PROPOSED RULE MAKING

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

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FILED

DATE: February 21, 2024
TIME: 7:44 AM

WSR 24-05-079

Agency: Dept. of Agriculture

☐ **Original Notice**

☒ **Supplemental Notice to WSR** 23-03-045

☐ **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:**
April 9, 2024	1:00 PM	Microsoft Teams meeting **Join on your computer, mobile app or room device** https://teams.microsoft.com/l/meetup-join/19%3ameeting_MGFhMjllMWYtZjRhYi00ZDNmLWI4MWMtM2E0ZmIxZTU2NTAy%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 Meeting ID: 275 870 779 25 Passcode: 49xZ8h **Or call in (audio only)** +1 564-999-2000 Phone Conference ID: 590 850 398#	

Date of intended adoption: April 16, 2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Gloriann Robinson, Agency Rules Coordinator	Contact Trecia Ehrlich, Cannabis Programs Manager
Address: PO Box 42560, Olympia WA 98504-2560	Phone: 360-584-3711
Email: wsdarulescomments@agr.wa.gov	Fax:
Fax: 360-902-2092	TTY: (800) 833-6388
Other:	Email: tehrlich@agr.wa.gov
By (date) April 9, 2024	Other:
	By (date) April 2, 2024

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 (WSLCB) as required by House Bill 1859 (HB 1859). To complete the mandate of HB 1859, the department is proposing the following rules:

1. Creating education and training requirements for laboratory personnel, which depend on position, or testing responsibilities (WAC 16-309-050 through WAC 16-309-080).
2. Requiring standard operating procedure (SOP) criteria for all laboratory testing (WAC 16-309-090).
3. Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-100).
4. Requiring security and safety protocols for the laboratory and for the laboratory staff (WAC 16-309-110).
5. Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-120).
6. Establishing facilities and equipment maintenance criteria for the laboratory (WAC 16-130).
7. Establishing method performance criteria for laboratory testing (WAC 16-309-140).
8. Establishing quality control and method performance criteria specific to each required test: water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological testing; residual solvent testing; mycotoxin testing; pesticide testing; and heavy metals testing (WAC 16-309-140 through WAC 16-309-210).
9. Establishing required standardized testing procedures for cannabinoid concentration analysis, residual solvents testing, and heavy metals testing. (WAC 16-309-160, WAC 16-309-190, and WAC 16-309-220).
10. Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by the LCB (WAC 16-309-230).
11. Creating laboratory computers and information system requirements (WAC 16-309-240).
12. Establishing method validation criteria for laboratory testing (WAC 16-309-2640).
13. Establishing a process by which laboratories can submit their own methods for approval. (WAC 16-309-250)
14. Establishing minimum proficiency testing standards for laboratories (WAC 16-309-270).
15. Establishing certificate of analysis (CoA) report requirements (WAC 16-309-280).
16. Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-290).
17. Establishing sample subcontracting requirements for third party services (WAC 16-309-300).

The proposed rules are developed in collaboration with WSLCB and the DOH. As such, both agencies are heavily involved with this rule. Since the interagency team is required to consider the recommendations made by the Cannabis Science Task Force (CSTF) 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.

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 (WSLCB), 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.

On November 22nd, 2023, the WSDA filed a CR-102 with proposed rule language of the laboratory standards which incorporated all components recommended by the CSTF. On December 28th, 2023, the WSDA held a public meeting in which stakeholders expressed concern primarily related to the required methods embedded and referenced in rule, as well as some of the costs associated with the new standards. Based on the comments received, the WSDA determined that substantive changes were needed to the rule language and that they would proceed to file a supplemental CR-102 in order to have more time to take stakeholder comments into consideration.

From December 2023 to February 2024, the WSDA offered multiple updated drafts for review, and one-on-one meetings with laboratories who had engaged in the initial CR-102 feedback process. Areas in which laboratories offered cost mitigation strategies were considered and incorporated when possible. Changes that were identified as “substantive” to the scientific rigor of the standard were discussed between scientists at all three participating agencies (WSDA, WSLCB, and DOH) in order to ensure consultation across a larger number of scientists.

The most substantive change made was extracting the methods from the rule, and instead requiring that laboratories use a method that had undergone the method approval process by the department. The previously required methods were edited and will exist as a list of “pre-approved” methods, and a process has been provided in rule by which laboratories can submit their own methods for approval. The WSDA also provided additional definitions and clarity in rule related to how methods are used and validated.

Statutory authority for adoption: RCW 15.150.030, House Bill 1859

Statute being implemented: Chapter 15.150 RCW

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ 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:	Trecia Ehrlich	1111 Washington Street SE, Olympia, WA 98504	360-584-3711
Implementation:	Trecia Ehrlich	1111 Washington Street SE, Olympia, WA 98504	360-584-3711
Enforcement:	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 Department 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)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ 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 led by the Washington State Department of Agriculture (WSDA/the department) in coordination and consultation with the Washington State Liquor and Cannabis Board (WSLCB) and the Department of Health ((DOH).

In response, the Legislature passed HB 1859, which required the department 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.

On November 22nd, 2023, the department filed a CR-102 of the laboratory standard which incorporated all components recommended by the CSTF. On December 28th, 2023 the department held a public meeting in which stakeholders expressed concern primarily related to the state of the required methods embedded and referenced in rule, as well as some of the costs associated with the new standards. After the public hearing, the department determined that they would proceed to file a supplemental CR-102 in order to have more time to take stakeholder comments into consideration. The most substantive change made was extracting the methods from the rule, and instead requiring that laboratories use a method that had undergone the method approval process by the department. The previously required methods were edited and will exist as a list of "pre-approved" methods, and a process has been provided in rule by which laboratories can submit their own methods for approval. The department also provided additional definitions and clarity in rule related to how methods are used and validated. During this time, the department offered multiple updated drafts for review, and one-on-one meetings with laboratories who had engaged in the initial CR-102 feedback process. Areas in which laboratories offered cost mitigation strategies were considered and adopted when possible. Changes that were identified as "substantive" to the scientific rigor of the standard were discussed between scientists at all three participating agencies, WSDA, WSLCB, and DOH, in order to ensure consultation across a larger number of scientists. As several changes did create significant cost mitigation strategies, and multiple laboratories were able to provide the department with more specific financial data in our second round of engagement, we also have updated our initial SBEIS in order to reflect the additional data and cost mitigation strategies that were provided.

Proposed Rule

As required by HB 1859, the department 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 16-309-050 through WAC 16-309-080).
2. Requiring standard operating procedure (SOP) criteria for all laboratory testing (WAC 16-309-090).
3. Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-100).
4. Requiring security and safety protocols for the laboratory and for the laboratory staff (WAC 16-309-110).
5. Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-120).
6. Establishing facilities and equipment maintenance criteria for the laboratory (WAC 16-130).
7. Establishing method performance criteria for laboratory testing (WAC 16-309-140).
8. Establishing quality control and method performance criteria specific to each required test: water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological testing; residual solvent testing; mycotoxin testing; pesticide testing; and heavy metals testing (WAC 16-309-140 through WAC 16-309-210).
9. Establishing required standardized testing procedures for cannabinoid concentration analysis, residual solvents testing, and heavy metals testing. (WAC 16-309-160, WAC 16-309-190, and WAC 16-309-220).
10. Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by the LCB (WAC 16-309-230).
11. Creating laboratory computers and information system requirements (WAC 16-309-240).
12. Establishing method validation criteria for laboratory testing (WAC 16-309-260).
13. Establishing a process by which laboratories can submit their own methods for approval. (WAC 16-309-250)
14. Establishing minimum proficiency testing standards for laboratories (WAC 16-309-270).
15. Establishing certificate of analysis (CoA) report requirements (WAC 16-309-280).
16. Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-290).
17. Establishing sample subcontracting requirements for third party services (WAC 16-309-300).

Probable Compliance Costs and Professional Services Requirements

As standards rise, 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.

While there will be added costs for the industry to come into compliance, both the expenses and associated work needed to meet the department's regulations will be contingent upon each of the laboratories' current operations. The department has adapted the proposed regulations from a variety of leading scientific industry standards, and thus, laboratories currently operating at or near these industry standards will not incur expenses as high as a laboratory operating further way from those standards.

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.

The rulemaking to establish chapter 16-309 WAC, has undergone two separate trajectories- an initial path from January 2023 – December 2023, and an amended/iterative course between December 2023 – February 2024.

Throughout the initial trajectory, the department, in collaboration with stakeholders, researched and discussed probable costs that laboratories may expect to incur with the 'then-current' rule language and methods. While probable costs of compliance were generally dependent upon the laboratories' methods, instrumentation, equipment, and personnel, the following cost areas were researched and identified:

Anticipated Costs to Laboratories, Generally - Original Rulemaking Proposal *(January 2023 – December 2023 Assessment)*	
1.	Matrix blanks/spikes requirements along with the number of controls has increased. While the current WSLCB rules require that laboratories use 'appropriate matrix blank and controls', the new rules elaborate on how many. Cost for spiking standards and matrix could range between $10,000 - $50,000 per year depending on the laboratory's current processes

2.	The proposed rule increases storage requirements from the current WSLCB rule from 3 years to 5 years. Laboratories may see a cost in hard-copy storage, or storage of electronic documents. Estimates range between $360 - $5,000 per year.
3.	The proposed rule requires lab personnel conducting high complexity testing have a Bachelor of Science degree. Should a laboratory need to hire an additional scientist, costs could range between $0 and $90,000 per year. Most labs would not need to hire additional staff as they likely already have highly experienced analysts qualified to perform high complexity testing. ***Note:*** Please see Section 6 for available cost mitigations.
4.	The proposed rule requires that specific types of analytical instrumentation be used for different testing methods. 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 to be transferred to another lab for testing if they are unable to perform the method with their current instrumentation.
5.	The proposed rule requires refrigerated storage of samples if they were not processed within 7 days. This concerned labs 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) necessary for the storage of standards and samples. Cost of a laboratory grade refrigerator or freezer could range from $0 - $10,000 each. ***Note:*** This requirement has since been removed. Please see Section 6.
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 could range from $50 to $500.
7.	The proposed rule requires annual validation of each testing method. This requirement could 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).

Based on feedback provided during the initial public hearing on December 28th, 2023, the department decided to make substantial revisions to the rule language to incorporate concerns shared by the impacted laboratories.
In addition to the feedback provided both during and following the first public hearing, the department has since conducted several stakeholder meetings and Q&A webinars to provide general rule language clarification, as well as to better understand any economic concerns related to compliance. The expenses and associated work needed to meet the department's proposed regulations, however, will be contingent upon each of the labs' current operations and procedures. That is, laboratories currently operating at or near accepted scientific benchmarks will not incur expenses as high as a laboratory operating further way from those standards.
Following a series of collaborative assessments and discussions conducted between December 2023 – February 2024, the department redetermined that laboratories affected by the proposed rule may experience increased costs of compliance related to the following fields of testing: (1) Water Testing, (2) Cannabinoid Concentration Analysis, (3) Foreign Matter Inspection, (4) Residual Solvent Testing, (5) Pesticide Testing, (6) Heavy Metals Testing, (7) Microbiological Testing (Culture), (8) Microbiological Testing (Immunoassay), (9) Microbiological Testing (Polymerase Chain Reaction (PCR)), and (10) Microbiological Testing (Mycotoxins).
A laboratory's potential costs of compliance for the above referenced tests are as follows:

1. **Water Testing – Per Sample**

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Instrument Calibration	$0.03	$0.03	$0.00
Standards & Controls	$0.11	$0.11	$0.00
Reagents & Consumables	$1.87	$1.87	$0.00
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $3.00 $4.15 $4.15	 $3.00 $4.15 $4.15	 $0.00 $0.00 $0.00
Preparation, Sanitation, and Disposal	$0.11	$0.11	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *Water Testing*: **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$0.00

The department does not anticipate any significant cost increases for any of the laboratories in Washington state due to the new regulations pertaining to *Water Testing*. Based on discussion and feedback provided from industry representatives, the department had confirmed its notion that laboratories will likely not incur any additional costs beyond current operations and procedures as it relates to *Water Testing*.

Water testing is a moderate complexity test meaning the method validation is minor. A lab would only have to show the instrument is performing according to the manufacturer's expectations. This would only require running 6-10 standard samples to verify unless the manufacturer has a greater requirement.

(3.1)(a) Water Testing – Method Validation

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Initial Setup Verification **(Required)**	N/A	~ $1,000.00	~ $1,000.00
Reverification based on: (1) Implementing a New Instrument, (2) Moving Instrument to New Location, (3) Instrument Repair, or	" "	~$100.00 — $500.00	~$100.00 — $500.00

(4) Instrument Recalibration.			
Modifying Existing Method or Instrument for Each Matrices	" "	~$100.00 — $500.00	~$100.00 — $500.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

At minimum, a laboratory offering *Water Testing* services will incur an initial setup verification expense of ~$1,000.00. Beyond this one-time cost, if a laboratory decides to (1) implement a new instrument, (2) move instrument to a new location, (3) have the instrument repaired, or (4) recalibrate the instrument, then a 'reverification cost' will be incurred estimated between ~$100.00 — $500.00. Further, if a laboratory is modifying an existing method or instrument for *Water Testing*, they may also expect to incur costs ranging between ~$100.00 — $500.00.

2. **Cannabinoid Concentration Analysis – Per Sample**

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards & Controls	$0.76 – $1.50	$107.00	$105.50 – $106.24
Reagents & Consumables	$0.36 – $0.60	$5.70	$5.10 – $5.34
Personnel (i) Tester (ii) Reviewer	 $0.94 $1.06	 $2.50 $3.40	 $1.56 $2.34
Preparation, Sanitation, and Disposal	$0.3 – $1.50	$.03 – $1.50	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *Cannabinoid Concentration Analysis:* **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			**Safe Range** $2,806.60 - $3,355.48 **Maximum** $2,806.60 – $7025.00

The department anticipates cost increases for laboratories due to the new regulations related to *Cannabinoid Concentration Analysis*. The expenses and associated work needed to meet the department's regulations will be contingent upon each of the laboratories' current operations. That is, laboratories currently operating at or near accepted scientific benchmarks will not incur expenses as high as a laboratory operating further way from those standards.

The most significant cost increase identified by the department, as related to *Cannabinoid Concentration Analyses*, is a direct result of the regulated timing for the spiking of a cannabinoid matrix spike. Laboratories currently spiking a cannabinoid matrix spike post-extraction will need to make procedural changes (following

review of dynamic ranges, etc.) to ensure they are able to spike a cannabinoid matrix spike pre-extraction for compliance. This departmental decision was based on the determination that there is insufficient data to support whether post-extraction spikes can adequately monitor the extraction process.

While the laboratories' need to spike a cannabinoid matrix spike pre-extraction poses as an area for increased costs, the department has researched and determined that cost mitigations are available by utilizing a customer's sample. In essence, laboratories may run a customer sample in duplicate to replace the matrix spike duplicate. Laboratories would still incur typical costs for running the customer sample—that is, costs for methanol, injection, etc.—but would be able to forego the matrix spike duplicate requirement and only need to spike one matrix per batch.

(3.2)(a) Cannabinoid Concentration Analysis – Method Validation

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Re-Validation **(Required)**	**Minimum** • $5,948.00 **Mean** • $7,024.00 **Maximum** • $8,100.00	**Minimum** • $8,640.00 **Mean** • $11,820.00 **Maximum** • $15,000.00	**Safe Range** • $2,692.00 – $4,796.00 **Maximum** • $6,900.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% — 50%)(Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	**Safe Range** • $2,692.00 – $4,796.00 **Maximum** • $2,692.00 – $6,900.00	**Safe Range** • $2,692.00 – $4,796.00 **Maximum** • $2,692.00 – $6,900.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

(3.2)(b) Cannabinoid Concentration Analysis — Instrument Calibration

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)

Instrument Calibration **Note:** Costs are based per calibration- costs were found to be incalculable per sample. 'Labor' includes preparation, review, and documentation	**Frequency** • 2-4 times/yr. **Standards** • $3000.00 per calibration **Consumables** • $30.00 per calibration **Labor** • $135.00 per calibration	**Frequency** • 12 times/yr. **Standards** • $36,000.00 **Consumables** • $360.00 **Labor** • $1,620.00	**Frequency** • 8-10 times more/yr. **Standards** • $24,000.00 – $30,000.00 **Consumables** • $240.00 - $300.00 **Labor** • $1,080.00 - $1,350.00

In sum, the department recognizes that the proposed rule will impose additional costs to laboratories related to *Cannabinoid Concentration Analyses* and other fields of testing. With this, the department has both considered requests and made concessions—where feasible and legal—without adversely impacting the *Cannabis Laboratory Accreditation Standards Program's* objectives or Washington's scientific merit.

3. **Foreign Matter Inspection – Per Sample**

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Instrument	$0.00	$0.00 – $500.00, if needed.	$0.00 – $500.00, if needed.
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $0.00 – $1.25 $0.00 – $8.33 $0.00 – $2.00	 $0.00 – $1.25 $0.00 – $8.33 $0.00 – $2.00	 $0.00 $0.00 $0.00
Preparation, Sanitation, and Disposal	$0.00 – $1.50	$0.00 – $1.50	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *Foreign Matter Inspection*: **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			No cost increases so long as camera/phone with magnification/resolution to document presence of foreign matter is on-hand.

The department does not anticipate any significant cost increases for any of the laboratories due to the proposed regulations related to *Foreign Matter Inspection*. Based on discussion and feedback provided from laboratories, the department has confirmed its evaluation that *Foreign Matter Inspection* will likely not cause laboratories to incur any additional costs beyond their current operations. Should a camera need to be purchased to meet the department's proposed regulations, the department has identified several ≤ $50.00 digital cameras sufficient for

Foreign Matter Inspection purposes. These adequate budget friendly options are available at major retailers such as Amazon, Best Buy, Target, and Walmart.

4. **Residual Solvent Testing – Per Sample**

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards & Controls	$0.58 – $1.00	**Minimum** • $0.83 if subsample mass ~0.04g and no extraction required **Maximum** • $20.00 - $25.00 if sample mass ~0.2g and extraction required	**Minimum** • $0.83 – $1.00 if subsample mass ~0.04g and no extraction required **Maximum** • $19.00 – $24.00 if sample mass ~0.2g and extraction required
Reagents & Consumables	$3.50 – $4.00	$4.10 - $10.00	$0.60 – $6.00
Personnel (i) Tester (ii) Reviewer	 $0.78 - $5.00 $1.06 - $10.33	 $2.18 - $10.00 $3.40 - $12.50	 $1.40 – $9.22 $2.17 – $11.44
Preparation, Sanitation, and Disposal	$0.02	$.02	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *Residual Solvent Testing:* **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			**<u>~.04g Subsample Mass</u>** $5.00 – $27.66 **<u>.2g Sample Mass</u>** $23.17 – $44.66

(3.4)(a) Residual Solvent Testing – Method Validation

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)

Method Validation or Annual Method Re-Validation **(Required)**	**Minimum** • $5,585.00 **Mean** • $6,935.00 **Maximum** • $8,285.00	**Minimum** • $5,585.00 **Mean** • $17,792.50 **Maximum** • $30,000.00	**Minimum** • $0.00 **Mean** • $10,857.50 **Maximum** • Without a current cost to support the maximum, the dept. cannot calculate the expected increase to a laboratory's existing cost if they operate within that range.
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% — 50%)(Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	$0.00 if a laboratory is operating within the Minimum, Maximum, or Mean range. Without a current cost to support the maximum, the dept. cannot calculate the expected increase to a laboratory's existing cost if they operate within that range.	$0.00 if a laboratory is operating within the Minimum, Maximum, or Mean range. Without a current cost to support the maximum, the dept. cannot calculate the expected increase to a laboratory's existing cost if they operate within that range.

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

(3.4)(b) Residual Solvent Testing — Instrument Calibration

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Instrument Calibration **Note:** Costs are based on per calibration-	**Frequency** • 2-4 times/yr. **Standards**	**Frequency** • 12 times/yr. **Standards**	**Frequency** • 8-10 more times **Standards**

costs were found to be incalculable per sample. 'Labor' includes preparation, review, and documentation.	• $300.00 **Consumables** • $17.00 **Labor** • $59.00	• $300.00 **Consumables** • $17.00 **Labor** • $59.00	• $2,400.00 – $3,000.00 **Consumables** • $270.00 **Labor** • $1,215.00

The department anticipates cost increases for the laboratories due to the new regulations pertaining to *Residual Solvent Testing*. As previously noted, the expenses and associated work needed to meet the department's regulations will be contingent upon each of the lab's current operations. Laboratories at or near leading scientific benchmarks will not incur expenses as high as those operating further from those standards.

The department recognizes that the proposed rule will impose additional costs to laboratories related to *Residual Solvent Testing* and other fields of testing. In assessing the areas for potential cost mitigations related to *Residual Solvent Testing*, the department fielded requests regarding the removal of the sample mass requirement. The department took the inquiry into consideration but was unable to offer concessions in the matter. The department made this decision because the removal of the sample mass requirement would significantly minimize the scientific integrity and merit of *Residual Solvent Testing*, and through causation, would then reduce laboratory credibility which adversely affects consumer protections.

5. **Pesticide Testing**

Based on discussion, research, and provided feedback between the department and industry, it was determined that laboratories may incur minimal costs related to *Pesticide Testing*.

Current Cost

Cost for two (2) lots of pesticide standards: $1,000.00 - $1,100.00 every ~6 months.

Expected Cost

Due to the small volume of standard required to prepare calibrators and controls, coupled with the compounds' stability after cracking an ampule, the department does not anticipate any of the laboratories to incur costs beyond their current operations and procedures. Additionally, if a laboratory adheres to widely accepted scientific standards calling for weekly—or frequent—pesticide method calibrations, the department does not expect for laboratories to incur any additional costs to comply with the regulations related to *Pesticide Testing* calibration workflow and requirements.

(3.5)(a) Pesticide Testing – Method Validation

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Re-Validation **(Required)**	N/A - Labs are currently not required to re-validate their methods.	$0.00 – $25,000.00	$0.00 – $25,000.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% — 50%)(Full Val.)

Modifying Existing Method or Instrument for Each Matrices	" "	N/A	**Dept. Calculation** **Staff Time:** $250.00 – $2,000.00 (Assuming ~5 — 40 hours @ 50/hr) **New Matrix:** $0.00 – $50.00 **Standards:** $50.00 – $200.00 (Assuming 10 spikes per mod. @ $5.00 - $20.00 per) **Minimum:** $300.00 **Mean:** $1,275.00 **Maximum:** $2,250.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

As previously noted, there will be added costs for the industry to come into compliance, however, the range of expenses and associated work needed to meet the department's regulations will be contingent upon the laboratories' current operations. The department has adopted these regulations with leading scientific industry standards in mind, and thus, laboratories currently operating at or near these benchmarks will not incur as expenses as high as a laboratory operating further way from those standards.

6. Heavy Metals Testing

Through research and collaborative discussion between the department and laboratories, it was determined that laboratories that offer *Heavy Metals* Testing will likely not incur any additional costs beyond their current operations and procedures. Generally, *Heavy Metals Testing* analyses warrant calibration with every batch that is tested. Further, this testing utilizes both stable and inexpensive standards and the number of required compounds is minimal. Thus, a laboratory should not expect to incur any additional or increased costs beyond their current workflow and requirements because of the department's proposed rule language.

7. Microbiological Testing (Culture Method) – Per Sample

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards & Controls	$0.05	$0.05	$0.00
Reagents & Consumables	$2.20	$2.20	$0.00
Personnel (Low Range)			
(i) Tester	$2.50	$2.59	$0.09
	$8.33	$8.62	$0.29
(ii) Reviewer	$2.00	$2.60	$0.60
(iii) Admin/Reporter			
Personnel (High Range)		$2.83	$0.34
(i) Tester	$2.50	$9.03	$0.70

(ii) Reviewer (iii) Admin/Reporter	$8.33 $2.00	$2.00	$0.00
Preparation, Sanitation, and Disposal	$1.50	$1.50	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *Microbiological Testing (Culture Method):* **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$0.98 — $1.04

Based on extensive research and dialogue between the department and laboratories, it was determined that the only noteworthy cost increase relates to an additional 2-3 hours of analyst time per day to capture pictures of all controls and samples. For laboratories testing fifty (50) – eighty (80) samples per day, an expected increase to their existing *Microbiological Testing (Culture Method)* daily costs may range from $52.00 – $78.00, meaning a per sample increase of $0.98 – $1.04.

(3.7)(a) Microbiological Testing (Culture Method) – Method Validation

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Re-Validation **(Required)**	N/A - Labs are currently not required to re-validate their methods.	$1,000.00	$1,000.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%)(Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	N/A – No need to control for matrix interference, and thus, there should be no added cost.	N/A – No need to control for matrix interference, and thus, there should be no added cost.

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

8. **Microbiological Testing (Immunoassay Method) – Per Sample**

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards & Controls	N/A	$2.22	$2.22
Reagents & Consumables	$7.28	$8.88	$1.60
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $3.32 $8.33 $2.00	 $5.25 $12.50 $2.00	 $1.93 $4.17 $0.00
Preparation, Sanitation, and Disposal	$1.00	$5.00	$4.00
Total expected increase to a laboratory's existing cost(s) per sample for *Microbiological Testing (Immunoassay Method):* **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$13.92

Beyond costs that have been identified in the table above, the department, with industry input, has also identified that there may be slight cost increases resulting from the spill and handling instructions. As mentioned previously, should a laboratory's operations be at or near widely accepted scientific benchmarks, the costs incurred from this expense subject should be minimal, if any.

(3.8)(a) Microbiological Testing (Immunoassay Method) – Method Validation

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Re-Validation **(Required)**	N/A - Labs are currently not required to re-validate their methods.	$5,000.00 - $10,000.00	$5,000.00 - $10,000.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%)(Full Val.)

Modifying Existing Method or Instrument for Each Matrices	" "	N/A	$5,000.00 - $10,000.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

As previously noted, there will be added costs for the industry to come into compliance, however, the range of expenses and associated work needed to meet the department's regulations will be contingent upon the laboratories' current operations. The department has adopted these regulations with leading scientific industry standards in mind, and thus, laboratories currently operating at or near these benchmarks will not incur as expenses as high as a laboratory operating further way from those standards.

9. **Microbiological Testing (Polymerase Chain Reaction Method)** – **Per Sample**

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards & Controls	$1.00	$1.00	$0.00
Reagents & Consumables	$25.00	$25.00	$0.00
Personnel			
(i) Tester	$4.50	$4.50	$0.00
(ii) Reviewer	$8.33	$8.33	$0.00
(iii) Admin/Reporter	$2.00	$2.00	$0.00
Preparation, Sanitation, and Disposal	$1.50	$1.50	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *Microbiological Testing (Polymerase Chain Reaction (PCR) Method):* **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$0.00

Based on extensive research and dialogue between the department and industry representatives, it was determined that laboratories will likely not incur any noteworthy cost increases beyond their current operations and procedures related to *Microbiological Testing (Polymerase Chain Reaction (PCR))*.

(3.9)(a) Microbiological Testing (Polymerase Chain Reaction) – Method Validation

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Re-Validation **(Required)**	N/A – Labs are currently not required to re-validate their methods.	$5,000.00	$5,000.00

Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% — 50%)(Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	N/A	N/A

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

(3.10) Mycotoxin Testing (ELISA Method)

The department was unable to gather sufficient data from industry for (1) current costs and (2) perceived costs from the proposed regulations related to *Mycotoxin Testing*. As a result, department staff conducted an independent cost analysis and furnished information to calculate an expected '*Mycotoxin Testing (ELISA Method) Item Costs'*, '*Mycotoxin Testing (ELISA Method) Quality Control Items'*, and *'Researched Costs Relating to Method Validation and Personnel'*.

Utilizing the ELISA Method, the department determined that a laboratory may expect to incur either the following or comparable *Mycotoxin Testing* costs:

Mycotoxin Testing (ELISA Method) Item Costs

Microbial Flower (1g) Testing Item	Cost per Unit	Use per Sample	Total Cost
AgraQuant® Ochratoxin ELISA Test	$3.54	1	$3.54
AgraQuant® Total Aflatoxin ELISA Test	$3.54	1	$3.54
Whirl-Pak® Sterile Sample Bag	$0.29	1	$0.29
Methanol, ACS Reagent	$0.31	3.5	$1.09
Certified Filter Pipette Tip, 1-1000uL	$0.17	0.05	$0.01
Certified Filter Pipette Tip, 1-200uL	$0.14	3	$0.42

Total Testing Item Costs for Mycotoxin Testing (ELISA Method), Per Sample:	$8.89

Mycotoxin Testing (ELISA Method) Quality Control Item Costs

Quality Control Items Positive & Negative Controls	Cost per Unit	Use per Batch	Total Cost
AgraQuant® Ochratoxin ELISA Test	$3.54	7	$24.77
AgraQuant® Total Aflatoxin ELISA Test	$3.54	7	$24.77
Whirl-Pak® Sterile Sample Bags	$0.29	2	$0.57
Methanol, ACS Reagent	$0.31	7	$2.19
Certified Filter Pipette Tip, 1-1000uL	$0.17	0.05	$0.01
Certified Filter Pipette Tip, 1-200uL	$0.14	21	$2.94
Aflatoxin Mix	$18.54	0.000004	$0.0001
10µg/mL Ochratoxin A in Methanol	$38.20	0.000004	$0.0002
Flower Matrix	$6.51	2	$13.02
Total Quality Control Item Costs for Mycotoxin Testing (ELISA Method), Per Batch (20 samples):			$68.28

Department Researched Method Validation & Personnel Costs

Expense Subject	Department Researched Current Cost(s)	Department's Perceived Cost Increase w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Personnel			
(i) Tester	$2.50	$2.75	$0.25
(ii) Reviewer	$8.33	$8.33	$0
(iii) Admin/Reporter	$2.00	$2.00	$0
Department's expected increase to a laboratory's existing cost(s) per sample of *Mycotoxin Testing (ELISA Method)*: This calculation omits the following: (1) Standards & controls costs, (2) reagents & consumables costs, and (3) any other costs associated with preparation, sanitation, and disposal.			$0.25

Note: *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*	

Based on the department's research and cost analysis related to *Mycotoxin Testing (ELISA Method)*, a laboratory may expect a cost increase of $0.25 on top of their existing per sample costs.

(3.10)(a) Mycotoxin Testing (ELISA Method) – Method Validation

Expense Subject	Department Researched Current Cost(s)	Department's Perceived Cost Increase w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Re-Validation **(Required)**	N/A - Labs are currently not required to re-validate their methods.	$1,500.00	$1,500.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%)(Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "		**<u>Dept. Calculation</u>** **Staff Time:** $400.00 – $800.00 (Assuming ~8 - 16 hours @ 50/hr) **Reagents & Consumables:** ~$200.00 **Minimum:** $600.00 **Mean:** $800.00 **Maximum:** $1,000.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103 (32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *Method Validation* figures are estimates based on the laboratories' varying operational levels.

If a method validation is needed for *Mycotoxin Testing (ELISA Method)*, laboratories may also expect to incur an additional $1,500.00 expense.

Throughout the discussions with the impacted laboratories, it was expressed that most increases in costs related to testing samples would be passed on to the growers (clients) submitting samples for testing. This increase in price to test samples could potentially result in loss of sales or revenue. As previously discussed, laboratories that are further away from operating under typical industry standards would experience greater increases to their

operating costs and could also potentially experience the largest loss in sales and revenue as customers naturally tend to seek out the most cost-effective ways to operate their businesses.

SECTION 4:

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

Based on the data provided in Section 3, the proposed rule may 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 and meet these new accreditation requirements. 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.

Through assessments, surveys, and meetings, the department determined that laboratories currently have all the necessary instruments to provide their currently offered services. Businesses may have more than minor costs imposed on them even 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).

With per test method validations ranging from $1000.00 – $30,000.00, it is also likely that this is an area where businesses will exceed the minor cost threshold. Similarly, annual instrument calibrations range from $3,000.00 – $30,000.00, and thus would cause a business to exceed the minor cost threshold.

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 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: Summary of potential cost increases in relation to 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 the department, it was determined that all eight laboratories currently providing cannabis testing are considered small businesses with fewer than 50 employees.

Since there are no large businesses offering cannabis testing services in Washington, the department 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 for 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.

Additionally, the proposed rule allows for laboratories to engage in a method approval process should they deem that the methods provided by the department are uneconomical, or more expensive to validate than using their pre-existing methods. In essence, this allows for laboratories to submit their current methods to the department—as it relates to the fields of testing described herein—and be notified whether their submitted method is acceptable or not.

Moreover, the amended proposed rule now allows for laboratories to potentially waive the academic requirements listed in WAC 16-309-050 through 16-309-070, which would presumably eliminate the need to hire additional staff. The academic requirement waivers are assessed by the accrediting authority on a case-by-case basis and are intended for a laboratory's current employee(s) that already function as a highly experienced analyst.

Further, the department decided to remove the refrigeration requirement listed under WAC 16-309-090. This decision may reduce the need for some of the laboratories to purchase new equipment, so long as laboratories test the sample(s) they are in receipt of before seven days have elapsed. Laboratories that we talked to were already testing their samples below the seven-day mark, and therefore would receive the benefit of this change.

Lastly, laboratories may now run a customer sample in duplicate to replace the matrix spike duplicate. Laboratories would still incur typical costs for running the customer sample—that is, costs for methanol, injection, etc.—but would be able to forego the matrix spike duplicate requirement and only need to spike one matrix per batch.

b. *Simplifying, reducing, or eliminating recordkeeping and reporting requirements* –

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 the department sets and adopts the standards for accreditation, the current accrediting authority is responsible for compliance and enforcement of the standards. Delaying the compliance timetables is outside this rulemaking's scope. If the department becomes the accrediting authority, it plans to issue a separate policy statement delaying enforcement of these requirements until December 31, 2024.

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 laboratories 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.

Through informed research and analysis, the department has considered all suggested cost mitigations for laboratories as it relates to the proposed rule. All cost mitigation requests reviewed by the department were both thoroughly analyzed and discussed by the interagency team. For inquiries that could not be put into effect, the department made these decisions by determining that their amendments and/or removal would significantly minimize the scientific integrity and merit of the cannabis testing laboratory quality standards. The department further determined that some of the requests would reduce laboratory credibility, which then negatively affects consumer protections and lowers the public's overall trust in government.

SECTION 7:
Describe how small businesses were involved in the development of the proposed rule.

The department facilitated several opportunities for small businesses to be involved in the rule making process. Before creation of the first draft of the proposed rule, the department arranged for meetings with all the laboratories as indicated in Table 1. The department shared the first draft of the rule with all eight impacted 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. The department arranged a video conference call with all eight impacted laboratories to discuss their feedback. The department revised the proposed rule to create a second draft and documented the changes made in a separate secondary document. The department shared the second draft of the proposed rule and secondary document with all eight impacted laboratories, asking for additional feedback. The department revised the second draft based on the feedback and has created a third and final version of the proposed rule amendment.

Based on the comments received during the public comment period and the public hearing held on December 28th, 2023, the department determined that substantive changes were necessary to the proposed rule language to address the concerns that were provided. Over the following month, the department held one-on-one meetings with the heavily engaged laboratories. Following this round of meetings to solicit feedback from laboratories regarding the current regulations and cost implications, the department then decided to hold an open Q&A forum for laboratory representatives to voice any final concerns.

Table 1 - Stakeholder Engagement Interactions

Meeting with	Meeting Venue	Date	Discussion
Medicine Creek Analytics	In-Person	Thursday, February 2nd, 2023	Introduction to CLASP and next steps for lab standards.
Green Growers Labs	In-Person	Wednesday, February 22nd, 2023	Introduction to CLASP and next steps for lab standards.
True Northwest, Inc.	In-Person	Tuesday, April 4th, 2023	Concerns with current cannabis laboratory regulations.
Integrity Labs	In-Person	Tuesday, April 11th, 2023	Concerns with current cannabis laboratory regulations.
Treeline Analytics, LLC.	In-Person	Friday, May 5th, 2023	Introduction to CLASP and next steps for lab standards.
Capitol Analysis	Phone call	Friday, May 12th, 2023	Concerns with current cannabis laboratory regulations.
Testing Technologies, Inc.	Phone Call	Friday, May 26th, 2023	Concerns with current cannabis laboratory regulations.
Confidence Analytics	Phone Call	Friday, May 26th, 2023	Concerns with current cannabis laboratory regulations.
All laboratories	Outbound Email	Thursday, June 22nd, 2023	Requesting feedback on draft rule, inviting to video conference.
All Laboratories	Video conference	Wednesday, June 28th, 2023	Requesting feedback on draft rule.
Treeline Analytics, LLC.	Inbound email	Monday, July 3rd, 2023	Response and comments on first draft.
True Northwest, Inc.	Inbound Email	Wednesday, July 5th, 2023	Response and comments on first draft.
Medicine Creek Analytics	Inbound Email	Thursday, July 6th, 2023	Response and Comments on first draft.
Capitol Analysis	Inbound Email	Friday, July 7th, 2023	Response and comments on first draft.
All laboratories	Outbound email	Friday, July 21st, 2023	Sent second draft of rules and responses to original questions and concerns.
Integrity Labs	Inbound Email	Wednesday, July 26th, 2023	Response and comments on second draft.
Treeline Analytics, LLC.	Inbound Email	Friday, July 28th, 2023	Response and comments on second draft.
Confidence Analytics	Inbound Email	Friday, July 28th, 2023	Response and comments on second draft.
Capitol Analysis	Inbound Email	Thursday, August 10th, 2023	Follow up question on rule section.

Treeline Analytics, LLC.	Video Conference	Friday, January 26th, 2024	Concerns with current cannabis laboratory regulations/cost implications.
Medicine Creek Analytics	Video Conference	Wednesday, January 31st, 2024	Concerns with current cannabis laboratory regulations/cost implications.
Confidence Analytics	Video Conference	Thursday, February 1st, 2024	Concerns with current cannabis laboratory regulations/cost implications.
All laboratories invited	Video Conference	Monday, February 5th, 2024 10 a.m.	Feedback / Q&A Session.
All laboratories invited	Video Conference	Monday, February 5th, 2024 2 p.m.	Feedback / Q&A Session.

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 personnel hours. If laboratories need to hire one additional person to meet the requirements, then the proposed rule amendment may create up to eight new jobs.

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

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Date: 02/21/2024	**Signature:** 
Name: Jessica Allenton	
Title: Assistant Director	