Washington State
Liquor Control Board

Washington State Liquor Control Board (WSLCB) Accreditation Certification Good Laboratory Practice (GLP) Checklist (Draft 1)

ORGANIZATON	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 with 24 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 rule requirement of the WSLCB.					
c. Chain of command, personnel organization/flow chart, dated and signed by the laboratory director					
d. Written Documentation of delegation of responsibilities (assigned under rule of 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.					

HUMAN RESOURCES	Document Reference	Y	N	NA	Comments
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 exposures, including follow-up examinations without cost or loss of pay					
g. Biosafety and sterile technique training					

STANDARD OPERATING PROCEDURES	Document Reference	Y	N	N/A	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 sampling handling j. Control of standards, reagents and water quality k. Cleaning of glassware i. Waste minimization and disposition					

STANDARD OPERATING PROCEDURES	Document Reference	Y	N	N/A	Comments
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 set-up 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	N/A	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					
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.					
a. Prospective suppliers shall be evaluated and selected on the basis of specified criteria.					

FACILITIES AND EQUIPMENT	Document Reference	Y	N	N/A	Comments
b. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.					
c. 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. no 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 , 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					

FACILITIES AND EQUIPMENT	Document Reference	Y	N	N/A	Comments
a. Regular preventive maintenance of equipment demonstration in log book 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 log book, 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 responsible 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.					
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.					

FACILITIES AND EQUIPMENT	Document Reference	Y	N	N/A	Comments
23. Security					
a. Written facility security procedures during operating and non-working 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: fire-proof 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 five years.					

QA PROGRAM and TESTING	Document Reference	Y	N	N/A	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	N/A	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 non-specific (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 r2 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	N/A	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 95%), 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. CO2 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 .					
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	N/A	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.					

APPENDIX A
WAC 314-55-102

WAC 314-55-102 Quality Assurance Testing

(1) A person with financial interest in an accredited third-party testing lab may not have direct or indirect financial interest in a licensed marijuana producer or processor for whom they are conducting required quality assurance tests.

(2) As a condition of accreditation, each lab must employ a scientific director responsible to ensure the achievement and maintenance of quality standards of practice. The scientific director shall meet the following minimum qualifications:
(a) Has earned, from a college or university accredited by a national or regional certifying authority a doctorate in the chemical or biological sciences and a minimum of two years' post-degree laboratory experience; or
(b) Has earned a master's degree in the chemical or biological sciences and has a minimum of four years' of post-degree laboratory experience; or
(c) Has earned a bachelor's degree in the chemical or biological sciences and has a minimum of six years of post-education laboratory experience.

(3) As a condition of accreditation, labs must follow the most current version of the Cannabis Inflorescence and Leaf monograph published by the American Herbal Pharmacopoeia or notify the board what alternative scientifically valid testing methodology the lab is following for each quality assurance test. The board may require third-party validation of any monograph or analytical method followed by the lab to ensure the methodology produces scientifically accurate results prior to them using those standards when conducting required quality assurance tests.

(4) As a condition of accreditation, the board may require third-party validation and ongoing monitoring of a lab's basic proficiency to correctly execute the analytical methodologies employed by the lab.

(5) Labs must adopt and follow minimum good lab practices (GLPs), and maintain internal standard operating procedures (SOPs), and a quality control/quality assurance (QC/QA) program as specified by the board. The board or authorized third-party organization can conduct audits of a lab's GLPs, SOPs, QC/QA, and inspect all other related records.

(6) The general body of required quality assurance tests for marijuana flowers, infused products, and extracts may include moisture content, potency analysis, foreign matter inspection, microbiological screening, pesticide and other chemical residue and metals screening, and residual solvents levels.

(7) Table of required quality assurance tests.

Product	**Test(s) Required**	**Sample Size Needed to Complete All Tests**
Extract (solvent based) made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity	1. Potency analysis 2. Residual solvent test 3. Microbiological screening (only if using flowers and other plant material that failed initial test)	Up to 2 grams
Extract made with a CO2 extractor like hash oil	1. Potency analysis 2. Microbiological screening (only if using flowers and other plant material that failed initial test)	Up to 2 grams
Extract made with food grade ethanol	1. Potency analysis 2. Microbiological screening (only if using flowers and other plant material that failed initial test)	Up to 2 grams
Extract made with food grade glycerin or propylene glycol	1. Potency analysis	Up to 1 gram
Infused edible	1. Potency analysis 2. Microbiological screening	1 unit
Infused liquid like a soda or tonic	1. Potency analysis 2. Microbiological screening	1 unit
Infused topical	1. Potency analysis	1 unit

(8) Independent testing labs may request additional sample material in excess of amounts listed in the table in subsection (7) of this section for the purposes of completing required quality assurance tests. Labs meeting the board's accreditation requirements may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab.

(9) Labs meeting the board's accreditation requirements are not limited in the amount of useable marijuana and marijuana products

they may have on their premises at any given time, but they must have records to prove all marijuana and marijuana-infused products only for the testing purposes described in WAC 314-55-102.

(10) At the discretion of the board, a producer or processor must provide an employee of the board or their designee samples in the amount listed in subsection (7) of this section for random compliance checks. Samples may be screened for pesticides and chemical residues, unsafe levels of metals, and used for other quality assurance tests deemed necessary by the board. All costs of this testing will be borne by the producer or processor.

(11) No lot of usable flower or batch of marijuana-infused product may be sold or transported until the completion of all required quality assurance testing.

(12) Any useable marijuana or marijuana-infused product that passed the required quality assurance tests may be labeled as "Class A." Only "Class A" useable marijuana or marijuana-infused product will be allowed to be sold.

(13) If a lot of marijuana flowers fail a quality assurance test, any marijuana plant trim, leaf and other usable material from the same plants automatically fails quality assurance testing also. Upon approval of the board, a lot that fails a quality assurance test may be used to make a CO2 or solvent based extract. After processing, the CO2 or solvent based extract must still pass all required quality assurance tests in WAC 314-55-102.

(14) At the request of the producer or processor, the board may authorize a retest to validate a failed test result on a case-by-case basis. All costs of the retest will be borne by the producer or the processor.

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