actions through resolution.					
34. Periodic management review.					
a. Laboratory management shall periodically review its quality system and associated procedures to evaluate continued adequacy. This review shall be documented.					