



PROPOSED RULE MAKING

CR-102 (July 2022) (Implements RCW 34.05.320) Do NOT use for expedited rule making

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DATE: November 20, 2023

TIME: 12:38 PM

WSR 23-23-145

Agency: Department of Agriculture

- Original Notice
- Supplemental Notice to WSR _____
- Continuance of WSR _____

- Preproposal Statement of Inquiry was filed as WSR 23-03-045 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or
- Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject) Chapter 16-309 WAC Cannabis Laboratory Accreditation Standards Program

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
Thursday, December 28, 2023	11:00 a.m.	Microsoft Teams Conference Line: Join by link: https://teams.microsoft.com/l/meeting/join/19%3ameeting_YzY5MjY2OTYtNzdIMy00OTQ5LTk2N2MtN2JjNGU1ZDQ0NjEy%40thread.v2/0?context=%7b%22Tid%22%3a%2211d0e217-264e-400a-8ba0-57dcc127d72d%22%2c%22Oid%22%3a%22838c55c7-c187-44ae-8de0-2be684ce5d4a%22%7d Join by phone: (audio only) +1 564-999-2000 .,698814391# United States, Olympia Phone Conference ID: 698 814 391#	

Date of intended adoption: Thursday, January 4, 2023 (Note: This is **NOT** the effective date)

Submit written comments to:
 Name: Gloriann Robinson, Agency Rules Coordinator
 Address: PO Box 42560, Olympia WA 98504-2560
 Email: wsdarulescomments@agr.wa.gov
 Fax: 360-902-2092
 Other:
 By (date) Thursday, December 28, 2023

Assistance for persons with disabilities:
 Contact Elisha Chambers, Division Rules Coordinator
 Phone: 360-902-1931
 Fax: (360) 902-2085
 TTY: (800) 833-6388
 Email: elisha.chambers@agr.wa.gov
 Other:
 By (date) Thursday, December 21, 2023

Purpose of the proposal and its anticipated effects, including any changes in existing rules: This proposed rule creates a new chapter of rule that is intended to expand the laboratory quality standards first created by the Washington State Liquor and Cannabis Board (LCB) as required by House Bill 1859 (HB 1859). To complete the mandate of HB 1859, the department is proposing the following rules:

- Creating education and training requirements for laboratory personnel, which depend on position, or testing responsibilities (WAC 16-309-040 through WAC 16-309-080).
- Requiring standard operating procedure (SOP) criteria for all laboratory testing (WAC 16-309-090).
- Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-100).
- Requiring security and safety protocols for the laboratory and for the laboratory staff (WAC 16-309-110).
- Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-120).
- Establishing facilities and equipment maintenance criteria for the laboratory (WAC 16-309-130).
- Establishing method performance criteria for laboratory testing (WAC 16-309-140).
- Establishing quality control and method performance criteria specific to each required test: water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological screening; residual solvent screening; mycotoxin screening; pesticide screening; and heavy metals screening (WAC 16-309-150 through WAC 16-309-220).
- Establishing required standardized testing method procedures for cannabinoid concentration analysis, residual solvents screening, and heavy metals screening. (WAC 16-309-160, WAC 16-309-190, and WAC 16-309-220).
- Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by the WSLCB (WAC 16-309-230).
- Creating laboratory computers and information system requirements (WAC 16-309-240).
- Establishing method validation criteria for laboratory testing (WAC 16-309-250).
- Requiring proficiency testing by laboratories as per the standards of the accrediting authority (WAC 16-309-260).
- Establishing certificate of analysis (CoA) report requirements (WAC 16-309-270).
- Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-280).
- Establishing sample subcontracting requirements for third party services (WAC 16-309-290).

Reasons supporting proposal: HB 1859 created an interagency coordination team for cannabis laboratory quality standards. The team consists of the Department of Agriculture (WSDA), the Washington State Liquor and Cannabis Board (LCB), and the Department of Health (DOH). The WSDA is designated lead agency for the team and must provide all necessary administrative support.

The WSDA must establish and maintain cannabis testing laboratory quality standards by rule. The cannabis testing laboratory quality standards must include but are not limited to: approved methods for testing cannabis for compliance with product standards established by rule by the LCB or the DOH; method validation protocols; and performance measures and criteria applied to testing of cannabis products.

The rules are developed in collaboration with the Washington State Liquor and Cannabis Board (LCB) and the Department of Health (DOH). As such, both agencies are heavily involved with this rule. Since the cannabis analysis lab accreditation program will be overseen by the Washington State Department of Ecology, WSDA will also be coordinating with Ecology.

Since the interagency team is required to consider the recommendations made by the Cannabis Science Task Force on the development of appropriate laboratory quality standards for cannabis product testing laboratories the department will also coordinate rule development with the members of the task force which includes members of the cannabis scientific community.

Statutory authority for adoption: RCW 15.150.030, House Bill (HB) 1859

Statute being implemented: Chapter 15.150 RCW

Is rule necessary because of a:

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

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: Private Public Governmental

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Elisha Chambers	1111 Washington Street SE, Olympia, WA 98504	360-902-1931
Implementation:	Trecia Ehrlich	1111 Washington Street SE, Olympia, WA 98504	360-584-3711

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)?

Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

No: Please explain: The Washington State Dept. of Agriculture is not a listed agency under RCW 34.05.328(5)(a)(i).

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570](#)(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(3). Check all that apply:

[RCW 34.05.310](#) (4)(b)
(Internal government operations)

[RCW 34.05.310](#) (4)(e)
(Dictated by statute)

[RCW 34.05.310](#) (4)(c)
(Incorporation by reference)

[RCW 34.05.310](#) (4)(f)
(Set or adjust fees)

[RCW 34.05.310](#) (4)(d)
(Correct or clarify language)

[RCW 34.05.310](#) (4)(g)
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(4) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.

The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs. _____
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

Small Business Economic Impact Statement
Chapter 16-309 WAC
Cannabis Testing Laboratory Quality Standard

SECTION 1:

Describe the proposed rule, including: a brief history of the issue; an explanation of why the proposed rule is needed; and a brief description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

Background and Overview

Cannabis products sold in Washington State are required to be tested for harmful substances and for cannabinoid concentration. The science required to develop adequate testing protocols has been slow to meet industry needs. In 2019, Washington enacted House Bill (HB) 2052, which established and directed the Cannabis Science Taskforce (CSTF) to recommend laboratory standards to be used in support of accrediting cannabis testing laboratories in Washington State. In June 2020, the Department of Ecology (ECY) published a report of laboratory quality standards for testing cannabis plants and products created by CSTF; this report recommended the creation of an inter-agency cooperative team consisting of the Washington State Liquor & Cannabis Board (WSLCB), the Department of Health (DOH) and led by the Washington State Department of Agriculture (WSDA).

In response, the Legislature passed HB 1859, which required the WSDA to establish and maintain cannabis testing laboratory quality standards by rule. The cannabis testing laboratory quality standards must include but are not limited to: approved methods for testing cannabis for compliance with product standards established by rule by the WSLCB or the DOH; method validation protocols; and performance measures and criteria applied to the testing of cannabis products. The WSDA Cannabis Laboratory Analysis Standards Program (CLASP) is responsible for creating and establishing these standards.

Proposed Rule

As required by HB 1859, the WSDA is establishing cannabis testing laboratory quality standards under chapter 16-309 WAC, which include:

1. Creating education and training requirements for laboratory personnel, which depend on position, or testing responsibilities (WAC 16-309-040 through WAC 16-309-070).
2. Requiring standard operating procedure (SOP) criteria for all laboratory testing (WAC 16-309-080).
3. Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-090).
4. Requiring security and safety protocols for the laboratory and for the laboratory staff (WAC 16-309-100).
5. Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-110).
6. Establishing facilities and equipment maintenance criteria for the laboratory (WAC 16-120).
7. Establishing method performance criteria for laboratory testing (WAC 16-309-130).
8. Establishing quality control and method performance criteria specific to each required test: water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological screening; residual solvent screening; mycotoxin screening; pesticide screening; and heavy metals screening (WAC 16-309-140 through WAC 16-309-210).
9. Establishing required standardized testing procedures for cannabinoid concentration analysis, residual solvents screening, and heavy metals screening. (WAC 16-309-150, WAC 16-309-180, and WAC 16-309-210).
10. Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by the LCB (WAC 16-309-220).
11. Creating laboratory computers and information system requirements (WAC 16-309-230).
12. Establishing method validation criteria for laboratory testing (WAC 16-309-240).
13. Establishing minimum proficiency testing standards for laboratories (WAC 16-309-250).
14. Establishing certificate of analysis (CoA) report requirements (WAC 16-309-260).
15. Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-270).
16. Establishing sample subcontracting requirements for third party services (WAC 16-309-280).

Probable Compliance Costs and Professional Services Requirements

As standards are raised, so does the cost of compliance. Cannabis testing laboratories will need to spend more time completing quality control and quality assurance steps to ensure the quality of the data being produced. This will be paired with an increased usage of solvents and standards from chemical manufacturers.

Probable compliance costs for businesses may be accrued from changing personnel to meet new personnel requirements; purchasing of reagents and consumables from laboratory suppliers to meet new and changing testing requirements; increased hours of operation and purchasing of new instrumentation to meet new and changing method performance requirements, method validation requirements, standardized methods requirements, and proficiency testing requirements.

The proposed rule does not require professional services. A laboratory may choose to begin or continue to use professional services for maintenance of computer information systems, maintenance of security systems, and facilitation of lab-to-lab sample transfers; however, it will not be mandatory.

There are currently eight (8) laboratories in Washington state providing cannabis testing services.

SECTION 2:

Identify which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS) codes and what the minor cost thresholds are.

NAICS Code (4, 5 or 6 Digit)	NAICS Business Description	Number of Businesses in Washington	Minor Cost Threshold = 1% of Average Annual Payroll	Minor Cost Threshold = 0.3% of Average Annual Revenue
541380	Testing Laboratories	8	\$8,577.31	\$4,842.86

*Data source: 2020 Employment Security Department

**Data source: 2020 Department of Revenue

SECTION 3:

Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule, including: cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue.

Probable costs related to the implementation of these rules depend on the laboratory's current methods, instrumentation, equipment, and personnel. After reviewing the proposed rule language, the current cannabis testing laboratories noted the following list of costs they are most likely to incur in order to comply with the rule:

1. Matrix blanks/spikes requirements along with the number of controls has increased. Current WSLCB rules require that laboratories use appropriate matrix blank and controls, the new rules just elaborate on how many. Cost for spiking standards and matrix could range between \$10,000 - \$50,000 per year depending on the laboratory's compliance to current rules.
2. The proposed rule increases storage requirements from the current WSLCB rule from 3 years to 5 years. Stakeholders may see a cost in hard-copy storage, or storage of electronic documents. This cost should be minor, if any, depending on the current storage capabilities of each laboratory. Estimates range between \$360 - \$5,000 per year.
3. Personnel cost may change for some laboratories due to the Bachelor of Science degree requirement for high complexity testing. Should a laboratory need to hire an additional scientist, cost could range between \$0 and \$90,000 per year. Most labs would not need to hire additional staff.
4. From the information we have received all laboratories have the instrumentation to perform the testing required. The proposed rule does not require the purchasing of any new analytical instrumentation and laboratories may arrange for a sample lab-to-lab transfer for testing if they are unable to perform the method with their current instrumentation. Laboratory analytical Instrumentation can range from \$0 to \$400,000.
5. The refrigerator storage requirements concerned stakeholders about the need to purchase additional refrigerators or freezers to store standards and samples. From the information we have received, all laboratories have current refrigerator(s) and/or freezer(s) used for storage of standards and samples. Cost of a laboratory grade refrigerator or freezer would range from \$0 - \$10,000 each.

6. The proposed rule requires a photo record to perform the foreign matter inspection in addition to a written record to document test results. Some laboratories may need to purchase some type of camera or system to meet this requirement. Cost of equipment capable of capturing photos would range from \$50 to \$500.
7. The annual validation requirement would increase the use of standards, solvents, personnel, and equipment. Costs would be between \$2,000 - \$10,000 per year.
8. The proposed rule sets more quality control and quality assurance standards which increases the possibility that a laboratory may need to repeat or redo work to meet data quality standards. Any repetition of work increases costs without increasing revenue. Quality assurance failures can be as simple as a reinjection (\$5) to a more complex need, such as instrument maintenance (\$25,000).

SECTION 4:

Analyze whether the proposed rule may impose more than minor costs on businesses in the industry.

The proposed rule will impose more than minor costs on some businesses in the industry.

It is assumed that businesses will choose the least expensive options to maintain adequate testing laboratories. Businesses that choose to purchase expensive capital equipment, like analytical instruments, will likely do so because the equipment can be used to bring in additional revenue and uses.

The survey determined that laboratories currently have all necessary instruments. Businesses will not have more than minor costs imposed on them if they are able to continue using current equipment and utilize lab-to-lab transfers for testing. Businesses may exceed the minor cost threshold if they need to purchase equipment, or hire additional scientist(s).

Table 4.1 shows a range of estimated costs to run testing laboratories. These costs can be as low as \$0 and as high as \$400,000.00 for proper refrigeration and instrumentation to perform testing requirements. In some cases, these costs can be as low as \$0 and as high as \$90,000.00 to maintain proper controls, storage, equipment, consumables, or increased staffing.

Table 4.1: Businesses with estimated cost increases expected to exceed the minor cost threshold.

NAICS	541380
Industry Type	Testing Laboratories
Minor cost threshold**	\$8,577.31
Cost for matrix blanks/spiking standards	\$10,000.00 - \$50,000.00
Cost for increased storage	\$360.00 - \$5,000.00
Costs for additional staff	\$0 - \$90,000.00
Cost for analytical instruments	\$0 - \$400,000.00
Cost for refrigeration storage	\$0 - \$10,000.00
Cost for camera equipment	\$0 - \$500.00
Cost for increased standards, solvents, personnel, & equipment	\$2,000.00 - \$10,000.00
Cost of re-analysis and re-extraction work	\$5.00 - \$25,000.00

Sources: Census Bureau, WSLCB, DOH, WSDA

*Minor cost thresholds calculated as 1% of average annual payroll.

SECTION 5:

Determine whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

RCW 19.85.040(1) requires the department to compare the cost of compliance for small businesses with the cost of compliance for the ten percent of businesses that are the largest businesses required to comply with the proposed rules using one or more of the following as a basis for comparing costs: (a) cost per employee; (b) cost per hour of labor; or (c) cost per one hundred dollars of sales.

After several surveys and interviews conducted by WSDA, it was determined that all eight laboratories currently providing cannabis testing are considered small businesses with fewer than 50 employees. Any cost of compliance should affect each laboratory equally, with slight variances due to current instrumentation and personnel.

No large businesses of the type categorized by NAICS 541380 have been identified by the Census Bureau's County Business Pattern (CBP) database. Therefore, the WSDA was not able to compare the costs of compliance for small businesses with the costs of compliance for large businesses.

Without any large businesses to compare costs of compliance with, the proposed rule is considered inherently disproportionate.

SECTION 6:

If the proposed rule has a disproportionate impact on small businesses, identify the steps taken to reduce the costs of the rule on small businesses. If the costs cannot be reduced provide a clear explanation of why.

RCW 19.85.030(2) requires consideration of the following methods of reducing the impact of the proposed amendment on small businesses:

(a) Reducing, modifying, or eliminating substantive regulatory requirements –

The proposed rule eliminates the necessity of laboratories to be certified for multiple fields of testing. A laboratory will be able to specialize in one or a few tests that share instrumentation and personnel needs. This increased flexibility allows laboratories to do only the work they find profitable and allows them to outsource all other work required.

(b) Simplifying, reducing, or eliminating recordkeeping and reporting requirements –

Transcripts of educational course work in personnel folders were a component of the first draft of the proposed rule, but have been removed as a requirement based on the first round of stakeholder feedback. A copy of the degree may be added to a personnel folder.

While the proposed rule increases the total time that records must be maintained from 3 years (WSLCB rule) to 5 years, the creation of hard copies of data and reports is not a requirement. The use of electronic data and storage of the electronic data is allowed and must be maintained for the minimum period described in the proposed rule. Electronic storage of records is generally less expensive than storage of hard copy records.

(c) Reducing the frequency of inspections –

Inspections will be performed annually. The laboratories and the department agree this schedule is suitable as it is standard for accreditations across fields.

(d) Delaying compliance timetables –

While WSDA sets and adopts the standards for accreditation, but the accrediting authority is responsible for compliance and enforcement of the standards. Delaying the compliance timetables is outside of the work of this rule making.

(e) Reducing or modifying fine schedules for noncompliance –

Currently, there are no scheduled fines for noncompliance. It is the intent of this program to work with the laboratories to support compliance.

(f) Any other mitigation techniques including those suggested by small businesses or small business advocates –

Conditions were added to allow non-degreed laboratory technicians to perform several of the tests, but not all. This may require some laboratory to hire degreed staff. A grandfather clause is included in the proposed rule, which may qualify some of the laboratory technicians to perform high complexity testing.

SECTION 7:

Describe how small businesses were involved in the development of the proposed rule.

CLASP facilitated several opportunities for small businesses to be involved in the rule making process. Before creation of the first draft of the proposed rule, CLASP arranged for meetings with all the laboratories as indicated in Table 1. CLASP shared the first draft of the rule with all 8 laboratories, with instructions for the laboratories to identify the probable costs to comply with the proposed rule, including: cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue. Laboratories were also asked to identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule. CLASP arranged a video conference call with all 8 laboratories to discuss their feedback. CLASP revised the proposed rule to create a second draft and documented the changes made in a separate secondary document. CLASP shared the second draft of the proposed rule and secondary document with all 8 laboratories, asking for additional feedback. CLASP revised the second draft based on the feedback and has created a third and final version of the proposed rule amendment.

Table 1 - Stakeholder Engagement Interactions

Meeting with	Meeting Venue	Date	Discussion
Medicine Creek Analytics	In-Person	Thursday, February 2 nd , 2023	Introduction to CLASP and next steps for lab standards.
Green Growers Labs	In-Person	Wednesday, February 22 nd , 2023	Introduction to CLASP and next steps for lab standards.
True Northwest, Inc.	In-Person	Tuesday, April 4 th , 2023	Concerns with current cannabis laboratory regulations.
Integrity Labs	In-Person	Tuesday, April 11 th , 2023	Concerns with current cannabis laboratory regulations.
Treeline Analytics, LLC.	In-Person	Friday, May 5 th , 2023	Introduction to CLASP and next steps for lab standards.
Capitol Analysis	Phone call	Friday, May 12 th , 2023	Concerns with current cannabis laboratory regulations.
Testing Technologies, Inc.	Phone Call	Friday, May 26 th , 2023	Concerns with current cannabis laboratory regulations.
Confidence Analytics	Phone Call	Friday, May 26 th , 2023	Concerns with current cannabis laboratory regulations.
All laboratories	Outbound Email	Thursday, June 22 nd , 2023	Requesting feedback on draft rule, inviting to Video conference
All Laboratories	Video conference	Wednesday, June 28 th , 2023	Requesting feedback on draft rule
Treeline Analytics, LLC.	Inbound email	Monday, July 3, 2023	Response and comments on first draft
True Northwest, Inc.	Inbound Email	Wednesday, July 5, 2023	Response and comments on first draft
Medicine Creek Analytics	Inbound Email	Thursday, July 6, 2023	Response and Comments on first draft
Capitol Analysis	Inbound Email	Friday, July 7, 2023	Response and comments on first Draft
All laboratories	Outbound email	Friday, July 21, 2023	Sent second draft of rules and responses to original questions and concerns

Integrity Labs	Inbound Email	Wednesday, July 26, 2023	Response and comments on second draft
Treeline Analytics, LLC.	Inbound Email	Friday, July 28, 2023	Response and comments on second draft
Confidence Analytics	Inbound Email	Friday, July 28, 2023	Response and comments on second draft
Capitol Analysis	Inbound Email	Thursday, August 10, 2023	Follow up question on rule section

SECTION 8:


Identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule.

The proposed rule should not cause job loss.

Some laboratories have indicated that the additional validation requirements will require more person hours. If laboratories need to hire one additional person to meet the requirements, then the proposed rule amendment may create up to 8 new jobs.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name: Gloriann Robinson, Agency Rules Coordinator
Address: PO Box 42560, Olympia, WA 98504-2560
Phone: (360) 902-1802
Fax: (360) 902-2092
TTY: (800) 833-6388
Email: wsdarulescomments@agr.wa.gov
Other:

Date: November 20, 2023	Signature: 
Name: Jessica Allenton	
Title: Assistant Director	

Chapter 16-309 WAC
CANNABIS LABORATORY ACCREDITATION STANDARDS PROGRAM

NEW SECTION

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

NEW SECTION

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

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

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

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

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

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

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

"Analytical batch" means a group of samples, standards, and blanks which are analyzed together with the same method sequence and same lots of reagents and with the manipulations common to each sample within the same time period.

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

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

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

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

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

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

"Blank" means a substance that does not contain the analytes of interest and is subjected to the usual measurement process. Blanks can be further classified as method blanks, matrix blanks, reagent blanks, system blanks, and field blanks.

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

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

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

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

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

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

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

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

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

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

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

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

"Certifying scientist" means the person authorized by the scientific director to review the analytical results and issue the certificate of analysis for cannabis samples who has the appropriate education, training, and competencies to perform such duties.

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

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

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

"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.

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

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

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

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

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

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

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

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

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

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

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

"Limit of quantitation (LOQ)" means the minimum amount or concentration of analyte in the test sample that can be quantified with ac-

ceptable 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.

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

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

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

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

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

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

"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.

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

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

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

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

technical guidance documents, permits, work plans, or enforcement orders.

"Precision" means the closeness of agreement between independent test results obtained under specified conditions. This is described by statistical methods such as a standard deviation or confidence limit of test results. See also "random error." Precision can be further classified as repeatability, intermediate precision, and reproducibility.

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

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

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

"Quality assurance (QA)" means activities intended to assure that a quality control program is effective. A QA program is a totally integrated program for assuring reliability of measurement data.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

bration standards, then the reported analyte recoveries should be calculated according to those procedures.

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

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

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

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

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

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

"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.

"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.

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

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

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

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

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

NEW SECTION

WAC 16-309-030 Laboratory instructions. (1) A cannabis testing laboratory must be accredited by the accrediting authority prior to conducting quality assurance tests on any cannabis flower or products derived under chapter 69.50 RCW.

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

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

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

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

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

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

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

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

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

NEW SECTION

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

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

(a) Resume of training and experience.

(b) Job description of current position.

(c) Copies of certificates.

(d) Copies of diploma(s).

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

(f) Documentation of continuing education, if any.

(g) Documentation of demonstrated abilities and competencies.

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

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

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

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

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

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

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

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

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

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

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

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

NEW SECTION

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

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

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

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

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

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

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

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

(b) Establishing a training program for personnel;

(c) Ensuring that personnel are sufficiently trained;

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

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

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

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

(h) Ensuring that analytical methods are properly validated;

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

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

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

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

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

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

(o) Fully understanding the role of any external service providers and the functions of external information systems and computer systems in the laboratory's activities associated with cannabis testing;

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

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

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

NEW SECTION

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

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

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

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

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

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

(i) Six semester hours of chemistry;

(ii) Six semester hours of biology; and

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

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

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

NEW SECTION

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

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

(2) Have documented training appropriate to perform the test;

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

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

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

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

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

NEW SECTION

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

- (1) Have at least a high school diploma or equivalent;
- (2) Have appropriate training to perform the test;
- (3) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;
- (4) Be approved by the scientific director to perform the test.

NEW SECTION

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

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

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

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

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

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

- (a) Title that identifies the activity or procedure;
- (b) Scope and principle;
- (c) Sample requirements;
- (d) Calibration and control preparation and usage protocol;
- (e) Instrumentation, equipment, materials and supplies used;
- (f) Instrument settings, data acquisition, system operation, parameters and conditions for testing;
- (g) Procedure for sample preparation and testing;
- (h) Results review and acceptability;
- (i) Additional information, notes, safety requirements, and precautions to include calculations, interferences, limitations, background corrections, and proper disposal of lab waste including biohazardous waste and cannabis waste compliant with WAC 314-55-097; and
- (j) References.

(7) The SOP must include a policy for the use of appropriate personal protective equipment (PPE) when working with samples, reagents, chemicals or potential hazards in the workplace along with a written and documented system on the competency of personnel on how to handle

chemical spills and appropriate action in the use of chemical spill kits.

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

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

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

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

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

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

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

NEW SECTION

WAC 16-309-100 Sampling and homogenization protocols. (1) Upon receipt, the laboratory must inspect each sample package and transportation manifest, assuring they meet the following minimum requirements as defined in chapter 314-55 WAC:

(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 manifest or when the container shows evidence of tampering.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NEW SECTION

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

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

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

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

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

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

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

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

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

(10) The laboratory must establish a system to ensure records are 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 year storage requirement.

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

NEW SECTION

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

(2) Laboratories must use 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 for appropriate methods 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 and each specimen preparation method being used for testing that batch.

(c) A positive or spiked control above the cutoff or decision point but below the upper limit of linearity for each matrix and each specimen preparation method being used for testing that batch.

(d) A matrix spiked duplicate at least every 20 samples per matrix for high complexity tests.

(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 manufac-

turer or a separate lot prepared independently by the same manufacturer.

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

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

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

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

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

(11) Quality control results must be reviewed by an 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 so that they can 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 use notebooks, logbooks, or other electronic means of communicating with staff regarding issues, problems, or communications between shifts.

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

(16) The laboratory must designate a quality manager who, irrespective of other duties and responsibilities, 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.

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

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

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

(20) Instruments that use a multipoint curve must be calibrated using a minimum of a four-point curve and no blanks can be used as a point. The linear correlation determination (r^2) must be ≥ 0.9950 or

the correlation coefficient (r) must be ≥ 0.9975 . Linear regression with $1/x$ or no weighting must be used. Forcing the curve through zero is not allowed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(25) The laboratory must use American Chemical Society (ACS) grade acids or bases, ultra-high purity grade gasses, Type II water, and analytical quality materials in the preparation of standards and sample processing.

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

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

NEW SECTION

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

(2) The laboratory must monitor, control, and record environmental conditions as required by the relevant specifications, methods, and procedures where they influence the quality of the results. Due attention 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 10 seconds unobstructed travel distance from the area in the laboratory where hazardous chemicals are present.

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

(7) 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.

(8) 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 vacuum traps, ventilation for fume hoods and around solvent use or storage of solvents or waste. There must be appropriate storage cabinets for flammable solvent, acids, and bases. There must be appropriate vented hoods for any microbiological analysis (i.e., Class II Type A biosafety cabinets as applicable).

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

(10) 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.

(11) 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.

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

(13) 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.

(14) 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.

(15) 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.

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

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

(18) 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.

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

NEW SECTION

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

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

(3) Laboratories may use historical calibrations for high complexity testing as long as it is supported by analytical data through quality control results. Historical calibrations can not extend past 30 days.

(4) The samples fail quality control testing if the results exceed the limits indicated in WAC 314-55-102.

(5) Sample results are positive for the analyte being tested if their results are greater than or equal to the decision point or cut-off limits as indicated in WAC 314-55-102.

(6) Sample results are to be reported out in the number of digits and units of measure described in WAC 314-55-102.

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

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

NEW SECTION

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

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

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

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

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

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

(b) The instrument has been cleaned.

(c) The manufacturer's instruction manual recommends.

NEW SECTION

WAC 16-309-160 Cannabinoid concentration analysis. (1) Cannabinoid concentration analysis, previously known as potency, is intended to quantitate and accurately report cannabinoids above the cutoff or decision points described in WAC 314-55-102.

(2) Laboratories must use the standard methods approved by the department to analyze cannabinoids:

(a) 977-CLASP Method CCSP - Cannabinoid Concentration Sample Preparation.

(b) 976-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 department. Laboratories must, at a minimum, do the following for a new method validation:

- (a) Communicate the intended method changes to the department.
- (b) Receive written approval from the department regarding the appropriate validation criteria.
- (c) Produce all data acquired from the validation.
- (d) Receive written approval from the department of the validated method for use on customer samples.

NEW SECTION

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

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

(3) The laboratory must use a microscope with photographic capabilities or a camera with magnification to assess the presence of foreign matter.

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

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

NEW SECTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(9) For qualitative methods, all results must be reported as qualitative designations such as "detected," "not detected," "positive," or "negative." For quantitative methods, the laboratory may only report results that are above the limit of quantification and below the upper limit of quantification.

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

NEW SECTION

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

(2) Laboratories must use the CLASP modified methods adapted for cannabis to analyze residual solvents:

(a) 972-CLASP Method - Residual Solvents by Gas Chromatography Flame Ionization Detector.

(b) 973-CLASP Method - Residual Solvents by Headspace Analysis.

(c) 975-CLASP Method - Residual Solvents by Gas Chromatography Mass Spectrometry.

(d) 795-CLASP Method - Liquid Extraction for Residual Solvents.

(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.

(b) Methanol and any other solvent listed in WAC 314-55-102 must not be used in any preparation or analysis procedure for residual solvent testing.

(c) All board 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.

(d) In the method, 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 regulations." The selected solvent must be specifically cited in a lab's standard operating procedure(s).

(5) Subsampling 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 board's sampling requirements.

(b) The container must contain a minimum of 0.25 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 at least 0.2 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 $< 8^{\circ}\text{C}$ 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.

NEW SECTION

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

(2) For qualitative methods, all results must be reported as qualitative designations such as "detected," "not detected," "positive," or "negative." For quantitative methods, the laboratory may only report numerical results that are above the limit of quantification and below the upper limit of quantification.

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

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

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

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

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

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

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

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

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

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

(5) The laboratory must perform a second-source calibration verification at the target concentration at the beginning of each day of testing.

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

NEW SECTION

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

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

(3) Laboratories must create and validate their own method for pesticide analysis using the guidelines provided in the 982-CLASP Method - Cannabis Pesticide Residue Analysis, 983-CLASP Method - Cannabis Pesticide Sample Processing, and 981-CLASP Method - Cannabis Pesticide Data Analysis Manuals. This includes following quality standards for extraction, clean-up, chromatography, and the analytical technique.

NEW SECTION

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

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

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

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

(5) Laboratories must use the CLASP modified methods adapted for cannabis to analyze heavy metals: 475-CLASP Method - Cannabis Analysis of Heavy Metals by Inductively Coupled Plasma Mass Spectrometry.

(6) The laboratory must properly prepare samples using a digestion method that provides total sample decomposition for metal analysis approved by the department: 980-CLASP Method - Sample Preparation of Cannabis and Cannabis Products for Heavy Metals Analysis.

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

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

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

(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.

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

NEW SECTION

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

- (1) Additional test results must be listed separately from the required analytes on the certificate of analysis.
- (2) Additional test results must be identified as analytes outside the scope of accreditation on the certificate of analysis.
- (3) Additional analytes that are tested using methods that also include required analytes for compliance must meet similar requirements for testing and reporting.
- (4) Additional analytes that are tested using methods that do not include required analytes for compliance must be validated and tested using standards established in this chapter.

NEW SECTION

WAC 16-309-240 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 or agreement with any external service providers that includes the priority elements of physical, technical, and administrative safeguards to protect their systems and data.

NEW SECTION

- ##### **WAC 16-309-250 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) The records must include sufficient information to allow for a comprehensive review of the studies performed. Laboratories must have criteria for acceptance of study data, for agreement of replicate study samples, and for defining true outlier values. Study samples for quantitative methods must meet the same qualitative criteria (e.g., the same retention time, mass ratio, internal standard abundance, and chromatography criteria) used for samples. The laboratory's acceptance criteria must be described in the SOP and in the study summary.

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

(4) If the laboratory modifies an existing test method or instrument parameter that affects the performance of the method, the revised method must be re-validated prior to use. If the modification is relatively minor, the validation studies may be focused on those parameters that have been affected.

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

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

(7) The laboratory must characterize the precision of a method based on replicate analysis, at least 20 results total. Analysis must be at significant concentrations around the cutoff/decision point and expected range. At least 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.

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

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

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

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

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

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

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

(15) The laboratory must investigate any possible matrix effect by evaluating the potential for components of the sample matrix to 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 or from 10 different plant lots).

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

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

(18) The laboratory must perform a positive/negative differentiation study when validating a qualitative test by analyzing positive and negative samples that have been verified by a quantitative method to assess the assay's ability to differentiate positive and negative samples. The laboratory may analyze a combination of positive and negative controls, proficiency test (PT) samples or previously tested samples. The laboratory should analyze a minimum of 10 positive samples at differing concentrations and 10 negative samples (i.e., 20 results total).

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

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

- (a) A stated purpose;
- (b) Description of test method(s);
- (c) Identity of the instrument(s) used for the study;
- (d) A listing of the instrument parameters used for the study;
- (e) A description of the study samples;
- (f) A summary of the statistical data collected to characterize the assay;
- (g) A discussion;

(h) A summary with conclusions; and
(i) All raw analytical data from the samples analyzed in the study.

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

(22) The laboratory must maintain the original assay validation study records for an indefinite period. Validation and reverification study records must be made available at the time of inspection or upon request.

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

- (a) Linearity;
- (b) Precision and accuracy around the cutoff;
- (c) Selectivity;
- (d) Carryover;
- (e) A parallel study using the existing and new/revised procedures;
- (f) Positive/negative sample differentiation studies.

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

- (a) Determination of LOQ, LOD, and ULOL;
- (b) Precision/accuracy around the cutoff;
- (c) Carryover;
- (d) Selectivity/interference;
- (e) For an assay validation: Method parameters including appropriate ion selection;
- (f) For full instrument validation: Instrument parameter optimization;
- (g) For LC-MS, and LC-MS/MS methods: Matrix effects;
- (h) For assays using a new technology: Parallel studies of PT samples and customer samples (e.g., when validating a technology different from the existing method);
- (i) For assays using an extraction: Extraction efficiency must be determined; and
- (j) Hydrolysis efficiency (if sample preparation includes a hydrolysis step).

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

- (a) Determination of the LOQ, LOD, and ULOL;
- (b) Carryover evaluation;
- (c) Interference studies;
- (d) Instrument parameter optimization; and
- (e) For LC, LC-MS, and LC-MS/MS methods: Evaluation of matrix effects.

NEW SECTION

WAC 16-309-260 Proficiency testing. The laboratory must participate in an approved proficiency testing (PT) program that reflects the best available science as determined by the accrediting authority.

NEW SECTION

WAC 16-309-270 Reports. (1) All sample test results must be supported by analytical data and all analytical data must have a documented review, once reviewed by an analyst, and once reviewed by a certifying scientist prior to being reported.

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

(3) For the purpose of reporting, decision points or cutoff limits have been written in WAC 314-55-102 to the number or significant digits that laboratories are expected to use when reporting results.

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

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

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

(a) A title: "Certificate of Analysis" or "Test Report";
(b) Laboratory name, lab ID number, and address;
(c) Unique identification of the test report certificate and on each page an identification in order to ensure that the page is recognized as a part of the COA, and a clear identification of the end of the report;

(d) The name, address, and license number of the customer;
(e) Date of sample collection;
(f) Date of transport;
(g) Sample identification number from transportation manifest;
(h) Driver's name and contact information;
(i) Sample/matrix type (flower, concentrate etc.);
(j) Product/sample name and category;
(k) Amount of sample received;
(l) Date received by laboratory;
(m) Name of certifying scientist;
(n) Date reported by the laboratory;
(o) Results of each test performed to include name of test, results, measurands (i.e., mg/g), cutoffs, and instrument/method of testing used;

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

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

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

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

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

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

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

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

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

NEW SECTION

WAC 16-309-280 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) New lots or materials received outside of expected environmental conditions must be documented and validated before use.

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

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

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

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

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

NEW SECTION

WAC 16-309-290 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 laboratory management for corrective action.