



Washington State
Liquor and Cannabis Board

Date: September 30, 2020

To: Jane Rushford, Board Chair
Ollie Garrett, Board Member
Russ Hauge, Board Member

From: Kathy Hoffman, Policy and Rules Manager

Copy: Rick Garza, Agency Director
Megan Duffy, Deputy Director
Justin Nordhorn, Chief of Enforcement
Becky Smith, Licensing Director

Subject: **WAC 314-55-101 – Quality assurance sampling protocols; WAC 314-55-102 – Quality assurance testing (effective until July 31, 2021); New Section WAC 314-55-1011 (Effective August 1, 2021); WAC 314-55-102 – Quality assurance testing (effective until July 31, 2021); New Section WAC 314-55-1021 – Quality Assurance and Quality Control (Effective August 1, 2021 until January 31, 2022); New Section WAC 314-55-1022 – Quality Assurance and Quality Control (Effective February 1, 2022); and WAC 314-55-1025 – Proficiency testing.**

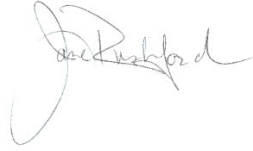
The Policy and Rules Manager requests approval to file a supplemental rule proposal (CR 102) for the rule making described in the supplemental CR 102 Memorandum attached to this order and presented at the Board meeting on September 30, 2020.

If approved for filing, the tentative timeline for this rule proposal is as follows:

September 30, 2020	Board is asked to approve filing the proposed rules (CR 102 filing).
October 21, 2020	Code Reviser publishes notice.
November 18, 2020	End of formal comment period.
November 18, 2020	Public hearing held.
January 6, 2021	Board is asked to adopt rules.
January 6, 2021	Agency sends notice to those who commented both at the public hearing and in writing.
January 6, 2021	Agency files adopted rules with the Code Reviser (CR 103)
February 6, 2021	Rules are effective consistent with RCW 34.05.380(2) (WAC 314-55-101; WAC 314-55-102 (effective until July 31, 2022); WAC 314-55-1025

August 1, 2021	WAC 314-55-1011 becomes effective; WAC 314-55-1021 becomes effective (until January 31, 2022)
February 1, 2022	WAC 314-55-1022 becomes effective.

☒ Approve ☐ Disapprove



Jane Rushford, Chair

9.30.2020
Date

☒ Approve ☐ Disapprove



Ollie Garrett, Board Member

9.30.2020
Date

☒ Approve ☐ Disapprove



Russ Hauge, Board Member

9.30.2020
Date

Attachments: Supplemental CR 102 Memorandum
Significant Analysis
Small Business Economic Impact Statement



Supplemental CR 102 Memorandum

Regarding WAC 314-55-101 – Quality assurance sampling protocols; WAC 314-55-102 – Quality assurance testing (effective until July 31, 2021); New Section WAC 314-55-1011 (Effective August 1, 2021); WAC 314-55-102 – Quality assurance testing (effective until July 31, 2021); New Section WAC 314-55-1021 – Quality Assurance and Quality Control (Effective August 1, 2021 until January 31, 2022); New Section WAC 314-55-1022 – Quality Assurance and Quality Control (Effective February 1, 2022); and WAC 314-55-1025 – Proficiency testing.

Date: September 30, 2020
Presented by: Kathy Hoffman, Policy and Rules Manager

Description of the Issue

In early 2018, several stakeholders, including medical marijuana patients, consumers, and licensees, urged WSLCB to require producers and processors to test recreational crops for pesticides and heavy metals. These partners asserted that such a move, already adopted in other states, would inspire confidence among consumers, increase access to medically compliant products, and bolster sales. In August 2018, the WSLCB began the initial stages of rule development regarding marijuana quality control and product requirements. Among the rule changes being considered was whether all marijuana products be tested for pesticides and heavy metals because neither test is required for recreational products.

As of the time of this analysis, there is currently one marijuana testing lab in Washington State capable of testing products for the full suite of I-502 tests, along with pesticides and heavy metals. There are currently a total of five labs capable of testing for the full suite of I-502 tests, plus with pesticides.

Marijuana grows operate on a wide spectrum of sophistication. Some grows are tightly controlled in technologically advanced indoor facilities; plants are grown in climate-controlled chambers where every aspect of the plant's cultivation is monitored. Other grows are comparatively "low tech," set outdoors and dependent on seasonable cycles. Which growth model a licensed producer chooses – either indoors or outdoors – is entirely a business decision of the licensee. Similarly, the variety of tests an accredited marijuana testing laboratory offers is entirely a business decision of the laboratory.

Marijuana cultivation, both indoor and outdoor, is associated with a variety of pests, bacteria, and fungi. Producers have used a wide variety of pesticides to

reduce insect infestation. Pesticide misuse poses serious health risks to consumers, and exposure can result in a variety of well-documented symptoms, such as difficulty breathing, abdominal pain, vomiting, dizziness, and muscle cramps. Additionally, some pesticides have been found to be carcinogenic (Taylor & Birkett, 2019).

Emerging literature and multiple studies, both nationally and globally, indicate that marijuana and marijuana products can become contaminated and must be tested to protect public health (Feldman, 2015; Subritzky, Pettigrew & Lenton, 2017; Feldman, 2015; Craven et. al., 2019; Seltenrich, 2019). Marijuana and its products can be contaminated with microbiological contaminants, such as mold or salmonella, potentially hazardous growth enhancers, and heavy metals such as chromium and lead. While marijuana in any form may be prone to contamination, extracts and concentrates may present a greater risk because any contaminants will become concentrated during processing (Seltenrich, 2019). To protect consumers against exposure to pesticides, solvents, and other contaminants, marijuana and marijuana products must be tested to ensure they are safe for human consumption.

Need for Supplemental Proposal

A public hearing was on the initial rule proposal for this project was held on July 8, 2020 consistent with WSR 20-12-026. After review of comments received, WSLCB made substantive revisions to the proposal that require an additional public hearing.

Rule Necessity

Rules are needed for the following reasons:

Current testing requirements for recreational marijuana are intended to ensure that products for sale are safe and have accurate potency levels. However, Washington state recreational marijuana products are not required to be tested for pesticides and heavy metals, and although not precluded from doing so, many producers and processors do not test for either. Based on a number of elements, including consumer concern and national best practices, it has become evident that standardized testing for *all* marijuana products produced, processed, and sold in Washington State is necessary. *Washington State is the only state with both recreational and medical programs that does not require such testing for all products.*

There is no guidance available to the WSLCB or any other state agency regulating marijuana from federal agencies who set standards for agriculture, food, and other products because marijuana remains classified as a Schedule I drug, and federally illegal. This presents regulatory challenges to the WSLCB, regulators throughout the country, and the industry since there is limited funding

to support research on how marijuana tainted with potential toxins affects humans. However, while the possible health impact of consuming marijuana products with unapproved pesticides is an emerging area of research, the overarching goal of the WSLCB is to protect public health and safety, and to assure that all products sold within the I-502 market are safe for all consumers.

Recently, concern around the composition and safety of marijuana concentrates for inhalation has highlighted the need to assure that all marijuana products are tested for the presence of harmful compounds and other contaminants. The proposed rule amendments and phase-in plan offer a reasonable time frame that provides both licensees and accredited labs the opportunity to adjust business models where necessary, and offers options to prepare for additional fields of testing either immediately or over an extended, but finite period of time.

Additionally, these revisions to quality control rules provide public benefit at a time when public safety is not only critical, but necessary. As of September 25, 2020, the CoronaVirus Disease 2019, or COVID-19 respiratory illness has resulted in 2,175 deaths in Washington State alone, and over 200,000 deaths nationally. Assuring that all marijuana product aligns with stringent product quality standards supports efforts to increase consumer protection when it is most needed to align with ongoing statewide public safety and harm reduction efforts. WSLCB's mission is to promote public safety through trust and fair administration of enforcement of liquor, cannabis, tobacco and vapor laws. This proposal not only promotes, but supports currently public safety efforts by assuring that all product entering the I-502 marketplace is safe for human consumption when it is needed most. This greater public benefit of safe, appropriately tested marijuana product outweighs compliance costs.

These new rule sections and amendments, in addition to proposed technical and clarifying revisions support the overarching agency goal of ensuring the highest level of public safety by continually improving and enforcing regulations that reflect the current, dynamic regulatory environment.

Description of Rule Changes

Amended Section. WAC 314-55-101 (Effective through July 31, 2021) – Reaffirms existing protocols designed to reduce, where possible, product contamination during and after sample reduction. Retains five-pound lot size for sample collection. Updates, reorganizes and streamlines rule language where appropriate to assure scientific accuracy.

New Section. WAC 314-55-1011 (Effective August 1, 2021) – Reaffirms existing protocols designed to reduce, where possible, product contamination during and after sample reduction. Increase five-pound lot size to

ten-pound lot size for sample collection. Updates, reorganizes and streamlines rule language where appropriate to assure scientific accuracy.

Amended Section. WAC 314-55-102 (Effective until July 31, 2021) – Reaffirms existing protocols, and updates reorganizes, and streamlines rule language where appropriate to assure scientific accuracy. Adds allowance for terpene testing.

New Section. WAC 314-55-1021 (Effective August 1, 2021 until January 31, 2022) – Will replace WAC 314-55-102 by adding pesticide testing requirement to the list of quality control tests for all marijuana products.

New Section. WAC 314-55-1022 (Effective February 1, 2022) - Will replace WAC 314-55-1021 by adding heavy metals testing requirement to the list of quality control tests for all marijuana products.

Amended Section. WAC 314-55-1025- Updates language to include “board” where appropriate consistent with statutory reference.

References

- Craven, C. B., Wawryk, N., Jiang, P., Liu, Z. & Li, X.-F. (2019). Pesticides and trace elements in cannabis: Analytical and environmental challenges and opportunities. *Journal of Environmental Sciences*, 85, 82–93. doi: 10.1016/j.jes.2019.04.028.
- Feldman, J. (2014). Pesticide Uses in Marijuana Production. *Beyond Pesticides*, 34(4).
- Seltenrich, N. (2019). Cannabis Contaminants: Regulating Solvents, Microbes, and Metals in Legal Weed. *Environmental Health Perspectives*, 127(8), 082001. doi: 10.1289/ehp5785.
- Seltenrich, N. (2019). Into the Weeds: Regulating Pesticides in Cannabis. *Environmental Health Perspectives*, 127(4), 042001. doi: 10.1289/ehp5265.
- Subritzky, T., Pettigrew, S. & Lenton, S. (2017). Into the void: Regulating pesticide use in Colorado's commercial cannabis markets. *International Journal of Drug Policy*, 42, 86–96. doi: 10.1016/j.drugpo.2017.01.014.
- Taylor, A. & Birkett, J. W. (2019). Pesticides in cannabis: A review of analytical and toxicological considerations. *Drug Testing and Analysis*. doi: 10.1002/dta.2747.



PROPOSED RULE MAKING

CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

CODE REVISER USE ONLY

Agency: Washington State Liquor and Cannabis Board

☒ **Original Notice**

☒ **Supplemental Notice to WSR 20-12-026**

☐ **Continuance of WSR _____**

☒ **Preproposal Statement of Inquiry was filed as WSR 18-17-041 ; 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) WAC 314-55-101 – Quality assurance sampling protocols (Effective until July 31, 2021) New Section WAC 314-55-1011 (Effective August 1, 2021); WAC 314-55-102 – Quality assurance testing (effective until July 31, 2021); New Section WAC 314-55-1021 – Quality Assurance and Quality Control (Effective August 1, 2021 until January 31, 2022); New Section WAC 314-55-1022 – Quality Assurance and Quality Control (Effective February 1, 2022); and WAC 314-55-1025 – Proficiency testing. The Washington State Liquor and Cannabis Board (Board) proposes amendments and new sections to current marijuana product testing standards that would require the addition of pesticide and heavy metal testing for all marijuana products produced, processed, and sold in Washington State.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
November 18, 2020	10:00 am	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the Board will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington state. A virtual public hearing, without a physical meeting space, will be held instead. Board members, presenters, and staff will all participate remotely. The public may login using a computer or device, or call-in using a phone, to listen to the meeting through the WebEx application. The public may provide verbal comments during the specified public comment and rules hearing segments.	For more information about board meetings, please visit https://lcb.wa.gov/boardmeetings/board_meetings

Date of intended adoption: January 6, 2021 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Katherine Hoffman

Address: 1025 Union Avenue, Olympia, WA 98501

Email: rules@lcb.wa.gov

Fax: 360-664-9689

Other:

By (date) November 18, 2020

Assistance for persons with disabilities:

Contact Clariss Nhanabu, ADA Coordinator, Human Resources

Phone: 360-664-1642
Fax: 360-664-9689
TTY: 7-1-1 or 1-800-833-6388
Email: Claris.Nhanabu@lcb.wa.gov
Other:
By (date) November 11, 2020

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed rule amendments revise and update current marijuana quality assurance sampling protocols described in WAC 314-55-101, and marijuana proficiency testing described in WAC 314-55-1025.

This proposal provides that as of August 2021, sample collection for flower lots would increase from five pounds to ten pounds. It also provides that in addition to the currently required suite of tests, all marijuana products produced, processed, and sold in Washington State be tested for pesticides as of August 2021, and heavy metals as of February 2022. If adopted, these revisions would be accomplished by revising and updating existing WAC 314-55-101 and WAC 314-55-102 by way of a phase-in plan, as follows:

- On August 1, 2021, WAC 314-55-101 would be repealed, and WAC 314-55-1011 would become effective, replacing the five pound lot size with a ten pound lot size.
- On August 1, 2021, WAC 314-55-102 would be repealed, and WAC 314-55-1021 would become effective until January 31, 2022, adding pesticide testing to the current suite of required product testing for all marijuana products produced and sold in Washington State.
- Finally, on January 31, 2022, WAC 314-55-1021 would be repealed, and effective February 1, 2022, WAC 314-55-1022 would become effective, requiring both pesticides *and* heavy metals to the current suite of required product testing for all marijuana products produced and sold in Washington State.

As a technical matter, this proposal renames and more appropriately refers to marijuana *quality control* sampling protocols and marijuana *quality control* and assurance testing standards. While quality control is a set of activities designed to evaluate a product, quality assurance pertains to activities that are designed to ensure that a *process* is adequate and the system meets its objectives. In contrast, quality control focuses on finding defects or anomalies in a product or deliverable, and checks whether defined requirements are the right requirements. Testing is one example of a quality control activity, but there are many more such activities that make up quality control. For these reasons, this proposal renames these sections.

Other proposed revisions include streamlined, clarified language; section reorganization to increase readability, along with reduction and removal of passive language where appropriate.

Reasons supporting proposal: Current testing requirements for recreational marijuana are intended to ensure that products for sale are safe and have accurate potency levels. However, Washington state recreational marijuana products are not required to be tested for pesticides and heavy metals, and although not precluded from doing so, many producers and processors do not test for either. Based on a number of elements, including consumer concern and national best practices, it has become evident that standardized testing for *all* marijuana products produced, processed, and sold in Washington State is necessary. Washington State is the only state with both recreational and medical programs that does not require such testing for all products.

There is no guidance available to the WSLCB or any other state agency regulating marijuana from federal agencies who set standards for agriculture, food, and other products because marijuana remains classified as a Schedule I drug, and federally illegal. This presents regulatory challenges to the WSLCB, regulators throughout the country, and the industry since there is limited funding to support research on how marijuana tainted with potential toxins affects humans. However, while the possible health impact of consuming marijuana products with unapproved pesticides is an emerging area of research, the overarching goal of the WSLCB is to protect public health and safety, and to assure that all products sold within the I-502 market are safe for all consumers.

A public hearing was on the initial rule proposal for this project was held on July 8, 2020 consistent with WSR 20-12-026. After review of comments received, WSLCB made substantive revisions to the proposal that require an additional public hearing.

Statutory authority for adoption: RCW 69.50.345 and RCW 69.50.348.

Statute being implemented: RCW 69.50.345 and RCW 69.50.348

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			
Name of proponent: (person or organization) Washington State Liquor and Cannabis Board		<input type="checkbox"/> Private <input type="checkbox"/> Public <input checked="" type="checkbox"/> Governmental	
Name of agency personnel responsible for:			
	Name	Office Location	Phone
Drafting:	Katherine Hoffman, Policy and Rules Manager	1025 Union Avenue, Olympia WA, 98501	360-664-1622
Implementation:	Kendra Hodgson, Marijuana Examiners Unit Manager	1025 Union Avenue, Olympia, WA. 98501	360-664-4555
Enforcement:	Justin Nordhorn, Chief of Enforcement	1025 Union Avenue, Olympia, WA, 98501	360-664-1726
Is a school district fiscal impact statement required under RCW 28A.305.135?			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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?			
<input checked="" type="checkbox"/> Yes: A preliminary cost-benefit analysis may be obtained by contacting: Name: Katherine Hoffman Address: 1025 Union Avenue, Olympia WA 98502 Phone: 360-664-1622 Fax: 360-664-9689 TTY: Email: rules@lcb.wa.gov Other:			
<input type="checkbox"/> No: Please explain:			
Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:			
This rule proposal, or portions of the proposal, may be exempt from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):			
<input type="checkbox"/> 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:			
<input type="checkbox"/> 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.			
<input type="checkbox"/> 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:
- | | |
|---|--|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input checked="" type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input type="checkbox"/> 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): WAC 314-55-1025.
Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If 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 analysis showing how costs were calculated.
- ☒ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

What is the scope of the rule package?

Compliance with the proposed, specific requirements described WAC 314-55-1011, WAC 314-55-102, WAC 314-55-1021, and WAC 314-55-1022 will likely result in additional compliance costs. This includes the incremental, phased-in requirement to test all marijuana products for pesticides and heavy metals. The remainder of the rule revisions are exempt.

Which businesses are impacted by the proposed rule package? What was their North American Industry Classification (NAICS) code or codes? What are their minor cost thresholds?

The NAICS code, business description, and minor cost thresholds are described and calculated below in two tables, representing monthly and annual costs, since these result in two outcomes: Table 1 indicates that the monthly cost of compliance does not exceed minor cost thresholds, and Table 2 indicates that the annual cost of compliance exceeds minor cost thresholds:

Table 1

2017 Industry NAICS Code	Estimated <u>Monthly</u> Cost of Compliance	Industry Description	NAICS Code Title	Minor Cost Estimate - Max of 1%Pay, 0.3%Rev, and \$100	1% of Avg Annual Payroll . (0.01*AvgPay)	0.3% of Avg Annual Gross Business Income (0.003*AvgGBI)
111 ¹	\$ 3,450	Marijuana Producers	Crop Production	\$4,082.13	\$4,082.13 2018 Dataset pulled from ESD	\$2,993.38 2018 Dataset pulled from DOR
312 ²	\$ 3,450	Marijuana Processors	Beverage and Tobacco Product Manufacturing	\$5,766.61	\$5,342.91 2018 Dataset pulled from ESDS	\$5,766.61 2018 Dataset pulled from DOR

¹ 111 Crop Production

Industries in the Crop Production subsector grow crops mainly for food and fiber. The subsector comprises establishments, such as farms, orchards, groves, greenhouses, and nurseries, primarily engaged in growing crops, plants, vines, or trees and their seeds.

² 312 Beverage and Tobacco Product Manufacturing

Industries in the Beverage and Tobacco Product Manufacturing subsector manufacture beverages and tobacco products. The Tobacco Manufacturing industry group includes two types of establishments: (1) those engaged in redrying and stemming tobacco and (2) those that manufacture tobacco products, such as cigarettes and cigars.

Table 2

2017 Industry NAICS Code	Estimated <u>Annual</u> Cost of Compliance	Industry Description	NAICS Code Title	Minor Cost Estimate - Max of 1%Pay, 0.3%Rev, and \$100	1% of Avg Annual Payroll . (0.01*AvgPay)	0.3% of Avg Annual Gross Business Income (0.003*AvgGBI)
111	\$ 41,400	Marijuana Producers	Crop Production	\$4,082.13	\$4,082.13 2018 Dataset pulled from ESD	\$2,993.38 2018 Dataset pulled from DOR
312	\$ 41,400	Marijuana Processors	Beverage and Tobacco Product Manufacturing	\$5,766.61	\$5,342.91 2018 Dataset pulled from ESDS	\$5,766.61 2018 Dataset pulled from DOR

Does the rule have a disproportionate impact on small businesses?

In particular, in order to calculate annual costs, we require information on a per entity basis describing the number of samples being tested per year. While we have some limited anecdotal information on the numbers of samples tested per year by individual producer/processors, we lack information on the myriad business models that could lead to a wide range in the number of samples tested per year, and thus a wide range of per entity compliance costs per year. Developing reliable estimates would require a comprehensive survey with a *reasonable* response rate, and even then, given the wide variability of business models and documented inconsistency in responses from licensees, per entity costs is difficult to determine.

Did the agency make an effort to reduce the impact of the rule?

The proposed rule changes include provisions that are intended to reduce the compliance costs for small businesses. These include:

- An increase in lot size from five pounds to ten pounds;
- An incremental phase-in period that contemplates full compliance by February 1, 2022; and
- Allowing labs to subcontract pesticide and heavy metals testing for a period of time.

It is difficult to accurately assess if small businesses will be disproportionately impacted by this rule proposal when there is both significant overlap and variance between the groups evaluated. As noted above, and throughout this SBEIS, most of the businesses impacted are small as defined by RCW 19.85.030.

Did the agency involve small businesses in the rule development process?

Throughout the rule development process, the WSLCB has engaged with businesses likely to be affected by the rule, and who volunteered to participate in the process. To support development of the SBEIS, a subset of six producer/processors spanning a range of both tiers and types of producers was contacted; interviews were conducted with two producers, one processor, and one producer/processor. In addition, interviews were conducted with three testing laboratories. Additional opportunity for public comment will be available when the proposed rule is published. Indoor and outdoor farmers, including sun growers, were included in the interviews.

During the rule development process, the WSLCB hosted two “Listen and Learn” sessions, one in April 2019 and the second in August 2019, inviting industry discussion and feedback on the proposed rules, and discuss potential mitigation strategies. The WSLCB’s stakeholder process encouraged interested parties and industry partners to:

- Identify burdensome areas of existing and proposed rules;
- Proposed initial or draft rule changes; and
- Refine those changes.

Although the WSLCB broadly messaged these sessions (messaging went directly to *all* licensees, as well as over 10,000 GovDelivery subscribers), few processors and producers attended the sessions. This rule project was the first employing the “Listen and Learn” model, and attendees were initially unfamiliar with not only the model, but the process, although detailed agendas were provided well in advance of each meeting.

These heavily facilitated sessions followed two thought streams: the first asked attendees to review draft conceptual rules offered well in advance of the meeting and provide feedback or specific rule language, specifically indicating what they liked, didn’t like, and what they proposed in the way of a solution. No rule language revisions were offered by attendees at either session. Solutions ranged from suggesting that figures and language be more concise in general without offering example, to unsupported assertions that adding pesticides and heavy metals to the suite of required tests would put certain producers out of business.

All comments received during these sessions were curated to the extent possible, although developing themes from sessions was difficult based on the broad range of comments. The proposed rules went through several stages of edits, review, discussion, and then further refinement before arriving at the initial proposal. The end result of this process are proposed rules that are offered as a framework and guidance for testing marijuana products that supports the overarching WSLCB goal of public health and safety.

A summary of the description of issues related to the proposed rule set and how the agency collaborated with stakeholders and industry partners to mitigate potential burden associated with rule compliance is more fully described in the Significant Analysis prepared consistent with RCW 34.05.328, including a phase-in plan, and offered as part of this initial rule proposal.

Will businesses have to hire or fire employees because of the requirements in the rule?

While the impacts to individual producer processors may depend on their ability to pass on increased testing costs (in the form of higher prices to retailers), the proposed rule is not expected to affect the amount of marijuana produced. Thus, the proposed rule is unlikely to affect the overall number of employees of producer/processors or retailers. For example, if increased testing costs lead some smaller entities to cease production, other entities may produce larger volumes. While it would be an indirect effect, the proposed rule may result in some limited additional employment in the labs conducting testing. In order to conduct the testing, a lab adding this testing capability may need to hire one or two additional scientists or technicians to operate equipment and conduct tests. The extent of potential employment gains are uncertain, but given the small number of labs in the industry (currently 13 certified labs) any employment gains would likely be limited.

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

Name: Katherine Hoffman

Address: 1025 Union Avenue, Olympia, WA 98501

Phone: 360-664-1622

Fax: 360-664-9689

TTY:

Email: rules@lcb.wa.gov

Other:

Date: September 30, 2020

Name: Jane Rushford

Title: Chair

Signature:



PROPOSED RULE MAKING

CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

CODE REVISER USE ONLY

Agency: Washington State Liquor and Cannabis Board

☒ **Original Notice**

☒ **Supplemental Notice to WSR 20-12-026**

☐ **Continuance of WSR _____**

☒ **Preproposal Statement of Inquiry was filed as WSR 18-17-041 ; 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) WAC 314-55-101 – Quality assurance sampling protocols (Effective until July 31, 2021) New Section WAC 314-55-1011 (Effective August 1, 2021); WAC 314-55-102 – Quality assurance testing (effective until July 31, 2021); New Section WAC 314-55-1021 – Quality Assurance and Quality Control (Effective August 1, 2021 until January 31, 2022); New Section WAC 314-55-1022 – Quality Assurance and Quality Control (Effective February 1, 2022); and WAC 314-55-1025 – Proficiency testing. The Washington State Liquor and Cannabis Board (Board) proposes amendments and new sections to current marijuana product testing standards that would require the addition of pesticide and heavy metal testing for all marijuana products produced, processed, and sold in Washington State.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
November 18, 2020	10:00 am	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the Board will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington state. A virtual public hearing, without a physical meeting space, will be held instead. Board members, presenters, and staff will all participate remotely. The public may login using a computer or device, or call-in using a phone, to listen to the meeting through the WebEx application. The public may provide verbal comments during the specified public comment and rules hearing segments.	For more information about board meetings, please visit https://lcb.wa.gov/boardmeetings/board_meetings

Date of intended adoption: January 6, 2021 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Katherine Hoffman

Address: 1025 Union Avenue, Olympia, WA 98501

Email: rules@lcb.wa.gov

Fax: 360-664-9689

Other:

By (date) November 18, 2020

Assistance for persons with disabilities:

Contact Clariss Nhanabu, ADA Coordinator, Human Resources

Phone: 360-664-1642
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Other:
By (date) November 11, 2020

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed rule amendments revise and update current marijuana quality assurance sampling protocols described in WAC 314-55-101, and marijuana proficiency testing described in WAC 314-55-1025.

This proposal provides that as of August 2021, sample collection for flower lots would increase from five pounds to ten pounds. It also provides that in addition to the currently required suite of tests, all marijuana products produced, processed, and sold in Washington State be tested for pesticides as of August 2021, and heavy metals as of February 2022. If adopted, these revisions would be accomplished by revising and updating existing WAC 314-55-101 and WAC 314-55-102 by way of a phase-in plan, as follows:

- On August 1, 2021, WAC 314-55-101 would be repealed, and WAC 314-55-1011 would become effective, replacing the five pound lot size with a ten pound lot size.
- On August 1, 2021, WAC 314-55-102 would be repealed, and WAC 314-55-1021 would become effective until January 31, 2022, adding pesticide testing to the current suite of required product testing for all marijuana products produced and sold in Washington State.
- Finally, on January 31, 2022, WAC 314-55-1021 would be repealed, and effective February 1, 2022, WAC 314-55-1022 would become effective, requiring both pesticides *and* heavy metals to the current suite of required product testing for all marijuana products produced and sold in Washington State.

As a technical matter, this proposal renames and more appropriately refers to marijuana *quality control* sampling protocols and marijuana *quality control* and assurance testing standards. While quality control is a set of activities designed to evaluate a product, quality assurance pertains to activities that are designed to ensure that a *process* is adequate and the system meets its objectives. In contrast, quality control focuses on finding defects or anomalies in a product or deliverable, and checks whether defined requirements are the right requirements. Testing is one example of a quality control activity, but there are many more such activities that make up quality control. For these reasons, this proposal renames these sections.

Other proposed revisions include streamlined, clarified language; section reorganization to increase readability, along with reduction and removal of passive language where appropriate.

Reasons supporting proposal: Current testing requirements for recreational marijuana are intended to ensure that products for sale are safe and have accurate potency levels. However, Washington state recreational marijuana products are not required to be tested for pesticides and heavy metals, and although not precluded from doing so, many producers and processors do not test for either. Based on a number of elements, including consumer concern and national best practices, it has become evident that standardized testing for *all* marijuana products produced, processed, and sold in Washington State is necessary. Washington State is the only state with both recreational and medical programs that does not require such testing for all products.

There is no guidance available to the WSLCB or any other state agency regulating marijuana from federal agencies who set standards for agriculture, food, and other products because marijuana remains classified as a Schedule I drug, and federally illegal. This presents regulatory challenges to the WSLCB, regulators throughout the country, and the industry since there is limited funding to support research on how marijuana tainted with potential toxins affects humans. However, while the possible health impact of consuming marijuana products with unapproved pesticides is an emerging area of research, the overarching goal of the WSLCB is to protect public health and safety, and to assure that all products sold within the I-502 market are safe for all consumers.

A public hearing was on the initial rule proposal for this project was held on July 8, 2020 consistent with WSR 20-12-026. After review of comments received, WSLCB made substantive revisions to the proposal that require an additional public hearing.

Statutory authority for adoption: RCW 69.50.345 and RCW 69.50.348.

Statute being implemented: RCW 69.50.345 and RCW 69.50.348

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			
Name of proponent: (person or organization) Washington State Liquor and Cannabis Board		<input type="checkbox"/> Private <input type="checkbox"/> Public <input checked="" type="checkbox"/> Governmental	
Name of agency personnel responsible for:			
	Name	Office Location	Phone
Drafting: Rules Manager	Katherine Hoffman, Policy and	1025 Union Avenue, Olympia WA, 98501	360-664-1622
Implementation: Examiners Unit Manager	Kendra Hodgson, Marijuana	1025 Union Avenue, Olympia, WA. 98501	360-664-4555
Enforcement: Enforcement	Justin Nordhorn, Chief of	1025 Union Avenue, Olympia, WA, 98501	360-664-1726
Is a school district fiscal impact statement required under RCW 28A.305.135?			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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?			
<input checked="" type="checkbox"/> Yes: A preliminary cost-benefit analysis may be obtained by contacting: Name: Katherine Hoffman Address: 1025 Union Avenue, Olympia WA 98502 Phone: 360-664-1622 Fax: 360-664-9689 TTY: Email: rules@lcb.wa.gov Other:			
<input type="checkbox"/> No: Please explain:			
Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:			
This rule proposal, or portions of the proposal, may be exempt from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):			
<input type="checkbox"/> 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:			
<input type="checkbox"/> 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.			
<input type="checkbox"/> 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:
- | | |
|---|---|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input checked="" type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input type="checkbox"/> 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): WAC 314-55-1025.
Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If 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 analysis showing how costs were calculated.
- ☒ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

What is the scope of the rule package?

Compliance with the proposed, specific requirements described WAC 314-55-1011, WAC 314-55-102, WAC 314-55-1021, and WAC 314-55-1022 will likely result in additional compliance costs. This includes the incremental, phased-in requirement to test all marijuana products for pesticides and heavy metals. The remainder of the rule revisions are exempt.

Which businesses are impacted by the proposed rule package? What was their North American Industry Classification (NAICS) code or codes? What are their minor cost thresholds?

The NAICS code, business description, and minor cost thresholds are described and calculated below in two tables, representing monthly and annual costs, since these result in two outcomes: Table 1 indicates that the monthly cost of compliance does not exceed minor cost thresholds, and Table 2 indicates that the monthly cost of compliance exceeds minor cost thresholds:

Table 1

2017 Industry NAICS Code	Estimated <u>Monthly</u> Cost of Compliance	Industry Description	NAICS Code Title	Minor Cost Estimate - Max of 1%Pay, 0.3%Rev, and \$100	1% of Avg Annual Payroll . (0.01*AvgPay)	0.3% of Avg Annual Gross Business Income (0.003*AvgGBI)
111 ¹	\$ 3,450	Marijuana Producers	Crop Production	\$4,082.13	\$4,082.13 2018 Dataset pulled from ESD	\$2,993.38 2018 Dataset pulled from DOR
312 ²	\$ 3,450	Marijuana Processors	Beverage and Tobacco Product Manufacturing	\$5,766.61	\$5,342.91 2018 Dataset pulled from ESDS	\$5,766.61 2018 Dataset pulled from DOR

¹ **111 Crop Production**

Industries in the Crop Production subsector grow crops mainly for food and fiber. The subsector comprises establishments, such as farms, orchards, groves, greenhouses, and nurseries, primarily engaged in growing crops, plants, vines, or trees and their seeds.

² **312 Beverage and Tobacco Product Manufacturing**

Industries in the Beverage and Tobacco Product Manufacturing subsector manufacture beverages and tobacco products. The Tobacco Manufacturing industry group includes two types of establishments: (1) those engaged in redrying and stemming tobacco and (2) those that manufacture tobacco products, such as cigarettes and cigars.

Table 2

2017 Industry NAICS Code	Estimated <u>Annual</u> Cost of Compliance	Industry Description	NAICS Code Title	Minor Cost Estimate - Max of 1%Pay, 0.3%Rev, and \$100	1% of Avg Annual Payroll . (0.01*AvgPay)	0.3% of Avg Annual Gross Business Income (0.003*AvgGBI)
111	\$ 41,400	Marijuana Producers	Crop Production	\$4,082.13	\$4,082.13 2018 Dataset pulled from ESD	\$2,993.38 2018 Dataset pulled from DOR
312	\$ 41,400	Marijuana Processors	Beverage and Tobacco Product Manufacturing	\$5,766.61	\$5,342.91 2018 Dataset pulled from ESDS	\$5,766.61 2018 Dataset pulled from DOR

Does the rule have a disproportionate impact on small businesses?

In particular, in order to calculate annual costs, we require information on a per entity basis describing the number of samples being tested per year. While we have some limited anecdotal information on the numbers of samples tested per year by individual producer/processors, we lack information on the myriad business models that could lead to a wide range in the number of samples tested per year, and thus a wide range of per entity compliance costs per year. Developing reliable estimates would require a comprehensive survey with a *reasonable* response rate, and even then, given the wide variability of business models and documented inconsistency in responses from licensees, per entity costs is difficult to determine.

Did the agency make an effort to reduce the impact of the rule?

The proposed rule changes include provisions that are intended to reduce the compliance costs for small businesses. These include:

- An increase in lot size from five pounds to ten pounds;
- An incremental phase-in period that contemplates full compliance by February 1, 2022; and
- Allowing labs to subcontract pesticide and heavy metals testing for a period of time.

It is difficult to accurately assess if small businesses will be disproportionately impacted by this rule proposal when there is both significant overlap and variance between the groups evaluated. As noted above, and throughout this SBEIS, most of the businesses impacted are small as defined by RCW 19.85.030.

Did the agency involve small businesses in the rule development process?

Throughout the rule development process, the WSLCB has engaged with businesses likely to be affected by the rule, and who volunteered to participate in the process. To support development of the SBEIS, a subset of six producer/processors spanning a range of both tiers and types of producers was contacted; interviews were conducted with two producers, one processor, and one producer/processor. In addition, interviews were conducted with three testing laboratories. Additional opportunity for public comment will be available when the proposed rule is published. Indoor and outdoor farmers, including sun growers, were included in the interviews.

During the rule development process, the WSLCB hosted two “Listen and Learn” sessions, one in April 2019 and the second in August 2019, inviting industry discussion and feedback on the proposed rules, and discuss potential mitigation strategies. The WSLCB’s stakeholder process encouraged interested parties and industry partners to:

- Identify burdensome areas of existing and proposed rules;
- Proposed initial or draft rule changes; and
- Refine those changes.

Although the WSLCB broadly messaged these sessions (messaging went directly to *all* licensees, as well as over 10,000 GovDelivery subscribers), few processors and producers attended the sessions. This rule project was the first employing the “Listen and Learn” model, and attendees were initially unfamiliar with not only the model, but the process, although detailed agendas were provided well in advance of each meeting.

These heavily facilitated sessions followed two thought streams: the first asked attendees to review draft conceptual rules offered well in advance of the meeting and provide feedback or specific rule language, specifically indicating what they liked, didn’t like, and what they proposed in the way of a solution. No rule language revisions were offered by attendees at either session. Solutions ranged from suggesting that figures and language be more concise in general without offering example, to unsupported assertions that adding pesticides and heavy metals to the suite of required tests would put certain producers out of business.

All comments received during these sessions were curated to the extent possible, although developing themes from sessions was difficult based on the broad range of comments. The proposed rules went through several stages of edits, review, discussion, and then further refinement before arriving at the initial proposal. The end result of this process are proposed rules that are offered as a framework and guidance for testing marijuana products that supports the overarching WSLCB goal of public health and safety.

A summary of the description of issues related to the proposed rule set and how the agency collaborated with stakeholders and industry partners to mitigate potential burden associated with rule compliance is more fully described in the Significant Analysis prepared consistent with RCW 34.05.328, including a phase-in plan, and offered as part of this initial rule proposal.

Will businesses have to hire or fire employees because of the requirements in the rule?

While the impacts to individual producer processors may depend on their ability to pass on increased testing costs (in the form of higher prices to retailers), the proposed rule is not expected to affect the amount of marijuana produced. Thus, the proposed rule is unlikely to affect the overall number of employees of producer/processors or retailers. For example, if increased testing costs lead some smaller entities to cease production, other entities may produce larger volumes. While it would be an indirect effect, the proposed rule may result in some limited additional employment in the labs conducting testing. In order to conduct the testing, a lab adding this testing capability may need to hire one or two additional scientists or technicians to operate equipment and conduct tests. The extent of potential employment gains are uncertain, but given the small number of labs in the industry (currently 13 certified labs) any employment gains would likely be limited.

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

Name: Katherine Hoffman

Address: 1025 Union Avenue, Olympia, WA 98501

Phone: 360-664-1622

Fax: 360-664-9689

TTY:

Email: rules@lcb.wa.gov

Other:

Date: September 30, 2020

Name: Jane Rushford

Title: Chair

Signature:

WAC 314-55-101 Quality ((assurance sampling protocols)) control sampling.

(Effective until July 31, 2021)

(1) ((To ensure quality assurance samples submitted to certified third-party laboratories (certified labs) are representative from the lot or batch from which they were sampled as required in RCW 69.50.348, licensed producers, licensed processors, certified labs, and their employees must adhere to the minimum sampling protocols as provided in this section.

~~(2) Sampling protocols for all marijuana product lots and batches:~~

~~(a) Samples must be deducted in a way that is most representative of the lot or batch and maintains the structure of the marijuana sample. Licensees, certified labs, and their employees may not adulterate or change in any way the representative sample from a lot or batch before submitting the sample to certified labs. This includes adulterating or changing the sample in any way as to inflate the level of potency, or to hide any microbiological contaminants from the required microbiological screening such as, but not limited to:~~

~~(i) Adulterating the sample with kief, concentrates, or other extracts;~~

~~(ii) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This subsection does not prohibit the treatment of failed lots or batches with methods approved by the WSLCB; or~~

~~(iii) Pregrinding a flower lot sample.~~

~~(b) All samples must be taken in a sanitary environment using sanitary practices and ensure facilities are constructed, kept, and maintained in a clean and sanitary condition in accordance with rules and as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.~~

~~(c) Persons collecting samples must wash their hands prior to collecting a sample from a lot or batch, wear appropriate gloves while preparing or deducting the lot or batch for sample collection, and must use sanitary utensils and storage devices when collecting samples.~~

~~(d) Samples must be placed in a sanitary plastic or glass container, and stored in a location that prevents the propagation of pathogens and other contaminants, such as a secure, low-light, cool and dry location.~~

~~(e) The licensee must maintain the lot or batch from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the marijuana from becoming contaminated or losing its efficacy.~~

~~(f) Each quality assurance sample must be clearly marked "quality assurance sample" and be labeled with the following information:~~

~~(i) The sixteen digit)) All licensed marijuana processors, producers, certified labs, and certified lab employees must comply with the sampling procedures described in this section, consistent with RCW 69.50.348. Noncompliance may result in enforcement action as described in this chapter and applicable law.~~

(2) **Sample collection.** All samples of marijuana, usable marijuana, or marijuana-infused products submitted to an accredited lab for testing consistent with this chapter must be collected or deducted in a way that is most representative of the lot or batch, and maintains the structure of the marijuana sample.

(a) Facilities must be constructed and maintained consistent with applicable rules and as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.

(b) To ensure the sample integrity, samples must be placed in a sanitary plastic or glass container, and stored in a location that prevents contamination and degradation, such as a secure, low-light, cool and dry location.

(c) The licensee must maintain the lot or batch from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the marijuana from becoming contaminated or losing its efficacy.

(d) Each quality control sample must be clearly marked "quality control sample" and labeled with the following information:

(i) The identification number generated by the traceability system;

(ii) The license number and name of the certified lab receiving the sample;

(iii) The license number and trade name of the licensee sending the sample;

(iv) The date the sample was collected; and

(v) The weight of the sample.

(3) ~~((Additional sampling protocols))~~ **Sample collection for flower lots:**

(a) Licensees or certified labs must collect a minimum of four separate ~~((samples))~~ subsamples from each marijuana flower lot up to five pounds. Licensees or certified labs may collect more samples or subsamples than this minimum, but must not collect less. The ~~((samples))~~ subsamples must be of roughly equal weight not less than one gram each.

(b) The four separate ~~((samples))~~ subsamples must be taken from different quadrants of the flower lot. A quadrant is the division of a lot into four equal parts. Dividing a lot into quadrants prior to collecting samples must be done in a manner that ensures the ~~((samples))~~ subsamples are collected from four evenly distributed areas of the flower lot and may be done visually or physically.

(c) The ~~((four samples))~~ subsamples may be placed together in one container conforming to the packaging and labeling requirements in subsection (2) of this section for storage and transfer to a certified lab.

(4) **Sample retrieval and transportation.** Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab. Certified labs may also return or destroy any unused portion of the samples.

(5) **Adulterated or altered samples.** All licensees, certified labs, or agents of a licensee or certified labs will not adulterate or alter, or attempt to adulterate or alter any marijuana samples for the purpose of circumventing contaminant testing detection limits or potency testing requirements such as, but not limited to:

(a) Adulterating the sample with kief, concentrates, or other extracts;

(b) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This subsection does

not prohibit the treatment of failed lots or batches with methods approved by the board; or

(c) Pregrinding a flower lot sample.

(6) **Sample rejection or failure.** Certified labs ((may)) must reject or fail a sample if the lab ((has reason to)) believes the sample was not collected in the manner required by this section, adulterated ((in any way)), contaminated with known or unknown solvents, or manipulated in a manner that violates the sampling protocols, limit tests, or action levels.

~~((6) The WSLCB or its designee will take immediate disciplinary action against any licensee or certified lab that fails to comply with the provisions of this section or falsifies records related to this section including, without limitation, revoking the license the licensed producer or processor, or certification of the certified lab.))~~

NEW SECTION

WAC 314-55-1011 Quality control sampling.

(Effective August 1, 2021)

(1) All licensed marijuana processors, producers, certified labs, and certified lab employees must comply with the sampling procedures described in this section, consistent with RCW 69.50.348. Noncompliance may result in enforcement action as described in this chapter and applicable law.

(2) **Sample collection.** All samples of marijuana, usable marijuana, or marijuana-infused products submitted to an accredited lab for testing consistent with this chapter must be collected or deducted in a way that is most representative of the lot or batch, and maintains the structure of the marijuana sample.

(a) Facilities must be constructed and maintained consistent with applicable rules and as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.

(b) To ensure the sample integrity, samples must be placed in a sanitary plastic or glass container, and stored in a location that prevents contamination and degradation, such as a secure, low-light, cool, and dry location.

(c) The licensee must maintain the lot or batch from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the marijuana from becoming contaminated or losing its efficacy.

(d) Each quality control sample must be clearly marked "quality control sample" and labeled with the following information:

(i) The identification number generated by the traceability system;

(ii) The license number and name of the certified lab receiving the sample;

(iii) The license number and trade name of the licensee sending the sample;

(iv) The date the sample was collected; and

(v) The weight of the sample.

(3) **Sample collection for flower lots.**

(a) Licensees or certified labs must collect a minimum of two separate samples consisting of eight separate subsamples from each

marijuana flower lot up to ten pounds. Licensees or certified labs may collect more samples or subsamples than this minimum, but must not collect less. The subsamples must be of roughly equal weight not less than one gram each.

(b) The eight separate subsamples must be taken from different octants of the flower lot. An octant is the division of a lot into eight equal parts. Dividing a lot into octants prior to sample collection must ensure the subsamples are collected from eight evenly distributed areas of the flower lot. This division may be done visually or physically.

(c) The eight subsamples may be placed together in one container conforming to the packaging and labeling requirements in subsection (2) of this section for storage and transfer to a certified lab.

(d) Two samples of no less than eight grams each must be selected as described in (a) through (c) of this subsection for a total of no less than sixteen grams.

(4) **Sample retrieval and transportation.** Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab. Certified labs may also return or destroy any unused portion of the samples.

(5) **Adulterated or altered samples.** All licensees, certified labs, or agents of a licensee or certified labs will not adulterate or alter, or attempt to adulterate or alter any marijuana samples for the purpose of circumventing contaminant testing detection limits or potency testing requirements such as, but not limited to:

(a) Adulterating the sample with kief, concentrates, or other extracts;

(b) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This subsection does not prohibit the treatment of failed lots or batches with methods approved by the board; or

(c) Pregrinding a flower lot sample.

(6) **Sample rejection or failure.** Certified labs must reject or fail a sample if the lab believes the sample was not collected in the manner required by this section, adulterated, contaminated with known or unknown solvents, or manipulated in a manner that violates the sampling protocols, limit tests, or action levels.

AMENDATORY SECTION (Amending WSR 17-12-032, filed 5/31/17, effective 8/31/17)

WAC 314-55-102 Quality assurance ((testing)) and quality control.

(Effective until July 31, 2021)

(1) Lab certification and accreditation for quality control testing. To become certified, a third-party ((testing)) lab must ((be certified by the WSLCB or the WSLCB's vendor as meeting the WSLCB's accreditation and other requirements prior to)) meet the board's certification and accreditation requirements as described in WAC 314-55-0995 and this chapter before conducting quality ((assurance)) control tests required under this section.

((1) Quality assurance fields of testing. Certified labs must be certified to the following fields of testing by the WSLCB or its des-

~~ignee and must adhere to the guidelines for each quality assurance field of testing listed below, with the exception of mycotoxin, heavy metal, or pesticide residue screening. Certification to perform mycotoxin, heavy metals and pesticides may be obtained but is not required to obtain certification as a testing lab. A lab must become certified in all fields of testing prior to conducting any testing or screening in that field of testing, regardless of whether the test is required under this section.))~~ (a) Certified labs must be certified to the following fields of testing:

- (i) Moisture analysis;
- (ii) Potency analysis;
- (iii) Foreign matter inspection;
- (iv) Microbiological screening;
- (v) Mycotoxin screening; and
- (vi) Residual solvents.

(b) Certified labs may be certified for heavy metal, pesticide, or terpene testing. Certified labs must comply with the guidelines for each quality control field of testing described in this chapter if they offer that testing service.

(c) Certified labs may reference samples for heavy metal, pesticide, or terpene testing by subcontracting for those fields of testing.

(2) General quality control testing requirements for certified labs.

(a) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the board seed to sale traceability system. Certified labs must also verify when any unused portion of the sample is destroyed or returned to the licensee after the completion of required testing.

(b) When applicable, certified labs must report quality control test results directly to the board traceability system when quality control tests for the field of testing are required.

(c) Product must not be converted, transferred or sold until the required tests are reported to the board and the licensee.

(d) Certified labs must fail a sample if the results for any limit test are above allowable levels regardless of whether the limit test is required in the testing tables in this chapter.

(e) Certified labs must test samples on an "as is" or "as received" basis.

(3) Quality control fields of testing. The following fields of testing are only required for samples of marijuana flower that have not been previously tested, or that have failed quality control testing.

(a) Potency analysis.

(i) Certified labs must test and report the following cannabinoids to the ((WSLCB)) board when testing for potency:

- (A) THCA;
- (B) THC;
- (C) Total THC;
- (D) CBDA;
- (E) CBD; and
- (F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: M total delta-9 THC = M delta-9 THC + (0.877 x M delta-9 THCA).

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: $M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$.

(iii) Any psychoactive cannabinoids intentionally added to the formula of a product must be tested for potency.

(iv) Regardless of analytical equipment or methodology, certified labs must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.

(b) **Potency analysis for flower lots.**

(i) Certified labs must test and report the results for the required flower lot samples as described in WAC 314-55-101(3) for the following required cannabinoids:

- (A) THCA;
- (B) THC;
- (C) Total THC;
- (D) CBDA;
- (E) CBD; and
- (F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: $M \text{ total delta-9 THC} = M \text{ delta-9 THC} + (0.877 \times M \text{ delta-9 THCA})$.

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: $M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$.

(c) Certified labs ~~((may combine in equal parts multiple samples from the same flower lot for the purposes of the following tests after the individual samples described in WAC 314-55-101(3) have been tested for potency analysis.))~~ must test each flower lot identified in WAC 314-55-101(3) for the following:

(i) **Moisture analysis.** The sample and related lot or batch fails quality ~~((assurance))~~ control testing for moisture analysis if the results exceed the following limits:

- (A) Water activity rate of more than 0.65 a_w ; ~~((and))~~ or
- (B) Moisture content more than fifteen percent.

(ii) **Foreign matter screening.** The sample and related lot or batch fail quality ~~((assurance))~~ control testing for foreign matter screening if the results exceed the following limits:

- (A) Five percent of stems 3 mm or more in diameter; ~~((and))~~ or
- (B) Two percent of seeds or other foreign matter; or
- (C) One insect fragment, one hair, or one mammalian excreta sample.

(iii) **Microbiological screening.** The sample and related lot or batch fail quality ~~((assurance))~~ control testing for microbiological screening if the results exceed the following limits:

	Enterobacteria (bile-tolerant gram-negative bacteria)	<i>E. coli</i> (pathogenic strains) and <i>Salmonella spp.</i>
Unprocessed Plant Material	10^4	Not detected in 1g
Extracted or processed Botanical Product	10^3	Not detected in 1g

(iv) **Mycotoxin screening.** ~~((The sample and related lot or batch fail quality assurance testing for mycotoxin screening if the results exceed the following limits:~~

- ~~((A) Total of Aflatoxin B1, B2, G1, G2: 20 $\mu\text{g/kg}$ of substance; and~~

~~(B) Ochratoxin A: 20 µg/kg of substance.))~~ For purposes of mycotoxin screening, a sample shall be deemed to have passed if it meets the following standards:

Test	Specification
The total of aflatoxin B1, aflatoxin B2, aflatoxin G1 and aflatoxin G2	≤20 µg/kg of substance
Ochratoxin A	≤20 µg/kg of substance

(d) **Residual solvent screening.** Except as otherwise provided in this subsection, a sample and related lot or batch fail quality ((~~assurance~~)) control testing for residual solvents if the results exceed the limits provided in the table below. Residual solvent results of more than 5,000 ppm for class three solvents, 50 ppm for class two solvents, and 2 ppm for class one solvents as defined in *United States Pharmacopoeia, USP 30 Chemical Tests / <467> - Residual Solvents (USP <467>)* not listed in the table below fail quality ((~~assurance~~)) control testing. When residual solvent screening is required, certified labs must test for the solvents listed in the table below at a minimum.

Solvent*	ppm
Acetone	5,000
Benzene	2
Butanes	5,000
Cyclohexane	3,880
Chloroform	2
Dichloromethane	600
Ethyl acetate	5,000
Heptanes	5,000
Hexanes	290
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	5,000
Propane	5,000
Toluene	890
Xylene**	2,170

*And isomers thereof.

**Usually 60% *m*-xylene, 14% *p*-xylene, 9% *o*-xylene with 17% ethyl benzene.

(e) **Heavy metal screening.** A sample and related lot or batch fail quality ((~~assurance~~)) control testing for heavy metals if the results exceed the limits provided in the table below.

(Metal	µ/daily dose (5 grams)
Inorganic arsenic	10.0
Cadmium	4.1
Lead	6.0
Mercury	2.0

~~(2) Quality assurance testing required.))~~

<u>Metal</u>	<u>µg/g</u>
<u>Arsenic</u>	<u>2.0</u>
<u>Cadmium</u>	<u>0.82</u>
<u>Lead</u>	<u>1.2</u>
<u>Mercury</u>	<u>0.40</u>

(f) **Pesticide screening.** For purposes of the pesticide screening, a sample shall be deemed to have passed if it meets the standards described in WAC 314-55-108 and applicable department of agriculture rules.

(g) **Terpenes.** Testing for terpene presence and concentration is required if:

(i) The producer or processor states terpene content on any product packaging, labeling, or both; or

(ii) The producer or processor adds terpenes to their product.

(4) **Required quality control tests.** The following quality ((assurance)) control tests are ((the minimum)) required ((tests)) for each of the ((following)) marijuana products((, respectively)) described below. Licensees and certified labs may ((elect to do multiple)) opt to perform additional quality ((assurance)) control tests on the same lot ((or testing for mycotoxin, pesticides, or heavy metals pursuant to chapter 246-70 WAC)).

(a) ~~((General quality assurance testing requirements for certified labs.~~

(i) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the WSLCB seed to sale traceability system. Certified labs must also verify if any unused portion of the sample was destroyed or returned to the licensee after the completion of required testing.

(ii) Certified labs must report quality assurance test results directly to the WSLCB traceability system when quality assurance tests for the field of testing are required within twenty-four hours of completion of the test(s).

(iii) Certified labs must fail a sample if the results for any limit test are above allowable levels regardless of whether the limit test is required in the testing tables in this section.

(b)) **Marijuana flower lots ((and other material lots)).** Marijuana flower lots ((or other material lots)) require the following quality ((assurance)) control tests:

Product	Test(s) Required
Lots of marijuana flowers ((or other material that will not be extracted))	1. Moisture ((content)) <u>analysis</u> 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening

((e)) (b) **Intermediate products.** Intermediate products must meet the following requirements related to quality ((assurance)) control testing:

(i) All intermediate products must be homogenized prior to quality ((assurance)) control testing;

(ii) For the purposes of this section, a batch is defined as a single run through the extraction or infusion process;

(iii) A batch of marijuana mix may not exceed five pounds and must be chopped or ground so no particles are greater than 3 mm; and

(iv) All batches of intermediate products require the following quality ((assurance)) control tests:

Product	Test(s) Required Intermediate Products
Marijuana mix	1. Moisture ((content *)) <u>analysis</u> 2. Potency analysis 3. Foreign matter inspection((*)) 4. Microbiological screening 5. Mycotoxin screening
Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity)	1. Potency analysis 2. Mycotoxin screening((*)) - <u>Field of testing is only required if using lots of marijuana flower that have not passed QA testing</u> 3. Residual solvent test
Concentrate or extract made with a CO ₂ extractor like hash oil	1. Potency analysis 2. Mycotoxin screening((*)) - <u>Field of testing is only required if using lots of marijuana flower that have not passed QA testing</u> 3. Residual solvent test
Concentrate or extract made with ethanol	1. Potency analysis 2. Mycotoxin screening((*)) - <u>Field of testing is only required if using lots of marijuana flower that have not passed QA testing</u> 3. Residual solvent test
Concentrate or extract made with approved food grade solvent	1. Potency analysis 2. Microbiological screening((*)) - <u>Field of testing is only required if using lots of marijuana flower that have not passed QA testing</u> 3. Mycotoxin screening((*)) - <u>Field of testing is only required if using lots of marijuana flower that have not passed QA testing</u> 4. Residual solvent test
Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash	1. Potency analysis 2. Microbiological screening 3. Mycotoxin screening

Product	Test(s) Required Intermediate Products
Infused cooking oil or fat in solid form	1. Potency analysis 2. Microbiological screening ^(*) - <u>Field of testing is only required if using lots of marijuana flower that have not passed QA testing</u> 3. Mycotoxin screening ^(*) - <u>Field of testing is only required if using lots of marijuana flower that have not passed QA testing</u>

(*) Field of testing is only required if using lots of marijuana flower and other plant material that has not passed QA testing.

~~(d))~~ (c) End products. All marijuana, marijuana-infused products, marijuana concentrates, marijuana mix packaged, and marijuana mix infused sold from a processor to a retailer require the following quality ~~((assurance))~~ control tests:

Product	Test(s) Required End Products
Infused solid edible	Potency analysis
Infused liquid (like a soda or tonic)	Potency analysis
Infused topical	Potency analysis
Marijuana mix packaged (loose or rolled)	Potency analysis
Marijuana mix infused (loose or rolled)	Potency analysis
Concentrate or marijuana-infused product for inhalation	Potency analysis
<u>Other</u>	<u>Potency analysis</u>

~~((e))~~ (d) End products consisting of only one intermediate product that has not been changed in any way are not subject to potency analysis.

~~((3) No lot of)~~ (5) Usable flower, batch of marijuana concentrate, or batch of marijuana-infused product may not be sold or transported until the completion and successful passage of required quality ((assurance)) control testing ((as required in this section)), except:

(a) Business entities with multiple locations licensed under the same UBI number may transfer marijuana products between the licensed locations ~~((under the same UBI number prior to quality assurance testing))~~; and

(b) Licensees may wholesale and transfer batches or lots of flower and other material that will be extracted and marijuana mix and nonsolvent extracts for the purposes of further extraction prior to completing required quality ~~((assurance))~~ control testing. Licensees may wholesale and transfer failed lots or batches to be extracted pursuant to subsection (5) of this section, unless failed for tests that require immediate destruction.

~~((4) Samples, lots, or batches that fail quality assurance testing-))~~ (6) Failed test samples.

(a) Upon approval by the ~~((WSLCB))~~ board, failed lots or batches may be used to create extracts. After processing, the extract must pass all quality ~~((assurance))~~ control tests required in this section

before it may be sold, unless failed for tests that require immediate destruction.

(b) **Retesting.** ~~((At the request of the))~~ A producer or processor ~~((, the WSLCB))~~ must request retesting. The board may authorize ~~((a))~~ the requested retest to validate a failed test result on a case-by-case basis. ~~((All costs of the retest will be borne by))~~ The producer or the processor requesting the retest ~~((. Potency retesting will generally not be authorized))~~ must pay for the cost of all retesting.

(c) **Remediation.** Remediation is a process or technique applied to marijuana harvests, lots, or batches. Remediation may occur after the first failure of the lot, batch, or both depending on the failure, or if a retest process results in a second failure. Pesticide failures may not be remediated.

(i) Producers and processors may remediate failed ~~((harvests,))~~ lots, ~~((or))~~ batches, or both so long as the remediation method does not impart any toxic or ~~((deleterious))~~ harmful substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to:

(A) A licensed processor;

(B) The producer or producer/processor who transfers the marijuana products ~~((to))~~;

(C) A licensed retailer carrying marijuana products derived from the remediated ~~((harvest,))~~ lot ~~((,))~~ or batch; or

(D) A consumer upon request.

(ii) The entire ~~((harvest,))~~ lot ~~((,))~~ or batch from which the failed sample(s) were deducted ~~((from))~~ must be remediated ~~((using the same remediation technique)).~~

(iii) No remediated ~~((harvest,))~~ lots ~~((or))~~, batches, or both may be sold or transported until ~~((the completion and successful passage of quality assurance testing as required in this section))~~ quality control testing consistent with the requirements of this section is completed.

(iv) If a failed lot or batch is not remediated or reprocessed in any way, it cannot be retested. Any subsequent COAs produced without remediation or reprocessing of the failed batch will not supersede the initial regulatory compliance testing COA.

~~((+5))~~ (7) A certificate of analysis issued by a certified lab for any marijuana product subject to the requirements of this chapter that has not already been transferred to a retail location expires twelve calendar months after issuance.

(8) **Referencing.** Certified labs may reference samples for ~~((mycotoxin))~~ terpenes, heavy metals, and pesticides testing to other certified labs by subcontracting for those fields of testing. Labs must record all referencing to other labs on a chain-of-custody manifest that includes, but is not limited to, the following information: Lab name, certification number, transfer date, address, contact information, delivery personnel, sample ID numbers, field of testing, receiving personnel.

~~((+6))~~ (9) Certified labs are not limited in the amount of usable marijuana and marijuana products they may have on their premises at any given time, but a certified lab must have records proving all marijuana and marijuana-infused products in the certified lab's possession are held only for the testing purposes described in this ~~((section))~~ chapter.

~~((+7))~~ ~~Upon the request of the WSLCB)~~ (10) The board or its designee ~~((,))~~ may request that a licensee or a certified lab ~~((must))~~

provide an employee of the ((WSLCB)) board or their designee samples of marijuana or marijuana products or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened randomly for pesticides, and chemical residues, unsafe levels of heavy metals, and used for other quality ((assurance)) control tests deemed necessary by the ((WSLCB)) board.

(11) Quality control tests meeting all requirements of this chapter must be conducted for any additive, solvent, ingredient, or compound used in the production and processing of marijuana products, including marijuana vapor products prohibited by the board under RCW 69.50.342 and this chapter.

NEW SECTION

WAC 314-55-1021 Quality assurance and quality control.

(Effective August 1, 2021, until January 31, 2022)

(1) Lab certification and accreditation for quality control testing. To become certified, a third-party lab must meet the board's certification and accreditation requirements as described in WAC 314-55-0995 and this chapter before conducting quality control tests required under this section.

(a) Certified labs must be certified to the following fields of testing:

- (i) Moisture analysis;
- (ii) Potency analysis;
- (iii) Foreign matter inspection;
- (iv) Microbiological screening;
- (v) Mycotoxin screening; and
- (vi) Residual solvents.

(b) Certified labs may be certified for heavy metal, pesticide, or terpene testing. Certified labs must comply with the guidelines for each quality control field of testing described in this section if they offer that testing service.

(c) Certified labs may reference samples for heavy metal, pesticide, or terpene testing by subcontracting for those fields of testing.

(2) General quality control testing requirements for certified labs.

(a) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the board seed to sale traceability system. Certified labs must also verify when any unused portion of the sample is destroyed or returned to the licensee after the completion of required testing.

(b) When applicable, certified labs must report quality control test results directly to the board traceability system when quality control tests for the field of testing are required.

(c) Product must not be converted, transferred, or sold until the required tests are reported to the board and the licensee.

(d) Certified labs must fail a sample if the results for any limit test are above allowable levels regardless of whether the limit test is required in the testing tables in this chapter.

(e) Certified labs must test samples on an "as is" or "as received" basis.

(3) **Quality control fields of testing.** The following fields of testing are only required for samples of marijuana flower that have not been previously tested, or that have failed quality control testing.

(a) **Potency analysis.**

(i) Certified labs must test and report the following cannabinoids to the board when testing for potency:

- (A) THCA;
- (B) THC;
- (C) Total THC;
- (D) CBDA;
- (E) CBD; and
- (F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: $M \text{ total delta-9 THC} = M \text{ delta-9 THC} + (0.877 \times M \text{ delta-9 THCA})$.

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: $M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$.

(iii) Any psychoactive cannabinoids intentionally added to the formula of a product must be tested for potency.

(iv) Regardless of analytical equipment or methodology, certified labs must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.

(b) **Potency analysis for flower lots.**

(i) Certified labs must test and report the results for the required flower lot samples as described in WAC 314-55-101(3) for the following required cannabinoids:

- (A) THCA;
- (B) THC;
- (C) Total THC;
- (D) CBDA;
- (E) CBD; and
- (F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: $M \text{ total delta-9 THC} = M \text{ delta-9 THC} + (0.877 \times M \text{ delta-9 THCA})$.

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: $M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$.

(c) Certified labs must test each flower lot identified in WAC 314-55-101(3) for the following:

(i) **Moisture analysis.** The sample and related lot or batch fails quality control testing for moisture analysis if the results exceed the following limits:

- (A) Water activity rate of more than 0.65 a_w ; or
- (B) Moisture content more than fifteen percent.

(ii) **Foreign matter screening.** The sample and related lot or batch fail quality control testing for foreign matter screening if the results exceed the following limits:

- (A) Five percent of stems 3 mm or more in diameter; or
- (B) Two percent of seeds or other foreign matter; or

(C) One insect fragment, one hair, or one mammalian excreta per sample.

(iii) **Microbiological screening.** The sample and related lot or batch fail quality control testing for microbiological screening if the results exceed the following limits:

	Enterobacteria (bile-tolerant gram-negative bacteria)	<i>E. coli</i> (pathogenic strains) and <i>Salmonella spp.</i>
Unprocessed Plant Material	10 ⁴	Not detected in 1g
Extracted or Processed Botanical Product	10 ³	Not detected in 1g

(iv) **Mycotoxin screening.** For purposes of mycotoxin screening, a sample shall be deemed to have passed if it meets the following standards:

Test	Specification
The total of aflatoxin B1, aflatoxin B2, aflatoxin G1 and aflatoxin G2	≤20 µg/kg of substance
Ochratoxin A	≤20 µg/kg of substance

(d) **Residual solvent screening.** Except as otherwise provided in this subsection, a sample and related lot or batch fail quality control testing for residual solvents if the results exceed the limits provided in the table below. Residual solvent results of more than 5,000 ppm for class three solvents, 50 ppm for class two solvents, and 2 ppm for class one solvents as defined in *United States Pharmacopoeia, USP 30 Chemical Tests / <467> - Residual Solvents (USP <467>)* not listed in the table below fail quality control testing. When residual solvent screening is required, certified labs must test for the solvents listed in the table below at a minimum.

Solvent*	ppm
Acetone	5,000
Benzene	2
Butanes	5,000
Cyclohexane	3,880
Chloroform	2
Dichloromethane	600
Ethyl acetate	5,000
Heptanes	5,000
Hexanes	290
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	5,000
Propane	5,000
Toluene	890
Xylene**	2,170

*And isomers thereof.

**Usually 60% *m*-xylene, 14% *p*-xylene, 9% *o*-xylene with 17% ethyl benzene.

(e) **Heavy metal screening.** A sample and related lot or batch fail quality control testing for heavy metals if the results exceed the limits provided in the table below.

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

(f) **Pesticide screening.** For purposes of the pesticide screening, a sample shall be deemed to have passed if it meets the standards described in WAC 314-55-108 and applicable department of agriculture rules.

(g) **Terpenes.** Testing for terpene presence and concentration is required if:

(i) The producer or processor states terpene content on any product packaging, labeling, or both; or

(ii) The producer or processor adds terpenes to their product.

(4) **Required quality control tests.** The following quality control tests are required for each of the marijuana products described below. Licensees and certified labs may opt to perform additional quality control tests on the same lot.

(a) **Marijuana flower lots.** Marijuana flower lots require the following quality control tests:

Product	Test(s) Required
Lots of marijuana flowers	1. Moisture analysis 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening 6. Pesticide screening

(b) **Intermediate products.** Intermediate products must meet the following requirements related to quality control testing:

(i) All intermediate products must be homogenized prior to quality control testing;

(ii) For the purposes of this section, a batch is defined as a single run through the extraction or infusion process;

(iii) A batch of marijuana mix may not exceed ten pounds and must be chopped or ground so no particles are greater than 3 mm; and

(iv) All batches of intermediate products require the following quality control tests:

Product	Test(s) Required Intermediate Products
Marijuana mix	1. Moisture analysis 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening 6. Pesticide screening

Product	Test(s) Required Intermediate Products
Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity)	1. Potency analysis 2. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Residual solvent test 4. Pesticide screening
Concentrate or extract made with a CO ₂ extractor like hash oil	1. Potency analysis 2. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Residual solvent test 4. Pesticide screening
Concentrate or extract made with ethanol	1. Potency analysis 2. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Residual solvent test 4. Pesticide screening
Concentrate or extract made with approved food grade solvent	1. Potency analysis 2. Microbiological screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 4. Residual solvent test 5. Pesticide screening
Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash	1. Potency analysis 2. Microbiological screening 3. Mycotoxin screening 4. Pesticide screening
Infused cooking oil or fat in solid form	1. Potency analysis 2. Microbiological screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 4. Pesticide screening

(c) **End products.** All marijuana, marijuana-infused products, marijuana concentrates, marijuana mix packaged, and marijuana mix infused sold from a processor to a retailer require the following quality control tests:

Product	Test(s) Required End Products
Infused solid edible	Potency analysis
Infused liquid (like a soda or tonic)	Potency analysis
Infused topical	Potency analysis
Marijuana mix packaged (loose or rolled)	Potency analysis
Marijuana mix infused (loose or rolled)	Potency analysis
Concentrate or marijuana-infused product for inhalation	Potency analysis
Other	Potency analysis

(d) End products consisting of only one intermediate product that has not been changed in any way are not subject to potency analysis.

(5) Usable flower, batch of marijuana concentrate, or batch of marijuana-infused product may not be sold or transported until the completion and successful passage of required quality control testing, except:

(a) Business entities with multiple locations licensed under the same UBI number may transfer marijuana products between the licensed locations; and

(b) Licensees may wholesale and transfer batches or lots of flower and other material that will be extracted and marijuana mix and nonsolvent extracts for the purposes of further extraction prior to completing required quality control testing. Licensees may wholesale and transfer failed lots or batches to be extracted pursuant to this subsection, unless failed for tests that require immediate destruction.

(6) Failed test samples.

(a) Upon approval by the board, failed lots or batches may be used to create extracts. After processing, the extract must pass all quality control tests required in this section before it may be sold, unless failed for tests that require immediate destruction.

(b) **Retesting.** A producer or processor must request retesting. The board may authorize retest to validate a failed test result on a case-by-case basis. The producer or the processor requesting the retest must pay for the cost of all retesting.

(c) **Remediation.** Remediation is a process or technique applied to marijuana harvests, lots, or batches. Remediation may occur after the first failure of the lot, batch, or both depending on the failure, or if a retest process results in a second failure. Pesticide failures may not be remediated.

(i) Producers and processors may remediate failed lots, batches, or both so long as the remediation method does not impart any toxic or harmful substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to:

(A) A licensed processor;

(B) The producer or producer/processor who transfers the marijuana products;

(C) A licensed retailer carrying marijuana products derived from the remediated lot or batch; or

(D) A consumer upon request.

(ii) The entire lot or batch from which the failed sample(s) were deducted must be remediated.

(iii) No remediated lots, batches, or both may be sold or transported until quality control testing consistent with the requirements of this section is completed.

(iv) If a failed lot or batch is not remediated or reprocessed in any way, it cannot be retested. Any subsequent COAs produced without remediation or reprocessing of the failed batch will not supersede the initial regulatory compliance testing COA.

(7) A certificate of analysis issued by a certified lab for any marijuana product subject to the requirements of this chapter that has not already been transferred to a retail location expires twelve calendar months after issuance.

(8) **Referencing.** Certified labs may reference samples for terpenes, heavy metals, and pesticides testing to other certified labs by subcontracting for those fields of testing. Labs must record all referencing to other labs on a chain-of-custody manifest that includes, but is not limited to, the following information: Lab name, certification number, transfer date, address, contact information, delivery personnel, sample ID numbers, field of testing, receiving personnel.

(9) Certified labs are not limited in the amount of usable marijuana and marijuana products they may have on their premises at any given time, but a certified lab must have records proving all marijuana and marijuana-infused products in the certified lab's possession are held only for the testing purposes described in this chapter.

(10) The board or its designee may request that a licensee or a certified lab provide an employee of the board or their designee samples of marijuana or marijuana products or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened randomly for pesticides, chemical residues, unsafe levels of heavy metals, and used for other quality control tests deemed necessary by the board.

(11) Quality control tests meeting all requirements of this chapter must be conducted for any additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products prohibited by the board under RCW 69.50.342 and this chapter.

NEW SECTION

WAC 314-55-1022 Quality assurance and quality control.

(Effective February 1, 2022)

(1) **Lab certification and accreditation for quality control testing.** To become certified, a third-party lab must meet the board's certification and accreditation requirements as described in WAC 314-55-0995 and this chapter before conducting quality control tests required under this section.

(a) Certified labs must be certified to the following fields of testing:

- (i) Moisture analysis;
- (ii) Potency analysis;
- (iii) Foreign matter inspection;
- (iv) Microbiological screening;
- (v) Mycotoxin screening; and

(vi) Residual solvents.

(b) Certified labs may be certified for heavy metal, pesticide, or terpene testing. Certified labs must comply with the guidelines for each quality control field of testing described in this section if they offer that testing service.

(c) Certified labs may reference samples for heavy metal, pesticide, or terpene testing by subcontracting for those fields of testing.

(2) General quality control testing requirements for certified labs.

(a) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the board seed to sale traceability system. Certified labs must also verify when any unused portion of the sample is destroyed or returned to the licensee after the completion of required testing.

(b) When applicable, certified labs must report quality control test results directly to the board traceability system when quality control tests for the field of testing are required.

(c) Product must not be converted, transferred, or sold until the required tests are reported to the board and the licensee.

(d) Certified labs must fail a sample if the results for any limit test are above allowable levels regardless of whether the limit test is required in the testing tables in this chapter.

(e) Certified labs must test samples on an "as is" or "as received" basis.

(3) Quality control fields of testing. The following fields of testing are only required for samples of marijuana flower that have not been previously tested, or that have failed quality control testing.

(a) Potency analysis.

(i) Certified labs must test and report the following cannabinoids to the board when testing for potency:

- (A) THCA;
- (B) THC;
- (C) Total THC;
- (D) CBDA;
- (E) CBD; and
- (F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: $M \text{ total delta-9 THC} = M \text{ delta-9 THC} + (0.877 \times M \text{ delta-9 THCA})$.

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: $M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$.

(iii) Any psychoactive cannabinoids intentionally added to the formula of a product must be tested for potency.

(iv) Regardless of analytical equipment or methodology, certified labs must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.

(b) Potency analysis for flower lots.

(i) Certified labs must test and report the results for the required flower lot samples as described in WAC 314-55-101(3) for the following required cannabinoids:

- (A) THCA;
- (B) THC;
- (C) Total THC;

- (D) CBDA;
- (E) CBD; and
- (F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: $M \text{ total delta-9 THC} = M \text{ delta-9 THC} + (0.877 \times M \text{ delta-9 THCA})$.

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: $M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$.

(c) Certified labs must test each flower lot identified in WAC 314-55-101(3) for the following:

(i) **Moisture analysis.** The sample and related lot or batch fails quality control testing for moisture analysis if the results exceed the following limits:

(A) Water activity rate of more than 0.65 a_w ; or

(B) Moisture content more than fifteen percent.

(ii) **Foreign matter screening.** The sample and related lot or batch fail quality control testing for foreign matter screening if the results exceed the following limits:

(A) Five percent of stems 3 mm or more in diameter; or

(B) Two percent of seeds or other foreign matter; or

(C) One insect fragment, one hair, or one mammalian excreta per sample.

(iii) **Microbiological screening.** The sample and related lot or batch fail quality control testing for microbiological screening if the results exceed the following limits:

	Enterobacteria (bile-tolerant gram-negative bacteria)	<i>E. coli</i> (pathogenic strains) and <i>Salmonella spp.</i>
Unprocessed Plant Material	10^4	Not detected in 1g
Extracted or Processed Botanical Product	10^3	Not detected in 1g

(iv) **Mycotoxin screening.** For purposes of mycotoxin screening, a sample shall be deemed to have passed if it meets the following standards:

Test	Specification
The total of aflatoxin B1, aflatoxin B2, aflatoxin G1 and aflatoxin G2	$\leq 20 \mu\text{g/kg}$ of substance
Ochratoxin A	$\leq 20 \mu\text{g/kg}$ of substance

(d) **Residual solvent screening.** Except as otherwise provided in this subsection, a sample and related lot or batch fail quality control testing for residual solvents if the results exceed the limits provided in the table below. Residual solvent results of more than 5,000 ppm for class three solvents, 50 ppm for class two solvents, and 2 ppm for class one solvents as defined in *United States Pharmacopoeia, USP 30 Chemical Tests / <467> - Residual Solvents (USP <467>)* not listed in the table below fail quality control testing. When residual solvent screening is required, certified labs must test for the solvents listed in the table below at a minimum.

Solvent*	ppm
Acetone	5,000

Solvent*	ppm
Benzene	2
Butanes	5,000
Cyclohexane	3,880
Chloroform	2
Dichloromethane	600
Ethyl acetate	5,000
Heptanes	5,000
Hexanes	290
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	5,000
Propane	5,000
Toluene	890
Xylene**	2,170

*And isomers thereof.

**Usually 60% *m*-xylene, 14% *p*-xylene, 9% *o*-xylene with 17% ethyl benzene.

(e) **Heavy metal screening.** A sample and related lot or batch fail quality control testing for heavy metals if the results exceed the limits provided in the table below.

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

(f) **Pesticide screening.** For purposes of the pesticide screening, a sample shall be deemed to have passed if it meets the standards described in WAC 314-55-108 and applicable department of agriculture rules.

(g) **Terpenes.** Testing for terpene presence and concentration is required if:

(i) The producer or processor states terpene content on any product packaging, labeling, or both; or

(ii) The producer or processor adds terpenes to their product.

(4) **Required quality control tests.** The following quality control tests are required for each of the marijuana products described below. Licensees and certified labs may opt to perform additional quality control tests on the same lot.

(a) **Marijuana flower lots.** Marijuana flower lots require the following quality control tests:

Product	Test(s) Required
Lots of marijuana flowers	1. Moisture analysis 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening 6. Pesticide screening 7. Heavy metals screening

(b) **Intermediate products.** Intermediate products must meet the following requirements related to quality control testing:

(i) All intermediate products must be homogenized prior to quality control testing;

(ii) For the purposes of this section, a batch is defined as a single run through the extraction or infusion process;

(iii) A batch of marijuana mix may not exceed ten pounds and must be chopped or ground so no particles are greater than 3 mm; and

(iv) All batches of intermediate products require the following quality control tests:

Product	Test(s) Required Intermediate Products
Marijuana mix	1. Moisture analysis 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening 6. Pesticide screening 7. Heavy metals screening
Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity)	1. Potency analysis 2. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Residual solvent test 4. Pesticide screening 5. Heavy metals screening
Concentrate or extract made with a CO ₂ extractor like hash oil	1. Potency analysis 2. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Residual solvent test 4. Pesticide screening 5. Heavy metals screening
Concentrate or extract made with ethanol	1. Potency analysis 2. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Residual solvent test 4. Pesticide screening 5. Heavy metals screening
Concentrate or extract made with approved food grade solvent	1. Potency analysis 2. Microbiological screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 4. Residual solvent test 5. Pesticide screening 6. Heavy metals screening

Product	Test(s) Required Intermediate Products
Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash	1. Potency analysis 2. Microbiological screening 3. Mycotoxin screening 4. Pesticide screening 5. Heavy metals screening
Infused cooking oil or fat in solid form	1. Potency analysis 2. Microbiological screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Mycotoxin screening - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 4. Pesticide screening 5. Heavy metals screening

(c) **End products.** All marijuana, marijuana-infused products, marijuana concentrates, marijuana mix packaged, and marijuana mix infused sold from a processor to a retailer require the following quality control tests:

Product	Test(s) Required End Products
Infused solid edible	Potency analysis
Infused liquid (like a soda or tonic)	Potency analysis
Infused topical	Potency analysis
Marijuana mix packaged (loose or rolled)	Potency analysis
Marijuana mix infused (loose or rolled)	Potency analysis
Concentrate or marijuana-infused product for inhalation	Potency analysis
Other	Potency analysis

(d) End products consisting of only one intermediate product that has not been changed in any way are not subject to potency analysis.

(5) Usable flower, batch of marijuana concentrate, or batch of marijuana-infused product may not be sold or transported until the completion and successful passage of required quality control testing, except:

(a) Business entities with multiple locations licensed under the same UBI number may transfer marijuana products between the licensed locations; and

(b) Licensees may wholesale and transfer batches or lots of flower and other material that will be extracted and marijuana mix and nonsolvent extracts for the purposes of further extraction prior to completing required quality control testing. Licensees may wholesale and transfer failed lots or batches to be extracted pursuant to this subsection, unless failed for tests that require immediate destruction.

(6) **Failed test samples.**

(a) Upon approval by the board, failed lots or batches may be used to create extracts. After processing, the extract must pass all

quality control tests required in this section before it may be sold, unless failed for tests that require immediate destruction.

(b) **Retesting.** A producer or processor must request retesting. The board may authorize the requested retest to validate a failed test result on a case-by-case basis. The producer or the processor requesting the retest must pay for the cost of all retesting.

(c) **Remediation.** Remediation is a process or technique applied to marijuana harvests, lots, or batches. Remediation may occur after the first failure of the lot, batch, or both depending on the failure, or if a retest process results in a second failure. Pesticide failure may not be remediated.

(i) Producers and processors may remediate failed lots, batches, or both so long as the remediation method does not impart any toxic or harmful substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to:

(A) A licensed processor;

(B) The producer or producer/processor who transfers the marijuana products;

(C) A licensed retailer carrying marijuana products derived from the remediated lot or batch; or

(D) A consumer upon request.

(ii) The entire lot or batch from which the failed sample(s) were deducted must be remediated.

(iii) No remediated lots, batches, or both may be sold or transported until quality control testing consistent with the requirements of this section is completed.

(iv) If a failed lot or batch is not remediated or reprocessed in any way, it cannot be retested. Any subsequent COAs produced without remediation or reprocessing of the failed batch will not supersede the initial regulatory compliance testing COA.

(7) A certificate of analysis issued by a certified lab for any marijuana product subject to the requirements of this chapter that has not already been transferred to a retail location expires twelve calendar months after issuance.

(8) **Referencing.** Certified labs may reference samples for terpenes, heavy metals, and pesticides testing to other certified labs by subcontracting for those fields of testing. Labs must record all referencing to other labs on a chain-of-custody manifest that includes, but is not limited to, the following information: Lab name, certification number, transfer date, address, contact information, delivery personnel, sample ID numbers, field of testing, and receiving personnel.

(9) Certified labs are not limited in the amount of usable marijuana and marijuana products they may have on their premises at any given time, but a certified lab must have records proving all marijuana and marijuana-infused products in the certified lab's possession are held only for the testing purposes described in this chapter.

(10) The board or its designee may request that a licensee or a certified lab provide an employee of the board or their designee samples of marijuana or marijuana products or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened randomly for pesticides, chemical residues, unsafe levels of heavy metals, and used for other quality control tests deemed necessary by the board.

(11) Quality control tests meeting all requirements of this chapter must be conducted for any additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products prohibited by the board under RCW 69.50.342 and this chapter.

AMENDATORY SECTION (Amending WSR 17-12-032, filed 5/31/17, effective 8/31/17)

WAC 314-55-1025 Proficiency testing. (1) For the purposes of this section, the following definitions apply:

(a) "Field of testing" means the categories of subject matter the laboratory tests, such as pesticide, microbial, potency, residual solvent, heavy metal, mycotoxin, foreign matter, and moisture content detection.

(b) "Proficiency testing (PT)" means the analysis of samples by a laboratory obtained from providers where the composition of the sample is unknown to the laboratory performing the analysis and the results of the analysis are used in part to evaluate the laboratory's ability to produce precise and accurate results.

(c) "Proficiency testing (PT) program" means an operation offered by a provider to detect a laboratory's ability to produce valid results for a given field of testing.

(d) "Provider" means a third-party company, organization, or entity not associated with certified laboratories or a laboratory seeking certification that operates an approved PT program and provides samples for use in PT testing.

(e) "Vendor" means an organization(s) approved by the ((WSLCB)) board to certify laboratories for marijuana testing, approve PT programs, and perform on-site assessments of laboratories.

(2) The ((WSLCB)) board or its vendor determines the sufficiency of PTs and maintains a list of approved PT programs. Laboratories may request authorization to conduct PT through other PT programs but must obtain approval for the PT program from ((WSLCB or WSLCB's)) the board or board's vendor prior to conducting PT. The ((WSLCB)) board may add the newly approved PT program to the list of approved PT programs as appropriate.

(3) As a condition of certification, laboratories must participate in PT and achieve a passing score for each field of testing for which the lab will be or is certified.

(4) A laboratory must successfully complete a minimum of one round of PT for each field of testing the lab seeks to be certified for and provide proof of the successful PT results prior to initial certification.

(5)(a) A certified laboratory must participate in a minimum of two rounds of PT per year for each field of testing to maintain its certification.

(b) To maintain certification, the laboratory must achieve a passing score, on an ongoing basis, in a minimum of two out of three successive rounds of PT. At least one of the scores must be from a round of PT that occurs within six months prior to the laboratory's certification renewal date.

(6) If the laboratory fails to achieve a passing score on at least eighty percent of the analytes in any proficiency test, the test

is considered a failure. If the PT provider provides a pass/fail on a per analyte basis but not on the overall round of PT the lab participates in, the pass/fail evaluation for each analyte will be used to evaluate whether the lab passed eighty percent of the analytes. If the PT provider does not provide individual acceptance criteria for each analyte, the following criteria will be applied to determine whether the lab achieves a passing score for the round of PT:

(a) +/- 30% recovery from the reference value for residual solvent testing; or

(b) +/- 3 z or 3 standard deviations from the reference value for all other fields of testing.

(7) If a laboratory fails a round of PT or reports a false negative on a micro PT, the laboratory must investigate the root cause of the laboratory's performance and establish a corrective action report for each unsatisfactory analytical result. The corrective action report must be kept and maintained by the laboratory for a period of three years, available for review during an on-site assessment or inspection, and provided to the ~~((WSLCB or WSLCB's))~~ board or board's vendor upon request.

(8) Laboratories are responsible for obtaining PT samples from vendors approved by ~~((WSLCB or WSLCB's))~~ the board or board's vendor. Laboratories are responsible for all costs associated with obtaining PT samples and rounds of PT.

(9) The laboratory must manage, analyze and report all PT samples in the same manner as customer samples including, but not limited to, adhering to the same sample tracking, sample preparation, analysis methods, standard operating procedures, calibrations, quality control, and acceptance criteria used in testing customer samples.

(10) The laboratory must authorize the PT provider to simultaneously release all results ~~((used for certification and/or remediation of failed studies to WSLCB or WSLCB's))~~, whether pass or fail, to the laboratory and the board or the board's vendor.

(11) The ~~((WSLCB))~~ board may require the laboratory to submit raw data and all photographs of plated materials along with the report of analysis of PT samples. The laboratory must keep and maintain all raw data and all photographs of plated materials from PT for a period of three years.

(12) The ~~((WSLCB))~~ board may waive proficiency tests for certain fields of testing if PT samples or PT programs are not readily available or for other valid reasons as determined by ~~((WSLCB))~~ the board.

(13)(a) The ~~((WSLCB))~~ board will suspend a laboratory's certification if the laboratory fails to maintain a passing score on an ongoing basis in two out of three successive PT studies. The ~~((WSLCB))~~ board may reinstate a laboratory's suspended certification if the laboratory successfully analyzes PT samples from a ~~((WSLCB or WSLCB's))~~ board or board's vendor approved PT provider, so long as the supplemental PT studies are performed at least fifteen days apart from the analysis date of one PT study to the analysis date of another PT study.

(b) The ~~((WSLCB))~~ board will suspend a laboratory's certification if the laboratory fails two consecutive rounds of PT. ~~((WSLCB))~~ The board may reinstate a laboratory's suspended certification once the laboratory conducts an investigation, provides the ~~((WSLCB))~~ board a deficiency report identifying the root cause of the failed PT, and successfully analyzes PT samples from a ~~((WSLCB or WSLCB's))~~ board or board's vendor approved PT provider. The supplemental PT studies must

be performed at least fifteen days apart from the analysis date of one PT study to the analysis date of another PT study.

(14) If a laboratory fails to remediate and have its certification reinstated under subsection (13)(a) or (b) of this section within six months of the suspension, the laboratory must reapply for certification as if the laboratory was never certified previously.

(15) A laboratory that has its certification suspended or revoked under this section may request an administrative hearing to contest the suspension as provided in chapter 34.05 RCW.

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	Date	Type	Commenter	Comment
1	1//22/2020	Email	Matthew Shellenberger	<p>Dear LCB Rules Coordinator,</p> <p>I would like to add comments to marijuana quality control rules WSR #20-03-176.</p> <p>We are in support of:</p> <ul style="list-style-type: none"> • increased sample lot size. • mandatory testing for pesticides and heavy metals. • more lab over site for apples to apples consistency. • access to the same array and level of testing the WSDA claims to achieve. <p>We have the following concerns with QA testing:</p> <ul style="list-style-type: none"> • we have seen gross inconsistency in results both pesticide and THC. • the WSDA lab is not certified by LCB. • the WSDA tests for things we have no access to test for in WA. • the LCB certified labs do not have the ability to test for many substances to the levels the WSDA claims to test to, if at all. • passing out fines for substances ubiquitous in the environment and that we have no access to discover is unethical and unreasonable. <p>Response: WSDA contract is for work that the WSDA performs for the LCB. LCB cannot accredit the AG lab. They already meet the standards (ISO 17025). Access to what WSDA is doing or not; labs to the minimum. Our labs could do everything WSDA does, but it comes down to price. Think about revisions to 108 when appropriate.</p>
2	5/26/2020	Email	Mark Ambler	<p>From: t1producerassociation@gmail.com <t1producerassociation@gmail.com> Sent: Tuesday, May 26, 2020 9:21 AM To: U-D-LCB-Rules <rules@lcb.wa.gov> Subject: WSR 20-07-052 Cost Benefit Analysis Request</p> <p>Kathy,</p> <p>Per the guidance on the Washington State Register for WSR 20-07-052, we would like to request a copy of the cost-benefit analysis.</p> <p>Thank You,</p>

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				<p>Mark Ambler</p> <p>TiPA</p>
2	5/26/2020	Email	<p>WSLCB (Response to Mr. Ambler)</p>	<p>On Tue, May 26, 2020 at 9:31 AM Hoffman, Katherine (LCB) <katherine.hoffman@lcb.wa.gov> wrote: Mark,</p> <p>Documents bulleted below are attached. The small business economic impact statement and significant analysis have been available on line under proposed rulemaking since they were presented to the Board on January 22.</p> <ul style="list-style-type: none"> • Small Business Economic Impact Statement • Significant Analysis <p>Let me know if you have questions.</p>
3	5/26/2020	Email	<p>Mark Ambler</p>	<p>Kathy,</p> <p>Thank you for the quick response. Here's an excerpt from the "<i>Significant Legislative Rule Analysis</i>" dated January 22, 2020 (page 9, second paragraph):</p> <p>"Retaining the five pound lot size for sample collection continues to reduce the possibility of non-representative samples. Although the concept of expanding lot size to ten pounds or more was discussed during rule development, no verifiable evidence or data was submitted to support the idea that a representative sample could be realized in larger lot sizes, nor was there any consensus between any of the commenters regarding lot size."</p> <p>I conducted some statistical calculations for you that I believe reveal the issue. Consider a 5 lb. lot consisting entirely of 1 gram nugs of which a percentage are "hot" which means they are unacceptably contaminated.</p> <p>The current sampling procedure of 4 nugs per 5 lbs.: Statistically results in a 25% failure rate (false negative for contaminants) in lots with 19% of the nugs being "hot" Statistically results in a 51% failure rate in lots with 12% of the nugs being "hot" Statistically results in an 82% failure rate in lots with 4% of the nugs being "hot" Statistically results in a 96% failure rate in lots with 1% of the nugs being "hot"</p> <p>A new sampling procedure of 50 nugs per 100 lbs.: Statistically results in a 0% failure rate in lots with 19% of the nugs being "hot" Statistically results in a 0% failure rate in lots with 12% of the nugs being "hot" Statistically results in a 0% failure rate in lots with 4% of the nugs being "hot" Statistically results in a 45% failure rate in lots with 1% of the nugs being "hot"</p> <p>Consider this scenario ending in a final product of all 1 gram bags of flower and the contaminant being a highly dangerous illegal pesticide. The sampling program is not currently, adequately protecting the consumer on this front. I would also recommend some sampling QA/QC. The program currently has none. I recommend triplicate samples per 100 lbs. which would also reduce the 1% hot nug failure rate of the new program to zero.</p>

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				<p>Regards, Mark Ambler</p> <p>Response: thank you for your comments. They did not result in rule revision.</p>
3	5/27/2020	Email	Exchange between Mr. Ambler/WSLCB	<p>Kathy,</p> <p>I provided comments because the Testing Program needed revision before filing the CR-102. Now I think the only choice is to remove the proposed rule set.</p> <p>This is a serious health issue. Every day of inaction results in consumer exposures. If anyone disagrees, they're wrong. This is simple math. This has the capability to blow up in your faces. Don't treat it lightly.</p> <p>Very Concerned, Mark Ambler</p> <p>On Wed, May 27, 2020 at 11:01 AM Hoffman, Katherine (LCB) <katherine.hoffman@lcb.wa.gov> wrote:</p> <p>Mark,</p> <p>Your comments have been provided to the Board.</p> <p>Remember, the Board just approved <i>filing</i> the CR102 <i>proposal</i> and establishing a hearing date. The Board has not adopted the proposed rules. Your comments will be considered, along with all other comments received before the public hearing, and during the public hearing on July 8.</p> <p>Kathy Hoffman, MPA</p> <p>From: t1producerassociation@gmail.com <t1producerassociation@gmail.com> Sent: Wednesday, May 27, 2020 10:53 AM To: Hoffman, Katherine (LCB) <katherine.hoffman@lcb.wa.gov> Cc: U-D-LCB-Rules <rules@lcb.wa.gov> Subject: Re: WSR 20-07-052 Cost Benefit Analysis Request</p> <p>Kathy,</p> <p>Did you share my comments with the Board before they made their decision today on the Testing CR-102?</p> <p>Regards,</p> <p>Mark</p>
4	6/1/2020	Email	John Kingsbury	<p>Hi Katherine,</p>


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				<p>Here are some comments for quality assurance.</p> <p><u>Mold testing.</u> I understand that, unlike other states, LCB has adopted mycotoxin testing in lieu of mold testing. We need a floor for mold CFUs. While most other states have action levels of 10,000 CFUs for molds, if we maintain mycotoxin testing, I believe we need to put our action level at 60,000 as an absolute minimum safety standard. I believe this number is too high to high for patients, but that is another issue.</p> <p>If LCB intends to persist with the view that medical product is not definable and does not matter, and that patients need to shut up and buy rec weed, then the highest safe number should be 30,000 CFUs. I got to 30,000 and 50,000 CFUs by reading research and picking the highest reasonable limits.</p> <p>In any case, we have had immune compromised patients in this state die from confirmed aspergillus inhaled from cannabis. That is a documentable fact.</p> <p>I could provide the research behind this but let me share the story instead.</p> <p>Given the re-growth of the unregulated medical market that I have been seeing since 2017 or so, I decided I wanted to begin testing unregulated samples. During that process, I had a good number of patients tell me that regulated product was making them sick. Given who these people are, and the process that they were going through to verify that it was the cannabis that was making them sick, I believed them when they said the products were making them ill. The people who had not thrown away their regulated product gave me the balances. Consequently, I built up a cabinet full of cheap 502 ounces.</p> <p>While I was having the unregulated product tested, I occasionally put one of these regulated samples in the mix. Much to my surprise, they were meeting Washington State standards. A couple of licensees suggested that I test these samples for mold. So, to be fair and reflect current conditions, I bought 502 ounces and I throw them in the mix with the unregulated products while I am taking tests to the label - (while they were fresh and otherwise uncontaminated, and not five year old samples that some patient gave to me.) What I found were astonishingly high levels of mold as the rule, not as the exception. I spoke to someone at UW medical center and UC Berkeley and they told me that high levels of mold, even outside the mycotoxins being tested for, could be life threatening for some patients.</p> <p>My point is that, since Washington State has decided that the recreational supply is going to be the medical supply, you need to set standards with that in mind -otherwise standards are being set with reckless disregard for the lives of some of its citizens. The minimums I suggest are high.</p> <p><u>Pyrethrin.</u> There needs to be maximum levels for pyrethrin and piperonyl butoxide -period. These agents are powerful neurotoxins -which is how they were designed to function. Many patients disproportionality suffer from neurological disorders. That is why they consuming cannabinoids in the first place.</p> <p>I am attaching a video of pyrethrin poisoning in cat who had a regulated product (flea medicine) applied to it. These things are not safe. Having action levels is not a radical notion. And, so long as LCB persists in the view that the patient community needs to just shut up and buy recreational cannabis, the standard matters here. https://www.youtube.com/watch?v=SAhZFo7dcUw</p> <p>I discovered from testing samples of old product that <u>piperonyl butoxide</u> is extremely persistent. It has a similar action as pyrethrin and again action levels are not a radical idea.</p> <p>In any case, I hope you will care about the public safety and account for my comments.</p> <p>John Kingsbury</p> <p>Response: Mold/action limits were determined several years ago; revisit work done years ago around myco and mold. Pyre asterisk was mistake. These comments did not result in rule change.</p>
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5	6/2/2020	Email	John Kingsbury	<p>Hi Katherine,</p> <p>I understand that azadirachtin and neem oil are allowed at any level on cannabis.</p> <p>Azamax, the most popular source of azadirachtin, is specific in its literature that it is not food safe, and its use should be limited to ornamental plants.</p> <p>Azadirachtin is systemic and extremely persistent, often detectable into a second generation copy (meaning: it can be detectable in a grown cutting when they chemical was applied to the mother plant).</p> <p>John</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3841499/</p> <div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>Neem oil poisoning: Case report of an adult with toxic encephalopathy - PubMed Central (PMC)</p> <p>Sundaravalli et al., in a case series of 12 children with neem oil poisoning, who were given single dose of Neem oil (25-60 ml), reported fatality in 10 cases with features of toxic encephalopathy and metabolic acidosis. Sinnai et al., reported Reyes-like syndrome in fatal cases of Neem oil poisoning in a case series of 13 children.</p> <p>www.ncbi.nlm.nih.gov</p> </div> </div>
6	6/4/2020	Email	John Kingsbury	<p>Katherine,</p> <p>You may add that study, but probably more important these general use studies. Note that the MSDS for azadirachtin (attached), mentions 'inhalation' as potentially hazardous. Azadirachtin is labeled as appropriate for use on non-food, ornamental plants></p> <p>http://gh.growgh.com/docs/MSDS/AzaMaxHCSv4_eng.pdf</p> <p>https://merrivane.com/health/the-curious-case-of-cannabis-hyperemesis-syndrome</p> <p>https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5234</p> <p>"Neem is POSSIBLY SAFE for most adults when taken by mouth for up to 10 weeks, when applied inside the mouth for up to 6 weeks, or when applied to the skin for up to 2 weeks. When neem is taken in large doses or for long periods of time, it is POSSIBLY UNSAFE. It might harm the kidneys and liver."</p> <p>"Auto-immune diseases" such as multiple sclerosis (MS), lupus (systemic lupus erythematosus, SLE), rheumatoid arthritis (RA), or other conditions: Neem might cause the <u>immune system</u> to become more active. This could increase the symptoms of auto-immune diseases. If you have one of these conditions, it's best to avoid using neem.</p>

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				<p>https://www.rxlist.com/neem/supplements.htm</p> <p><u>Summary at the top</u> https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.1858</p> <p>In this article, each claim is cited and the journal referenced at in footnotes.</p> <p>https://www.curejoy.com/content/side-effects-of-neem/</p>
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Marijuana Quality Control Rule Proposal – Public Comment Received Through 7/8/2020

7	6/12/2020	Email	Kristin Baldwin (Cannabis Alliance)	<p>June 12, 2020</p> <p>Katherine Hoffman Rules Coordinator Washington State Liquor and Cannabis Board Via email</p> <p>Dear Ms. Hoffman:</p> <p>The Cannabis Alliance commends the Washington State Liquor and Cannabis Board (LCB) for continuing to include stakeholder groups in the decision-making process. The complexities of our industry run deep, and only through continued collaboration between all affected parties can we reliably foster a progressive and long-lasting marketplace for safe and accountable marijuana in Washington state in accordance with voter initiative.</p> <p>The following are areas of concern with the proposed rules amending the current marijuana quality assurance sampling protocols described in WAC 314-55-101, and marijuana proficiency testing described in WAC 314-55-1025 that The Cannabis Alliance has identified. The cannabis industry as a whole is concerned with balancing both product safety for consumers as well as containing the costs and burdens on quality assurance testing.</p> <p>Cannabis Alliance has polled our members about the proposed Quality Assurance Rules and has the following barriers as well as proposed solutions around the new Quality Assurance testing rules:</p> <table><tr><th>Barriers</th><th>Proposed Solutions</th></tr><tr><td>Cost-effectiveness – testing small lot sizes makes testing cost-prohibitive to smaller producers.</td><td><p>Washington State Department of Agriculture (WSDA) should assist the Liquor and Cannabis Board (LCB) with developing a yearly randomized testing protocol for cannabis farms for pesticides and heavy metals. All required ISO2 testing still needs to be conducted for any product bound for retail stores.</p><p>For material meant for extraction, farms should be tested at a percentage of their crop based on the P/P's tier. This method of testing would equalize the cost over all of the tiers.</p></td></tr></table>	Barriers	Proposed Solutions	Cost-effectiveness – testing small lot sizes makes testing cost-prohibitive to smaller producers.	<p>Washington State Department of Agriculture (WSDA) should assist the Liquor and Cannabis Board (LCB) with developing a yearly randomized testing protocol for cannabis farms for pesticides and heavy metals. All required ISO2 testing still needs to be conducted for any product bound for retail stores.</p> <p>For material meant for extraction, farms should be tested at a percentage of their crop based on the P/P's tier. This method of testing would equalize the cost over all of the tiers.</p>
Barriers	Proposed Solutions							
Cost-effectiveness – testing small lot sizes makes testing cost-prohibitive to smaller producers.	<p>Washington State Department of Agriculture (WSDA) should assist the Liquor and Cannabis Board (LCB) with developing a yearly randomized testing protocol for cannabis farms for pesticides and heavy metals. All required ISO2 testing still needs to be conducted for any product bound for retail stores.</p> <p>For material meant for extraction, farms should be tested at a percentage of their crop based on the P/P's tier. This method of testing would equalize the cost over all of the tiers.</p>							

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				<p>Cost-effectiveness – testing small lot sizes makes testing cost-prohibitive to smaller producers. (continued)</p>	<p>Corrective action should be reflected by the Washington State Department of Agriculture (WSDA) protocols, which are solution-oriented. Punitive actions should carry the burden of proof of intent or negligence.</p> <p>Concentrate producers must get every finished lot of inhalable concentrate tested because these products present the highest incidence of pesticide contamination.</p> <p>If the product doesn't pass the pesticide/heavy metal test, the P/P would have an opportunity to have the crop or the concentrate remediated or retested at a second lab to ensure human error wasn't a factor and to account for a certain plus/minus range that is inherent in all testing</p>
				<p>Labs do not have a standardized testing methodology</p>	<p>The Washington State Department of Ecology should provide interim guidance to the labs by 2022.</p>
				<p>Lack of sufficient agency cooperation between the Liquor and Cannabis Board, Departments of Ecology, WSDA, and Health to staff such a large endeavor.</p>	<p>There must be a clear understanding of roles and responsibilities for the agencies involved with testing. A written interagency agreement may be needed for any testing issues not already addressed by existing interagency agreements.</p> <p>Information on agency roles and responsibilities for testing, including any interagency agreements, must be shared with the cannabis industry in a timely manner.</p>
				<p>There is not a technical ability to remediate pest/HM for conc or crop. WA State Dept of Ecy has not been tasked with writing the product standards.</p>	

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				<div style="border: 1px solid black; padding: 10px; margin-bottom: 10px;"> <p>Lack of research on appropriate pesticides and lack of sufficient interagency coordination for drift investigations</p> <p>The Liquor and Cannabis Board (LCB) and the Washington State Department of Agriculture (WSDA) should support industry efforts to form a Cannabis Commission. A Commission could help to fund needed pesticide research on cannabis to be shared with the hemp industry as well.</p> <p>The Washington State Department of Agriculture (WSDA) should be the lead agency for drift investigations. A written interagency agreement may be needed for any issues not already addressed by existing interagency agreements.</p> </div> <p>We respectfully submit these suggestions as we need the Liquor and Cannabis Board to continue working with industry leaders and other state agencies who have the requisite expertise to revise and revamp the testing procedures to keep up with the evolving science of cannabis. There is still much work to be done concerning the details about how we as an industry approach to quality assurance. An advisory panel is the next logical step for the progression of our testing rules.</p>
8	6/17/2020	Email	Kim Webster (Form letter, WSIA)	<p>Dear Kathy et al. I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026. Given the significant financial impact, these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue. Lot level testing for pesticides and heavy metals is not the answer, especially given the arbitrarily low limit on lot size and the reality that heavy metal contamination is most likely to be introduced by vape cartridge hardware. The SBEIS fails to consider the implication of these changes given the current business environment that has seen significant impacts from COVID19 including increased costs, supply chain interruptions, and additional safety requirements. COVID19 has also forced the economy into a recession and it remains to be seen how significantly this contraction in the economy will impact our nascent industry. Now is not the time to significantly increase the cost for small independent farmers to continue operating. In addition, the rulemaking seems premature given the lack of confidence in the consistency and reliability of Washington's labs since the WSDOE standardization and accreditation project has not been completed nor implemented. I would like the WSLCB to restart the rule-making process on this, going back to the CR 101 stage, putting together a</p>

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				diverse workgroup of representatives from all trade associations as well as stakeholder groups to have a more in-depth discussion of proposed rules with a commitment to exploring alternative approaches to testing and more effective cost mitigation strategies. Thank you
9	6/17/2020	Email	Galadriel Walser (Form letter)	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>Lot level testing for pesticides and heavy metals is not the answer, especially given the arbitrarily low limit on lot size and the reality that heavy metal contamination is most likely to be introduced by vape cartridge hardware.</p> <p>The SBEIS fails to consider the implication of these changes given the current business environment that has seen significant impacts from COVID19 including increased costs, supply chain interruptions, and additional safety requirements. COVID19 has also forced the economy into a recession and it remains to be seen how significantly this contraction in the economy will impact our nascent industry. Now is not the time to significantly increase the cost for small independent farmers to continue operating.</p> <p>In addition, the rulemaking seems premature given the lack of confidence in the consistency and reliability of Washington's labs since the WSDOE standardization and accreditation project has not been completed nor implemented.</p> <p>I would like the WSLCB to restart the rule-making process on this, going back to the CR 101 stage, putting together a diverse workgroup of representatives from all trade associations as well as stakeholder groups to have more in depth discussion of proposed rules with a commitment to exploring alternative approaches to testing and more effective cost mitigation strategies.</p> <p>We as a farm have just started to make enough money to offer our employees medical insurance, these kind of increased costs would prohibit us from adding any additional benefits.</p>
10	6/17/2020	Email	Wendy Griffiths (Form letter)	<p>Dear Kathy et al.</p> <p>My name is Wendy Griffiths, and I co-own and manage a family owned farm, Urban Farms of Washington, LLC, with my husband and son. We are a tier 2 producer/processor located in north central Washington.</p> <p>Having just survived the terrible growing season last year with the early hard freeze and snow last September, I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026. Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue. Lot level testing for pesticides and heavy metals is not the answer, especially given the arbitrarily low limit on lot size and the reality that heavy metal contamination is most likely to be introduced by vape cartridge hardware. The SBEIS fails to consider the implication of these changes given the current business environment that has seen significant impacts from COVID19 including increased costs, supply chain interruptions, and additional safety requirements. COVID19 has also forced the economy into a recession and it remains to be seen how significantly this contraction in the economy will impact our nascent industry.</p> <p>Now is not the time to significantly increase the cost for small independent farmers to continue operating. In addition, the rulemaking seems premature given the lack of confidence in the consistency and reliability of Washington's labs since the WSDOE standardization and accreditation project has not been completed nor implemented. I would like the WSLCB to restart the rule-making process on this, going back to the CR 101 stage, putting together a diverse workgroup of representatives from all trade</p>

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				associations as well as stakeholder groups to have more in depth discussion of proposed rules with a commitment to exploring alternative approaches to testing and more effective cost mitigation strategies.
11	6/18/2020	Email	Sean Stringer (Form letter)	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026</p> <p>There is a significant impact for everyone through the whole supply chain. There are alternative ways to handle testing than testing every 5lb lot. We have the Dept of Ag which I believe specializes in testing products produced on large farms, which could give everyone a better idea of what they are really smoking.</p> <p>We don't need to follow in the footsteps of others, nor do we need to re-invent this process on arbitrary science.</p> <p>I would like the WSLCB to restart the rule-making process on this, going back to the CR 101 stage, putting together a diverse workgroup of representatives from all trade associations as well as stakeholder groups to have more in depth discussion of proposed rules with a commitment to exploring alternative approaches to testing and more effective cost mitigation strategies.</p>
12	6/19/2020	Email	John Gereighty (Form letter)	<p>Dear Kathy et al. I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026. Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue. Lot level testing for pesticides and heavy metals is not the answer, especially given the arbitrarily low limit on lot size and the reality that heavy metal contamination is most likely to be introduced by vape cartridge hardware. The SBEIS fails to consider the implication of these changes given the current business environment that has seen significant impacts from COVID19 including increased costs, supply chain interruptions, and additional safety requirements. COVID19 has also forced the economy into a recession and it remains to be seen how significantly this contraction in the economy will impact our nascent industry. Now is not the time to significantly increase the cost for small independent farmers to continue operating. In addition, the rule making seems premature given the lack of confidence in the consistency and reliability of Washington's lab since the WSDOE standardization and accreditation project has not been completed nor implemented. I would like the WSLCB to restart the rule-making process on this, going back to the CR 101 stage, putting together a diverse workgroup of representatives from all trade associations as well as stakeholder groups to have more in depth discussion of proposed rules with a commitment to exploring alternative approaches to testing and more effective cost mitigation strategies. Thank you,</p>
13	6/25/2020	Email	Jamie Hoffman	<p>Adopting a pesticide and heavy metal testing plan makes good sense. However, we strongly oppose the rule as it stands now and encourage further research into how the ruling structure will severely hurt the Cannabis industry and its stakeholders.</p> <p>As an ISO2 licensed processor for the past 6 years, this recent political need of frequent testing is concerning. I've never been more concerned over a rule than <u>this</u> rule.</p> <p>Kathy, since we met last Fall, I asked your staff if they had any idea how many Lots are currently tested by the labs on a monthly basis and not one person on your staff had the answer. I also asked how long it takes to perform a pesticide and heavy metal test, again, not one person on the panel, including yourself had the answer. Do you know now? Deciding to test every five pounds is absurd. <i>We are in wonderment of how little thought was put into this suggestion.</i></p> <p>Our Stakeholders are constantly vetted, inspected and audited by the following agencies and methods:</p> <p>1) Finger printing stakeholders</p>

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				<p>2) Financial investigations 3) LCB annual inspections 4) City of Seattle annual inspections 5) WSDOA annual inspections 6) Puget Sound & Air semi-annual inspections 7) Fire Department semi-annual inspections 8) Potency & microbial batch weekly testing</p> <p>The pesticide & heavy metal testing plan is currently written to police our businesses on a daily basis. Testing for pesticides at the recommended rate of frequency would be devastating to our industry. <u>Many growers use ABSOLUTELY NO PESTICIDES but will be penalized by this rule.</u> Any business that needs that amount of policing for pesticides or heavy metals SHOULD NOT BE IN BUSINESS.</p> <p><i>Creating a practical and cost effective testing plan makes sense ONLY if managed by a third party inspector which will be hard government work to create an agency to oversee. We expect you to do the hard work and make sure our essential businesses stay intact.</i></p> <p>The 5 labs in Washington State have a financial burden of purchasing expensive equipment to test only a small variety of metals and pesticides. The LCB has done zero analysis proving that the Cannabinoid structure of the Cannabis plant will give accurate pesticide & heavy metal results. Again, hard work to provide analysis that the long list of pesticides and heavy metals can be detected within the plant structure.</p> <p>I suggest a practical annual inspection is considered for the future stability of our industry.</p> <ul style="list-style-type: none"> • ANNUAL inspection and testing for pesticides & metal for each plant variety performed by a third party agency. • Complete testing done for each stakeholder on their licensed anniversary date to eliminate bottleneck. • PENALTY if a trace amount of pesticide or metal is detected by THEN increasing the testing frequency. <p>There are only 5 businesses that will survive this absurd recommendation of 5 pound Lot testing.</p> <p>This rule is a serious blunder. It will effect jobs, businesses and the consumers plus ignite the blackmarket with serious fuel. I'm surprised by the lack of foresight and minimal planning. Taking the easy road to have this be a self-serving, self-run and self-funded is not practical. Do the hard work needed to have a government-run agency oversee this new initiative.</p> <p>Please show confidence in our industry stakeholders and reduce the frequency of testing.</p> <p>Respectfully - Jamie</p>
14	6/25/2020	Email	Ray Robbin	<p>Dear Ms. Hoffman,</p> <p>My name is Ray Robbin and I am a member of Emerald Jane's LLC, we are a tier 2 producer processor. We recently moved to a new larger facility. We now employ over 20 people.</p>

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				<p>I just took the time to read all of the documents you provided. We all understand and want the same thing, extremely safe products. That is a given. So I completely understand all of the science involved about wanting to test for pesticides and heavy metals.</p> <p>However if you roll this plan out with the the 5 pound lot size, It would put me out of business in no time. As I mentioned we just started at the new facility and are just now starting to break even. Hundreds of thousands of dollars in testing fee's would be untenable. Not only the cost, but the indirect cost of waiting weeks for samples to be processed, this would create a double whammy.</p> <p>As Jamie mentioned below, this added burden would increase cost to the consumer, reduce tax revenue and fuel the black market.</p> <p>I am 100% pesticide free and always have been. I spend tens of thousands of dollars on beneficial bugs that allows me to not have the need for pesticides. In that regard it is even worse for myself and other growers with high ethical standards.</p> <p>Perhaps a better approach would be to do random testing of all producers and processors, a system like that would meet the goal intended of providing safe products and it would not put everyone out of business.</p> <p>Thank you for your consideration,</p>
15	6/26/2020	Email	Scott Berka (Form letter, WSIA)	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>Lot level testing for pesticides and heavy metals is not the answer, especially given the arbitrarily low limit on lot size and the reality that heavy metal contamination is most likely to be introduced by vape cartridge hardware.</p> <p>The SBEIS fails to consider the implication of these changes given the current business environment that has seen significant impacts from COVID19 including increased costs, supply chain interruptions, and additional safety requirements. COVID19 has also forced the economy into a recession and it remains to be seen how significantly this contraction in the economy will impact our nascent industry. Now is not the time to significantly increase the cost for small independent farmers to continue operating.</p> <p>In addition, the rulemaking seems premature given the lack of confidence in the consistency and reliability of Washington's labs since the WSDOE standardization and accreditation project has not been completed nor implemented.</p> <p>I would like the WSLCB to restart the rule-making process on this, going back to the CR 101 stage, putting together a diverse workgroup of representatives from all trade associations as well as stakeholder groups to have more in depth discussion of proposed rules with a commitment to exploring alternative approaches to testing and more effective cost mitigation strategies.</p>
16	7/2/2020	Email	Kris Labanauskas	<p>Dear Kathy et al.</p> <p>I am a small family-owned producer processor and am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026. These rules as written would create additional costs to operate our business. I would ask that the WSLCB look into other options to testing that would still keep products safe but not put more financial burden on a small business such as</p>

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				mine.
17	7/2/2020	Email	Jade Stefano	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislatures intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p> <ul style="list-style-type: none"> -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing.
18	7/2/2020	Email	TJ McDonald	<p>Hey Kathy,</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislatures intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p> <ul style="list-style-type: none"> -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing.


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19	7/5/2020	Email	Steven McCombs	<p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Being that I am a Tier 2 Producer it will increase my cost of production significantly, which most of my customers will probably balk at. Here is an example of the increased cost - Produce 1000 pounds, at 5 pound lot size that is 200 tests. Current published cost, from a leading testing facility, for the complete test plus Pesticides and Heavy Metals is \$265. That would total \$53,000. Almost \$0.12 per gram! I would say that this is a significant impact on Producers without much benefit to the ultimate end user.</p> <p>Along with the existing issues of QC lab reliability and consistency these proposed rules should not be adopted.</p> <p>The major flaw that I see in the proposed rule is that the proposed testing system can be 'gamed' since there is not a 'third party' doing the 'sample collection'. Not saying that all the producers will be cheating by submitting 'clean' material for testing - but we all know that 'desperate people will do desperate things' without much of a chance being caught.</p> <p>Changes that I would like made like in Rules is to:</p> <ol style="list-style-type: none"> 1. Lot size limits should be abandoned 2. All QC testing should focus on end packaged products i.e. cartridges, prerolls, edibles, tinctures, etc.. What good does it do to test at the Producer level when the product then goes through multiple other 'hands' before it reaches the ultimate consumer. Kinda like testing a cow for E Coli and not testing the 'ground beef'. 3. Have an LCB employee collect the Pesticide sample at the Producer level. Different production styles would have different testing frequencies. 4. In section (5) (b), in regards to what lots that can be transferred without required quality control testing, add 'or conversion to other intermediate or final products' <p>Thanks for the time to present these points.</p>
20	7/6/2020	Email	Tina Morelli	<p>Dear Cathy</p> <p>Hi my name is Tina morelli . I am the owner of morelli enterprises a tier 1 producer processor . I have a few separate issues . The lot testing size can only be in 5 lb lots so it's costing me 120\$ per 5 lbs as the smallest their size their is I don't and haven't mDe any profit ever since I have started. Between the testing , failed lots and the test per ever 5 lbs makes it almost completely impossible for me to ever profit . I do believe strongly in the testing but the lot size needs change . The very few testing companies there are half the time I feel like farmers are paying a side person to pass there products I find it odd that when I go into a rec store their is stuff testing over 40-50 % . I came from the medical side if this I owned and operated a medical lounge before I switched to recreational. Mind you no one in 4 yrs ever came in to our shop to make sure the law was being followed and we we're buying products from strangers in the streets . I feel like this whole system is broken and the only people that are making money are the cheaters that are selling on the black market . I follow the law by the book and everyone (other farmers say u follow it so much it's actually hurting you) that hurts my heart to hear .</p>
21	7/7/2020	Email	Shawn DeNae	<p>Good morning,</p> <p>I am sharing the attached report incase you all have yet to see these recommendations. #5 & #11 are particular sections that addresses my concern on implementing the testing based upon lots vs by batch & final product level testing.</p> <p>A quote from section #11:</p> <p><i>"Legal cannabis businesses across the country are still competing with black market actors who are not subject to mandatory testing requirements or any other compliance costs. Therefore, "over-testing" is not just a harmless policy that only impacts an owner's bottom line; it actually damages public safety by shifting resources away from compliance initiatives that protect public safety and increasing the competitiveness of black market actors."</i></p>

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				<p>Thank you for taking the time to review these recommendations and add them to the inputs received.</p>  <p>NCIA-Policy-Council -Testing-Policy-Repc</p>
22	7/7/2020	Email	Nick Mosely	<p>Dear Kathy Hoffman et al.,</p> <p>Please see attached public comment regarding CR-102 Filed as WSR 20-12-026 on May 27, 2020 (Quality Control Testing and Products Requirements).</p> <p>I would appreciate an acknowledgement of receipt of this email and corresponding attachment.</p>

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TO: Kathy Hoffman, WSLCB Rule Coordinator
1025 Union Avenue SE
Olympia, WA 98504

2020-07-07

CC: Russell Hauge, WSLCB BOD Member; Jane Rushford, WSLCB BOD Member; Ollie Garrett, WSLCB BOD Member; Rick Garza, WSLCB Director; Kendra Hodgson, Cannabis Examiner Manager; Dustin Dickson, Executive Assistant

RE: CR-102 Filed as WSR 20-12-026 on May 27, 2020 (Quality Control Testing and Products Requirements)

VIA: Email

Dear Kathy Hoffman et. al.,

As the operator of an independent and certified testing laboratory under the scope of the Washington Recreational Cannabis industry, I write this letter concerning the currently proposed Quality Control rule revisions pursuant to the public hearing scheduled for tomorrow, July 8th, 2020.

Confidence Analytics is certified in good standing with the WSLCB for all testing regimens currently required under rule. Additionally, Confidence Analytics is certified for the optional tests "terpenes" and "pesticides." Furthermore, Confidence Analytics is voluntarily accredited by the internationally recognized American Association for Laboratory Accreditation (a2la) a member of the International Laboratory Accreditation Cooperation (ilac) under the International Standards Organization (ISO) 17025 quality management system. Our laboratory maintains these additional accreditations voluntarily and at our own expense for all testing performed in our laboratory as a demonstration of our continued commitment to good, honest science in support of the Washington cannabis industry.

For your consideration, Confidence Analytics has in-house capabilities for heavy metals testing. In our May 2020 audit by the RJLee group, the instrument we use for heavy metals analysis (ICP-MS) was observed in its operational configuration by the audit team. Our lab will be submitting validation reports to RJLee in the next 3 weeks to complete the addition of this test to our scope. We will be ready for heavy metals testing before September of 2020, more than a year in advance of the proposed testing requirements for this assay.

Attached you will find a photo of our ICP-MS. We additionally have in-house three LC-MS/MS instruments, which are used for pesticide testing. I mention this in my effort to assure you that the capacity needed to carry out the proposed rules is already deployed and ready in waiting.

With kind regards,



Nick Mosely, M.S.
Chief Executive Officer
Confidence Analytics



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www.conf labs.com



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Figure 1. Inductively Coupled Plasma Mass Spectrometer (ICP-MS) from Shimadzu Scientific. Picture taken at Confidence Analytics in Redmond Washington on July 6th, 2020. The unit can test up to 20 samples per hour for heavy metals analysis. This unit alone has enough capacity to test over 10,000 samples per month, giving it plenty of capacity to meet future demand. Confidence Analytics will be submitting a validation report to the RJLee Group in the coming weeks.

[END]

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23	7/7/2020	Email	Cari Thompson	<p>Kathleen, I am a buyer for an extract company, which means I buy wholesale flower and trim from growers, which we extract at our facility. We voluntarily test all our products before they get packaged and sent to retail stores. Sometimes our concentrates fail for pesticides, particularly for Piperonyl Butoxide, which isn't even a pesticide, but rather an additive in pesticides. The action level for concentrates for PB is 2.0 ppm. After a few failures of our concentrates, we decided to start testing the trim before using it and we are finding PB, usually in small amounts, but some higher amounts, and it is in everything we purchase.</p> <p>My question is: Why is there no action level for PB (or other pesticides) for flower and trim but there is an extremely low action level for concentrates? In my opinion, this makes no sense and is in fact backwards. This puts all the burden on the extract company to pay for testing and all the risk of buying product that "passed" as flower (due to no action level) yet fails as concentrate, which leaves us with money and time wasted and product we can't sell. The growers can use as much pesticide as they want (as long as it's on the approved list) with no repercussions and no accountability. There needs to be a low action level for flower. It would need to be less than 0.2ppm because when we concentrate, the pesticide also becomes concentrated. The rule of thumb according to Confidence Analytics is pesticides in flower will multiply by 10 in concentrate.</p> <p>I have attached a couple of test results for reference. Looking at the Piperonyl Butoxide, you'll see in the EHO results that we failed by 0.3ppm, yet the results for the flower results show 4.5ppm. This grower is allowed to sell his pesticide-laden flower for consumers to smoke, yet our concentrate is deemed unsafe. How does this even make sense?</p> <p>The fact that there is no action level for pesticide in flower and trim makes it nearly impossible for us to find product that is clean enough to produce extract that will pass the PB action level of 2.0ppm.</p> <p>If we truly want to get pesticides out of cannabis and protect the consumer, it needs to start at the grow. These farms need to be held accountable. They should be the ones paying for the pesticide testing. They are the only ones who can control what is used during the growing cycle. They should be required to provide a clean pesticide test for every lot they sell, and if their flower produces failed extract, there needs to be repercussions in the form of a refund to the extract company that purchased it. Maybe the added costs will finally force them to stop using pesticides.</p> <p>Thank you for taking the time to read this. I sincerely hope my comments and questions make it to whomever decides these things.</p>
24	7/7/2020	Email	Colin Lukey	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislature's intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p>

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				<ul style="list-style-type: none"> -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing.
25	7/7/2020	Email	Jian Malihi	<p>Hi Kathy,</p> <p>I just wanted to take this chance before the WSLCB meeting to reiterate some problems that I see with the current proposed rules:</p> <ul style="list-style-type: none"> -The biggest problem I see is that the WSLCB is not required to contract their testing through certified i502 labs. Currently they are conducting their testing through the WSDA. This will inevitably create situations with conflicting test results and will make it impossible for producers to be certain that the material they sell meets grade. It will also be a nightmare for LCB investigations as WSDA samples take months to process whereas i502 labs can turn samples around in 2-3 days. -It seems that the heavy metals testing requirement is wasteful and unnecessary as heavy metals have not been shown to be a problem in raw cannabis material. Instead the heavy metals issue is basically solely caused by vape hardware. -The 5 pound lot size still seems arbitrary and with the cost of new tests increasing the overall testing costs for farmers it would seem fair that the lot size should also increase to at least 15 pounds. <p>I would also like to note that we pretty much endorse the position offered by the WSIA on this issue. Unfortunately these rules are not ready and will only make the problems they wish to cure worse overall.</p> <p>Thanks a lot and please let me know if you would like any clarification on my comments.</p>
26	7/7/2020	Email	Azmyth Kaminski	<p>Dear Kathy et al.</p> <p>Quick note: Given that the hemp industry is still developing & seeking a consistent floor. Any increase in cost to produce & verify adds lost profitability based on the unknown and consistently fluctuating market pricing.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislature's intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p>

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27	7/7/2020	Email	Benjamin Schuster	<p>Dear Kathy et al.</p> <p>First, I acknowledge that the points below are likely consistent with many other comments you have received. I write separately to make it clear that they apply directly to my business Cascade Gnome, as much as all the other comments received.</p> <p>As an Owner/Operator, the financial burden of these proposed requirements is clear, abundant and be practically unmanageable. As noted below, I share serious concerns about consistency between labs as well as internal consistency. It's supposed to be science, after all.</p> <p>I support regulation, I support testing, but it needs to be economically feasible AND a worthwhile endeavor, thus I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislatures intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p> <p>-Arbitrary lot size limits should be abandoned.</p> <p>-Pesticide testing should be done at the farm level.</p> <p>-Cannabinoid & microbial testing should be done at the strain-harvest level.</p> <p>-Heavy metal testing should focus on vape cartridge hardware and end product testing.</p> <p>Should you have questions, concerns or further clarification, please feel free to contact me at this email address or at the phone number below.</p>
28	7/7/2020	Email	Jeff Wilhoit	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for</p>

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29	7/7/2020	Email	Cyrena Stefano	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislatures intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p> <ul style="list-style-type: none"> -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing.
30	7/7/2020	Email	Samuel Kannall	<p>Dear Kathy,</p> <p>My name is Samuel Kannall. I am the owner of Bodhi High Brands a small processing company.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026. Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue. It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislatures intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards. A few changes that should be made include: -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid &</p>

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31	7/7/2020	Email	Monica Martinez	<p>Dear Kathy et al. I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026. Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue. It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislature's intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards. A few changes that should be made include: -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing. Thank you,</p>
32	7/7/2020	Email	Troy Rushforth	<p>I am writing in concern on the proposed WSR 20-12-026. I STRONGLY urge you to NOT to adopt the new QC rules.</p> <p>This is yet another obstacle the State is trying to pass to further hurt our industry as a whole. We are a small farm that has barely survived the last pricing plunge. We are trying to make a living in an industry that is already hit with state taxes, and the inability to write off basic expenses at the Federal level. It seems as though every year, the State tries to come up with new ways to make money off of, or create new unnecessary costs, to an industry that is already hit harder than any other type business in the way of operating costs.</p> <p>Enough is enough. You need to realize we don't have the means to afford such increases in production costs. This is just going to put more struggling small companies out of business, and people out of work, at a desperate time in society with all the problems that we are currently faced with. These decisions are not being thought through by the WSLCB. You need to focus on things that will help our industry, not things that will effectively put us out of business. If you force us to fail at the farming level, that will only have a domino effect on all levels.</p> <p>Changes simply need to be made to help us, not hurt us.</p> <p>Lot size limits should be ended. It is added costs that make no sense, that no other industry has to endure. Test by the individual strain, not by the pound.</p> <p>You need to consider Producers to be able to sell locally at their own farms, exactly how you have set up the Microbreweries and Distilleries with Tap Rooms.</p> <p>Pesticide testing can be done at the farm level to cut costs, and can be supplied to buyers.</p> <p>Microbial testing needs to be done at the harvest level, as well as heavy metals need to be turned towards the end product device sector.</p> <p>I sincerely hope you listen to the farmers. Passing this proposal will have yet another HUGE negative impact on us that we cannot handle at this point.</p>
33	7/7/2020	Email	Anders Taylor	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p>


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				<p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue. Furthermore, the rules as proposed ignore the history of environmental lead contamination. For decades, the United States used leaded gasoline in vehicles and lead arsenic as a pesticide on orchards throughout Washington State. A majority of the state's agricultural land has been contaminated by these practices. Many small organic farms do everything possible to remediate the soil, but given the historical use as conventional orchards, it can be challenging to meet the arbitrarily low limits being proposed by the WSLCB.</p> <p>I would strongly urge the WSLCB to consider safe standards that are set by other industries as they relate to lead contamination and acceptable levels. Further, heavy metal testing should focus on the vape cartridge hardware and end product testing.</p> <p>Additionally, I would encourage the WSLCB to stop making rule changes to lab testing without solving the chain of custody issues that STILL – 6 years after inception – plague our industry's lab practices. It's absolutely criminal that you haven't fixed this problem still. It's not that hard. Make tests random and require labs to come take samples from producers. It's the only way to ensure accurate results. As it currently stands, bad actors thrive by cheating.</p>
34	7/7/2020	Email	ALPHABUDZ LLC	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislature's intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p> <ul style="list-style-type: none"> -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing.
35	7/7/2020	Email	Rian Takahashi	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for</p>


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36	7/7/2020	Email	Jeremy Moberg	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislatures intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p> <ul style="list-style-type: none"> -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing.
37	7/8/2020 (3:36AM)	Email	Mark Ambler	 <p>WSR_20-12-026 Breeze Trees Comme</p>
38	7/8/2020	Email	Laurel Friesen	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue.</p> <p>It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to</p>

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				<p>ignore the legislature's intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>A few changes that should be made include:</p> <ul style="list-style-type: none"> - Arbitrary lot size limits should be abandoned. - Pesticide testing should be done at the farm level and randomly sampled by the LCB from end products on retail shelves. - Cannabinoid & microbial testing should be done at the strain-harvest level. - Heavy metal testing should focus on vape cartridge hardware and end product testing.
39	7/8/2020	Email	Clayton Sperry	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026. Given the significant financial impact these rules present as outlined in the SBEIS it is clear that the WSLCB needs to explore other approaches to testing that will allow small businesses such as mine to continue. It is concerning that the WSLCB is considering rule making that will significantly increase the amount of money producers and processors spend with Washington's labs when the lack of confidence in the consistency and reliability of labs required the legislature to pass HB2052 in 2019 directing the WSDOE to put in place a standardization and accreditation program for Washington's labs. This standardization and accreditation program has not yet been implemented thus issues with the reliability and consistency with lab results persist. While the issue of accreditation is not considered in this rule making it is impossible to ignore the legislatures intent to address this issue and how it intersects with quality assurance sampling protocols and enhanced testing requirements and standards.</p> <p>It seems like every time we get to a point where we understand the rules... you change them!</p> <p>A few changes that should be made include:</p> <ul style="list-style-type: none"> -Arbitrary lot size limits should be abandoned. -Pesticide testing should be done at the farm level. -Cannabinoid & microbial testing should be done at the strain-harvest level. -Heavy metal testing should focus on vape cartridge hardware and end product testing.
40	7/8/2020	Email	Crystal Oliver/WSIA	<div style="text-align: center;">  </div> <p>WSIA2020QCComm entsFinal.pdf</p>
41	7/8/2020	Email	Kevin Oliver	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>Representing the world's oldest and largest marijuana consumer lobby, the National Organization for the Reform of Marijuana Laws (NORML), headquartered in Washington DC for 50 years with thousands of WA state residents as members, it is worth noting that these arbitrary rules are not grounded in scientific data regarding consumer safety.</p> <p>Washington state could set a precedent for consumer safety by committing to research that determines what, if any, pesticides and other contaminants are present in the marijuana consumed by adults. (i.e. evidence to suggest they survive the heating process as flower is consumed) and further, what actual danger - if any - exists to the consumer from said contaminants.</p> <p>Strictly speaking, the rules regarding pesticides presented in WA and other legal states, do nothing to determine actual thresholds of danger to consumers. Rather, they are set arbitrarily to the whims of unregulated for-profit labs.</p>


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				Before arbitrarily taxing industry participants, please consider rules based on epidemiological and forensic evidence that would set precedent through science in determining what if any dangers exist in consumer products. To date, there is zero evidence showing an increase in pathology arising from products obtained in legal marijuana markets.
42	7/8/2020	Email	Kelsey Taylor	<p>Dear Kathy et al.</p> <p>I am writing to request that the WSLCB NOT adopt the QC Rules proposed in WSR 20-12-026.</p> <p>These rules will cause significant impact to small businesses such as mine, and very well may put me out of business. I own a small organic cannabis farm on former orchard land. As you may know, orchards have a long history in Washington State of having lead-arsenic used as a pesticide. Much of the state's agricultural land has been contaminated by years of agricultural practices that used chemicals we now know can be dangerous.</p> <p>I am doing everything that I can to remediate the soil on my land, but it will take time. The timeline here is simply far too short and the limits arbitrarily low - a March 2021 compliance date for these levels means the plants I already have in the ground will need to meet these heavy metals thresholds. I am concerned that this will put me out of business. Yet another woman-owned business will bite the dust due to arbitrary WSLCB rules that favor the powerful and wealthy.</p> <p>We live in a world of environmental contamination, so it is important that we take a measured and science-based approach here. I strongly urge the WSLCB to consider safe standards that are set by other industries as they relate to lead contamination. Furthermore, heavy metal testing should focus on the vape cartridge hardware and end product testing. Lead can leach from the metal hardware over time and with heat, so it is critical that you consult experts in the field in order to protect consumers more effectively.</p> <p>And finally, the WSLCB should fix the fundamental issue of lab testing before they continue to add on testing to an already broken system. The chain of custody issues that plague the industry's lab practices completely undermine public safety, and the fact that they haven't been fixed in nearly six years is galling. They allow bad actors to thrive, while making it even harder to succeed for those of us who have the integrity not to cheat.</p> <p>Fix the chain of custody issues and do more research on action levels before tacking on more testing. These poorly written rules will only bankrupt women and minority-owned businesses, without even the benefit of improving public safety.</p>
43	7/8/2020	Email	Chris Marr	<p>Chair Rushford and Board Members,</p> <p>Thank you for the opportunity to comment on the proposed Quality Assurance rules. First, thanks to Kathy Hoffman and her Policy & Rules team, and the many stakeholders who committed so many hours to this rulemaking process.</p> <p>I support the breadth of the proposed testing requirements as well as the phase-in of new pesticide and heavy metal testing. While it may be necessary to slightly shift phase-in dates to accommodate for rulemaking delays, I ask that you oppose efforts to significantly delay their implementation. This industry has operated too long without robust product safety testing and we cannot afford to put at risk the health of consumers, who choose to buy from the regulated market because of the reassurance of oversight.</p> <p>My major concern is the decision to maintain the current 5-lb. lot size requirement, which will have huge cost impacts on the industry with no tangible public safety benefit. In fact, maintaining 5-lb. lots will only further the price disparity between the regulated and illicit markets, creating greater risks to public safety.</p> <p>According to the SBEIS, based on higher testing costs per sample, producers will see costs ranging from \$12,000 to \$832,000 based on full implementation of new testing standards. Those costs will be magnified as markup is taken throughout the supply chain and as excise, sales and other taxes are applied at the point of sale. That means the costs at the cash register could be two or three times that.</p>

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				<p>The SBEIS states “...it is assumed that these costs <u>will not</u> be passed on to retailers or consumers at this time...If producer/processors are able to pass on the costs of testing, then the impacts would more likely be borne by consumers.” We know that current margins experienced by producers and processors provide no basis for an assumption that additional testing costs will be absorbed by licensee.</p> <p>We’ve been told that lot sizes were not increased because there was “no consensus” among stakeholders during the rule development process. I would suggest that it is because testing labs were over-represented in the process and they see mitigating costs through lot size as a threat to their revenue stream. I can appreciate that. However, I think the interests of licensees and consumers should come first.</p> <p>Washington is an outlier, in both lack of product testing and lot-size. Oregon allows up to 15 lb. batches. California allows batches up to 50 lbs. and requires a minimum of .35% of each batch be tested. Colorado also increases sampling based on lot size: 10-20 lbs. requires 12 half gram samples, over 100 lbs. requires 29 half gram samples. You may hear from some labs that larger sizes limit accuracy. However, as other states have found, that can be addressed through appropriate testing protocols and increased sample quantities.</p> <p>Increased testing is vital, as is mitigating costs and our ability to compete with the illegal market. We can accomplish both by increasing lot sizes.</p> <p>Thank you for your consideration.</p>
44.	7/8/2020	Email	Joanna Monroe (Craft Cannabis Coalition)	 <p>7-7-20 - UPDATED Letter to LCB.pdf</p>

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DATE: July 6th, 2020

TO: Kathy Hoffman, WSLCB Rule Coordinator

CC: Bryan McConaughy, WSIA Lobbyist; Russell Hauge, WSLCB BOD Member; Jane Rushford, WSLCB BOD Member; Ollie Garrett, WSLCB BOD Member; Rick Garza, WSLCB Director

FROM: Washington Sun Growers Industry Association (WSIA)

RE: CR-102 WSR 20-12-026 Quality Control Testing and Product Requirements

Kathy et al,

Thank you for your continued dedication to collaborative rulemaking.

WSIA's mission is to support sustainably farmed sungrown cannabis by encouraging positive environmental and economic policy through advocacy, education, and research.

We represent 50 businesses who hold more than 90 WSLCB marijuana licenses. Most of our members are licensed marijuana producers and processors.

During the pre-proposal stage of this rulemaking WSIA offered verbal comment and submitted a white paper titled "Cannabis Quality Assurance Testing". Over 80 producers and labs have signed on to this paper. This paper outlines our concerns with the current QC testing rules and proposals in this CR102 as well as concerns related to regulations that intersect with the rules being reconsidered here.

We remain extremely concerned that the WSLCB is considering the adoption of rules that will significantly increase farmer's spending with Washington's private labs prior to the Washington State Department of Ecology (WSDOE) accreditation program being implemented. This rule-making is premature given the general lack of confidence in the consistency and reliability of Washington's current lab results and methods. The legislature recognized this deficiency and addressed it by passing legislation directing the WSDOE to develop standardization and accreditation for labs (HB 2052). WSLCB should continue to fully utilize the expertise of the WSDA and leverage the existing interagency agreement #813 to continue pesticide testing at production facilities as well as end products at retail stores.

The industry has done a very good job of policing itself since the topic came to head in 2017; producer/processors are now doing an unprecedented amount of voluntary private pesticide testing due to demands for clean material and many of these tests results are available to stores and the public. There have been a number of industry efforts to raise awareness of pesticide free products including the OK Program, Clean Green Certified, Testing with Confidence and many individual stores and processors require testing of products before they purchase them. These programs have shown a very high level of compliance with WSLCB's very strict pesticide restrictions.

If the WSLCB decides to move forward with this rulemaking we are hopeful that the WSLCB will consider the following substantive changes to the proposed rules. We believe that requirements

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for testing pesticides and the current cannabinoid panel testing are very different. Testing for pesticides should occur at the farm level as currently being done as part of the WSLCB-WSDA interagency agreement #813. Cannabinoid testing, mycotoxin testing, and microbial testing should be conducted at the strain-harvest level. It is with this separation in mind that we recommend the following changes to WSR 20-12-026.

- **The WSLCB should adopt strain-harvest level testing for cannabinoid, mycotoxin, and microbial testing.** Multiple tests could then be performed on the strain-harvest population and cannabinoid results could be reported as a range. By replacing testing of an arbitrary lot size with strain-harvest level testing while increasing cannabinoid testing the LCB would insure that the data meant to represent the population would be statistically valid. In fact, the current testing based upon 5lb lot, or any arbitrary lot size, violates the basic statistical requirements to represent a population such as not being able to calculate variance, using a single sample to represent a population instead of a range, and is essentially not valid data. This is important because the consumer uses this data to regulate consumption and should be presented with variance and ranges of cannabinoids on the product to make proper consumption decisions, data that is best collected at the strain- harvest level.
- **Enterobacteria testing should be an indicator test, not a pass-fail test.** The Enterobacteria testing has no legitimate scientific basis for being a pass-fail test and unfairly disadvantages farmers who cultivate outdoors and in living soils where a variety of bacteria are naturally present. The enterobacteria test that is currently performed is not specific to pathogens. In fact, the current testing requirements for the pathogens E. Coli and Salmonella are not adequate to detect these harmful bacteria. We recommend that the LCB create a threshold for enterobacteria as an indicator test, and if a harvest tested above this threshold then a direct test for these pathogens will be required to be submitted with a sample large enough to detect the presence of this harmful pathogen.
- **Compulsory pesticide testing should focus on annual random sampling of useable marijuana and other material at the farm level like other agricultural testing methods** Pesticides application isn't limited to lots, it's generally applied to the entire area, field, or harvest. In fact, testing at the lot level will make it very easy for producers to use illegal pesticides in their mother rooms or for entire crops that they plan on remediating. The LCB should rely on the current WSDA pesticide program while the WSDOE is developing the standardization and accreditation program.
- **Heavy metal testing should focus on vape cartridge hardware as the most likely source of heavy metal contamination in concentrates.** The WSLCB should perform random end-product testing for heavy metals in vape cartridges and supply third party analysis of heavy metal testing results of their hardware as many manufactures currently do. As far as we know, there has not been a single sample of cannabis flower that has tested above the heavy metal testing requirements in the Dept. of Health testing program. Heavy metal testing should not be required for flower or usable marijuana without first assessing that there is flower testing above the current DOH thresholds for

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heavy metals. Heavy metal testing should be limited to concentrates and focus on hardware.

- **A section addressing unavoidable residual environmental contamination (UREC) defined as background levels of naturally occurring or synthetic chemicals that are present in the soil, air, or water needs to be added to the WAC.** A farmer should not be fined or penalized for environmental contamination. Pesticides are used all around us, in homes, gardens, schools, parks and agricultural fields. It is impractical to expect marijuana farmers to be able to avoid contamination when even organic food is permitted to have small traces of conventional pesticides.
- **The WSLCB should be required to utilize the same testing labs that licensees use.** The WSLCB's current reliance on the WSDA's lab which tests for more chemicals than the private labs has created a number of conflicts between licensees and the WSLCB. There should not be two separate testing systems that do not allow for validation of the results.
- **A section outlining the WSLCB's pesticide sampling protocol, investigation process and a licensee's rights to appeal and refute WSLCB's results needs to be added to the WAC.** Voluntary pesticide testing has resulted in many false positive results and many of the WSLCB's pesticide investigations have been triggered by accusations from competitors and disgruntled employees who have weaponized the complaint process. There is little transparency in this process despite the significant ramifications a positive result and pesticide violation have on a business. It should be clear to the WSLCB and stakeholders what steps and procedures will be used.

We are happy to serve as a resource and support the WSLCB.

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July 7, 2020

Ms. Katherine Hoffman
Rule Coordinator
WSCLB
1025 Union Ave SE
Olympia, WA 98501

Re: CR-102 WSR 20-12-026 Quality Control Testing and Product Requirements

Dear Kathy,

The Craft Cannabis Coalition supports testing for pesticides and heavy metals, and we seek regulations that balance public safety and quality assurance with financial impact.

While we understand that the implementation of 2019 HB2052 will bring standardizations to the industry through WSDOE accreditation, we see the pressure the LCB is under from the legislature and public to address the lack of pesticide and heavy metal testing in a shorter timeframe. We would like to acknowledge the LCBs continued work towards improved public safety. This effort has not gone unnoticed and industry stakeholders would like to continue to be a part of the dialogue around rulemaking.

The economic impact of such changes has been outlined in the SBEIS regarding QA Testing, and while the weight of the cost increase is said to fall on the consumer, that scenario is not guaranteed for all stakeholders. We believe that increasing the lot size from 5 to 10 pounds will reduce the financial burden of the proposed rulemaking, giving all industry stakeholders a greater chance of success under the new requirements.

The current language in the proposed rulemaking does not allow for the remediation of product that has failed the new testing standards. As industry stakeholders, we feel this prohibition has the potential to increase product diversion and greatly increase the financial burden of this ruleset on producers. To maintain a robust coalition of producers, we request the rulemaking be amended to allow for product that has failed QA testing to be remediated through extraction.

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In addition, we would like to thank the LCB for setting up a phased-in plan for this rule change. The phased-in plan will allow stakeholders to better weather this increased financial burden. Our lab community currently has only two labs that have the equipment and approval to test for pesticides and heavy metals. To reduce the impact of a testing bottleneck, we would like the LCB to consider extending the timeline for implementation of the new standards to allow the market to balance out between phases and to allow for testing labs and producer/processors to further prepare for and accommodate the increase in wait time for final test results.

Rule Change	Current Timeline	Proposed Timeline
WAC 314-55-102	2/28/21-3/3/21	4/1/21-6/30/21
WAC 314-55-1021 (Pesticide testing required)	3/4/21-9/3/21	7/1/21-12/31/21
WAC 314-55-1022 (Pesticide & HM testing required)	9/4/21 and on	1/1/22 and on

We commend the LCB rules coordinating team for helping ensure that Washington cannabis stays safe for consumers. As an industry, we understand the value of a positive collaborative working relationship and we appreciate our regulators who consider stakeholder input when writing and rewriting rules. In conclusion, we would like lot size to be increased to 10 lbs., we would like the allowance of remediation for failed product and we would like the adoption timeline to be expanded. We feel the scope of these requested changes necessitate a supplemental CR-102 to this ruleset to further facilitate collaboration between the industry and our regulators, and to adequately balance the requested changes with the intent of the ruleset.

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Breeze Trees, LLC
4839 Meridian St.
Bellingham, WA 98226
July 8, 2020

Katherine Hoffman
Policy and Rules Manager
Washington State Liquor and Cannabis Board
1025 Union Avenue
Olympia, WA 98501
katherine.hoffman@lcb.wa.gov
rules@lcb.wa.gov

Subject: Comments on WSR 20-12-026 - Proposed Rules - Liquor and Cannabis Board

Thank you for the opportunity to provide these comments in regards to WSR 20-12-026. Breeze Trees, LLC is a Tier 1 Producer/Processor in Bellingham, Washington. The page number references are specific to the WSLCB weblink¹ document.

General Comment:

The economic analysis conducted for this proposed rule change makes no mention of the Covid-19 pandemic. There is additional economic pressure on small producer/processors because of Covid-19 that hasn't been accounted for. We agree that cannabis sampling rules should be revised in Washington, but this proposal has a few design flaws that make it a liability. We present some of the important issues below and are OPPOSED to the proposed rule changes as written.

Comment 1 (page 4):

In the section titled, "**Regulatory Act Cost Considerations for a Small Business Economic Impact Statement:**" the last box is checked which states, "**This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4)(d): WAC 314-55-101; WAC 314-55-1025.**"

RCW 19.85.025(4)(d) does not exist.

Comment 2 (page 4):

In the Table titled, "**The NAICS code, business description, and minor cost thresholds are described and calculated below:**" note #1 references that the 341 marijuana producer/processors in the table represent those that reported revenue, lab tests, and employment between 2018-05 and 2019-04. Note #2 states that all of the certified cannabis labs were included.

We are a WSLCB licensed producer/processor. Although we utilized our full licensed canopy in 2018, our harvest was destroyed by russet mites and so we had zero revenue between 2018-05 and 2019-04.

Why didn't WSLCB include farmers like us who lost their crop in 2018 in their analysis of the Regulatory Fairness Act?

Comment 3 (page 4):

Our farm doesn't have enough revenue to support hiring employees. Why didn't WSLCB include farmers who can't afford employees in their analysis of the Regulatory Fairness Act?

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Comment 4 (page 4):

For the question, “Does the rule have a disproportionate impact on small businesses?” WSLCB answered as follows:

“In particular, in order to calculate annual costs, we require information on a per entity basis describing the number of samples being tested per year. While we have some limited anecdotal information on the numbers of samples tested per year by individual producer/processors, we lack information on the myriad business models that could lead to a wide range in the number of samples tested per year, and thus a wide range of per entity compliance costs per year. Developing reliable estimates would require a comprehensive survey with a reasonable response rate, and even then, given the wide variability of business models and documented inconsistency in responses from licensees, per entity costs is [are] difficult to determine.”

As a producer/processor, we can log into the Leaf traceability system and view all of the samples we’ve conducted since being licensed.

Why didn’t WSLCB use Leaf data to determine the number of samples tested per year?

Comment 5 (page 4):

Before we were allowed to start growing cannabis, we were required to document with WSLCB our business model and prove that we had sufficient cash to execute that model. We were required to fill out WSLCB form “LIQ1227” which states at the top of page 1,

“Submission of an operating plan that demonstrates the applicant is qualified to hold the marijuana license applied for is required as part of the application process listed in Washington Administrative Code (WAC) 314-55-020. This operating plan must include a floor plan and/or site plan which illustrates the entire operation being proposed. (WAC 314.55.020(11))”

WSLCB claims, “...we lack information on the myriad business models...” when responses from form LIQ1227 “illustrate the entire operation” of each licensee.

Comment 6:

WSLCB states,

“The proposed rule changes include provisions that are intended to reduce the compliance costs for small businesses. These include: · An incremental phase in period that contemplates full compliance by March, 2021...”

How much does the proposed “incremental phase-in period” reduce the compliance costs for small businesses? We don’t anticipate any reduction in compliance costs due to incremental phase-in.

Comment 7 (page 5):

WSLCB states,

“It is difficult to accurately assess if small business will be disproportionately impacted by this rule proposal when there is both significant overlap and variance between the groups evaluated.”

Why did WSLCB include in its Regulatory Fairness Act compliance an assessment of the labs which are the economic beneficiary of the rule change? Is WSLCB using increased revenue to 14 labs to justify the impact to 1,441² licensed producers and/or processors?

² WSLCB Annual Report, 2018

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Comment 8:

Out of 1,441 licensed producers and/or processors, why were only 6 contacted in development of the SBEIS and how were they selected?

Comment 9 (page 5):

Under the heading “Will businesses have to hire or fire employees because of the requirements of the rule?” WSLCB states,

“While the impacts to individual producer processors may depend on their ability to pass on increased testing costs (in the form of higher prices to retailers), the proposed rule is not expected to affect the amount of marijuana produced. Thus, the proposed rule is unlikely to affect the overall number of employees of producer/processors or retailers. For example, if increased testing costs lead some smaller entities to cease production, other entities may produce larger volumes. While it would be an indirect effect, the proposed rule may result in some limited additional employment in the labs conducting testing.”

Consumer demand has driven the THC% up and the price down for cannabis in Washington State. Increased i502 retail prices due to this proposed testing would drive more consumers back to the black market and decrease i502 spending. Less volume would lead to layoffs. We believe WSLCB's statement that the overall producers and/or processors and retailer employee count will remain stable is incorrect especially with the Covid-19 pandemic.

Comment 10 (OTS-1932.2, page 2):

The subsample collection procedure proposed in this rule change only requires 4 nugs per lot. A 5 lbs. lot has thousands of nugs. For this example, we assume the lot has 2,000 nugs and that 500 of them are contaminated. The odds of selecting 4 clean nugs are as follows:

$$(1,500/2,000) \times (1,499/1,999) \times (1,498/1,998) \times (1,497/1,997) = 31.6\%$$

This example shows that 31.6% of the time, there would be 500 contaminated nugs that would be labeled clean by the proposed subsample collection procedure.

In another example, a 5 lbs. lot with 2,000 nugs has 200 that are contaminated. The odds of selecting 4 clean nugs are as follows:

$$(1,800/2,000) \times (1,799/1,999) \times (1,798/1,998) \times (1,797/1,997) = 65.6\%$$

This example shows that 65.6% of the time, there would be 200 contaminated nugs that would be labeled clean by the proposed subsample collection procedure.

In a final example, showing our recommendation, a 50 lbs. lot with 20,000 nugs has 2,000 that are contaminated. The odds of selecting 50 clean nugs is:

$$(18,000/20,000) \times (17,999/19,999) \times (17,998/19,998) \times (17,997/19,997) \times \dots \times \dots = 0.5\%$$

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This example shows that 0.5% of the time, there would be 2,000 contaminated nugs that would be labeled clean in a 50 lbs. lot with 50 subsamples.

The 50 lbs. lot with a 50 subsample approach catches a 10% contamination rate 131.2 times better than the proposed rule revision's 5 lb., 4 nug approach. The size of the lot doesn't determine the accuracy of the sample. The amount of subsamples you take does.

Comment 11 (OTS-1932.2, page 5):

The proposed rules continue to allow up to 2 ppm of benzene in dabs and vapes and reference United States Pharmacopoeia, USP 30 Chemical Tests / <467> - Residual Solvents (USP <467>). However, USP <467> explicitly warns,

"Solvents that are known to cause unacceptable toxicities (Class 1, Table 1) should be avoided in the production of drug substances, excipients, or drug products unless their use can be strongly justified in a risk-benefit assessment."

Benzene is the most toxic chemical in USP <467> Class 1, Table 1. WSLCB does not explicitly require by rule a risk-benefit assessment for using benzene in extractions. Dabs and vapes don't use chemical combustion (which could destroy the residual benzene). Rather, they volatilize the benzene into a gas which is delivered to the lungs. Benzene causes cancer. Ecology sets their limit for benzene at 0.03 ppm.

We recommend that the WSLCB take immediate, emergency action to address this issue.

Significant Legislative Rule Analysis

Chapter 314-55 Rules Concerning Marijuana Quality Assurance Testing and Product Requirements

September 30, 2020
Supplemental CR 102

SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

These supplemental, proposed rule amendments revise and update current marijuana quality assurance sampling protocols described in WAC 314-55-101, marijuana quality assurance and control described in WAC 314-55-102, and marijuana proficiency testing described in WAC 314-55-1025.

This proposal provides that as of August 2021, sample collection for flower lots would increase from five pounds to ten pounds. It also provides that in addition to the currently required suite of tests, all marijuana products produced, processed, and sold in Washington State be tested for pesticides as of August 2021, and heavy metals as of February 2022. If adopted, these revisions would be accomplished by revising and updating existing WAC 314-55-101 and WAC 314-55-102 by way of a phase-in plan, as follows:

- On August 1, 2021, WAC 314-55-101 would be repealed, and WAC 314-55-1011 would become effective, replacing the five pound lot size with a ten pound lot size.
- On August 1, 2021, WAC 314-55-102 would be repealed, and WAC 314-55-1021 would become effective until January 31, 2022, adding pesticide testing to the current suite of required product testing for all marijuana products produced and sold in Washington State.
- Finally, on January 31, 2022, WAC 314-55-1021 would be repealed, and effective February 1, 2022, WAC 314-55-1022 would become effective, requiring both pesticides *and* heavy metals to the current suite of required product testing for all marijuana products produced and sold in Washington State.

As a technical matter, this proposal renames and more appropriately refers to marijuana *quality control* sampling protocols and marijuana *quality control* and assurance testing standards. While quality control is a set of activities designed to evaluate a product, quality assurance pertains to activities that are designed to ensure that a *process* is adequate and the system meets its objectives. In contrast, quality control focuses on finding defects or anomalies in a product or deliverable, and checks whether defined requirements are the right requirements. Testing is one example of a quality control activity, but there are many more such activities that make up quality control. For these reasons, this proposal renames these sections.

Other proposed revisions include streamlined, clarified language; section reorganization to increase readability, along with reduction and removal of passive language where appropriate.

Background

In 2012, Washington State voters approved Initiative 502 (I-502) that created a “tightly regulated” system for the production, processing, and distribution of marijuana for recreational use by adults 21 years of age and older. The WSLCB was tasked with creating the licensing and enforcement frameworks for such a system, assuring that each of these structures supported an overarching agency goal of ensuring the highest level of public safety.

RCW 69.50.348(1) provides that on a schedule determined by the WSLCB, every licensed marijuana producer and processor must submit representative samples of marijuana, usable marijuana, or marijuana infused *products* produced or processed by the licensee to an independent, third-party testing laboratory meeting the accreditation requirements established by the WSLCB for inspection and testing to certify compliance with standards adopted by the WSLCB. The provisions regarding accreditation will likely change on July 1, 2024, when third-party testing laboratories must meet accreditation standards established by the Washington State Department of Ecology. However, all other elements regarding regulation of the *product*, including product testing standards, will remain the same, and provide that:

- Licensees submit the results of inspection and testing for quality assurance and product standards required under this section to the WSLCB on a form developed by the state liquor and cannabis board.
- If a representative sample inspected and tested under this section does not meet the applicable quality assurance and product standards established by the WSLCB, the entire lot from which the sample was taken must be destroyed.
- Any sample remaining after testing shall be destroyed by the laboratory or returned to the licensee submitting the sample.
- The WSLCB may adopt rules necessary to implement this section.

During the 2015 legislative session, the Cannabis Patient Protection Act (Senate Bill 5052) was introduced and adopted, creating a regulatory structure for the medical use of marijuana. Although this use had been permitted since 1998, the marijuana produced by individuals and under collective garden systems was not subject to the same testing and production standards as the newly established recreational market. Intended as a “...comprehensive act that uses the regulations in place for the recreational market to provide regulation for the medical use of marijuana,” the bill placed the authority to establish standards around product testing for “medically compliant” product with the Department of Health (DOH).

Specifically, the bill noted that the legislature, “...intends that medical specific regulations be adopted as needed and under consultation of the departments of health and agriculture so that safe handling practices will be adopted and so that testing standards for medical products meet or exceed those standards in use in the recreational market.” The enacted amendments authorized WSLCB to determine approved pesticides and pesticide testing requirements, and required DOH to adopt

rules related to products sold by licensed retailers holding a medical marijuana endorsement, including but not limited to pesticide testing requirements.

In 2016, the LCB formed a work group to reexamine marijuana quality assurance testing rules described in WAC 314-55-102, including but not limited to testing limits for residual solvents and microbial testing. Four meetings were held in 2016: April 28th, May 11th, June 7th, and July 1st. The work group consisted of 29 members (11 industry, 18 state agency and vendors, and 18 reviewers.)

Subsequently, the WSLCB adopted rules in 2016 related to sampling protocols under WAC 314-55-101, and amended portions of WAC 314-55-102 related quality assurance testing. Substantial amendments to both regulations occurred in 2017, and more specifically, to WAC 314-55-102, adding a new section (2) clearly describing minimum required testing for each product type. Because DOH had adopted rules related to medically compliant products under WAC 246-70-050, requiring both heavy metal and pesticide screening for medically compliant products, the *WSLCB* made these tests optional for recreational use marijuana products at that time, *based largely on industry concern that the costs of adding pesticide and heavy metals testing would reduce business viability*. Licensees producing and processing recreational marijuana products are not precluded or prevented from requesting pesticide and heavy metals testing for recreational product in addition to the basic suite of required I-502 tests.

Current Landscape

In early 2018, several stakeholders, including medical marijuana patients, consumers, and licensees, urged WSLCB to require producers and processors to test recreational crops for pesticides and heavy metals. These partners asserted that such a move, already adopted in other states, would inspire confidence among consumers, increase access to medically compliant products, and bolster sales. In August 2018, the WSLCB began the initial stages of rule development regarding marijuana quality control and product requirements. Among the rule changes being considered was whether all marijuana products be tested for pesticides and heavy metals.

As of the time of this analysis, there is currently one marijuana testing lab in Washington State capable of testing products for the full suite of I-502 tests, along with pesticides and heavy metals. There are currently a total of five labs capable of testing for the full suite of I-502 tests, along with pesticides.

Licensees are responsible for selecting and implementing their own business models, and as a result, marijuana grows operate on a wide spectrum of sophistication. Some grows are tightly controlled in technologically advanced indoor facilities; plants are grown in climate-controlled chambers where every aspect of the plant's cultivation is monitored. Other grows are comparatively "low tech," set outdoors and dependent on seasonable cycles. Which growth model a licensed producer chooses – either indoors or outdoors – is entirely a business decision of the licensee. Similarly, the variety of tests

an accredited marijuana testing laboratory offers is entirely a business decision of the laboratory.

Marijuana cultivation, both indoor and outdoor, is associated with a variety of pests, bacteria, and fungi. Producers have used a wide variety of pesticides to reduce insect infestation. Pesticide misuse poses serious health risks to consumers, and exposure can result in a variety of well-documented symptoms, such as difficulty breathing, abdominal pain, vomiting, dizziness, and muscle cramps. Additionally, some pesticides have been found to be carcinogenic (Taylor & Birkett, 2019).

Emerging literature and multiple studies, both nationally and globally, indicate that marijuana and marijuana products can become contaminated and must be tested to protect public health (Feldman, 2015; Subritzky, Pettigrew & Lenton, 2017; Feldman, 2015; Craven et. al., 2019; Seltenrich, 2019). Marijuana and its products can be contaminated with microbiological contaminants, such as mold or salmonella, potentially hazardous growth enhancers, and heavy metals such as chromium and lead. While marijuana in any form may be prone to contamination, extracts and concentrates may present a greater risk because any contaminants will become concentrated during processing (Seltenrich, 2019). To protect consumers against exposure to pesticides, solvents, and other contaminants, marijuana and marijuana products must be tested to ensure they are safe for consumption.

Current testing requirements for recreational marijuana are intended to ensure that products for sale are safe and have accurate potency levels. However, Washington state recreational marijuana products are not required to be tested for pesticides and heavy metals, and although not precluded from doing so, many producers and processors do not test for either, and Washington is the only state that does not require this testing. Based on a number of elements, including consumer concern and national best practices, it has become evident that standardized testing for *all* marijuana products produced, processed, and sold in Washington State is necessary.

There is no guidance available to the WSLCB or any other state agency regulating marijuana from federal agencies who set standards for agriculture, food, and other products because marijuana remains classified as a Schedule I drug, and federally illegal. This presents regulatory challenges to the WSLCB, regulators throughout the country, and the industry since there is limited funding to support research on how marijuana tainted with potential toxins affects humans. However, while the possible health impact of consuming marijuana products with unapproved pesticides is an emerging area of research, the overarching goal of the WSLCB is to protect public health and safety, and to assure that all products sold within the I-502 market are safe for all consumers.

Recently, concern around the composition and safety of marijuana concentrates for inhalation has highlighted the need to assure that all marijuana products are tested for the presence of harmful compounds and other contaminants. The proposed rule amendments and phase-in plan offer a reasonable time frame that provides both

licensees and accredited labs the opportunity to adjust business models where necessary, and offers options to prepare for additional fields of testing either immediately or over an extended, but finite period of time.

Need for Supplemental Proposal

A public hearing was on the initial rule proposal for this project was held on July 8, 2020 consistent with WSR 20-12-026. After review of comments received, WSLCB made substantive revisions to the proposal that require an additional public hearing.

SECTION 2:

Is a Significant Analysis required for this rule?

Under RCW 34.05.328(5)(a)(i), the WSLCB is not required to complete a significant analysis for this or any of its rules. However, RCW 34.05.328(5)(a)(ii) also provides that except as provided by applicable statute, significant analysis applies to any rule of any agency, if voluntarily made applicable by the agency.

The WSLCB voluntarily asserts that the proposed amendments to WAC 314-55-101 and proposed new section WAC 314-55-1011, and WAC 314-55-102, and proposed new sections WAC 314-55-1021, and -1022 meet the definition of legislatively significant as described in RCW 34.05.328(5)(c)(iii)(C) because they are rules other than procedural or interpretive rules that adopt new, or make significant amendments to, a policy or regulatory program.

The proposed amendments to WAC 314-55-1025 are exempt under RCW 34.05.328(5)(b)(iv) because they make changes and clarify language without changing rule effect.

For these reasons, the WSLCB voluntarily offers this significant analysis.

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The proposed rules implement chapters 69.50 and 69.51A RCW. These chapters codified Initiative 502 (2013), known as I-502, and Second Substitute Senate Bill 5052 (Chapter 70, Laws of 2015), known as 2SSB 5052.

The stated objective of I-502 was to “stop treating adult marijuana use as a crime and try a new approach” to achieve three specific goals, one of which was to bring marijuana into a tightly regulated, state-licensed system similar to that for controlling alcohol.

Similarly, the stated objective of 2SSB 5052 was to regulate the use of medical marijuana, to achieve three specific goals, one of which was to establish consistent testing, labeling, and product standards.

The proposed rules implement the goals and objectives of chapters 69.50 and 69.51A RCW by revising and updating product standards for marijuana products produced, processed, and sold within the regulated Washington State system.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rules realize and embody the intent I-502 and 2SSB 5052 by establishing appropriate, uniform marijuana product standard to assure all products available at retail are safe for human consumption, and that those products meet or exceed product purity standards. The proposed rules align the existing product standards for recreational and medically compliant marijuana products by supporting greater access to safe products for medically compromised consumers, while at the same time, assuring quality and purity standardization of all marijuana products available to Washington State consumers.

Rules are needed to establish enforceable standards for processors and producers, and assure that marijuana testing labs are aligned with and understand product standards and testing requirements.

SECTION 5:

Explain how the agency determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The proposed rules directly apply to licensed processors and producers who will bear the costs of additional testing requirements. *Ultimately, however, consumers will bear the cost of these additional tests.*

The proposed rules *indirectly* apply to accredited testing laboratories who will charge for, and conduct testing of marijuana products.

It is important to note the distinction in the applicability of these proposed rules. The proposed rules do not change or alter the laboratory accreditation process, or revise

any testing method development or validation processes labs may currently have in place. Marijuana testing labs in Washington State use varying business operating models, and each lab is responsible for, and independently chooses its own business model. While the proposed rules increase the required testing for marijuana products, they do not *require* testing labs to offer the full suite of tests. Marijuana testing labs have the *option* to offer all tests under the proposed rules. However, at this time, since the WSLCB's authority to regulate labs is limited solely to accreditation, whether or not labs offer all tests as proposed in these rules is a business decision borne solely by each lab, regardless of which agency administers an accreditation program.

Comparatively, the proposed rules will change marijuana product testing requirements as they apply to licensed processors and producers. As a result, the proposed rules are anticipated to have an initial cost impact on existing licensed processors and producers.

1. WAC 314-55-101 – Quality control (formerly assurance) testing protocols, and WAC 314-55-1011 (Effective August 1, 2021).

Description of the proposed rule:

Originally entitled, “quality assurance sampling protocols,” this section has been renamed “Quality control sampling.” This section describes how licensees collect representative samples of marijuana, usable marijuana, or marijuana infused products produced or processed by the licensee to accredited, independent third-party laboratories for inspection and testing to certify compliance with product quality control standards established by the WSLCB, consistent with RCW 69.50.348.

The proposed language has been updated and redesigned to increase readability, flow, and provide clarification, and because WAC 314-55-101 and WAC 314-55-102 are closely related, the WSLCB offers this analysis to transparently discuss and memorialize the agency's reasoning on these proposed amendments.

Proposed revisions include:

- Referring to “separate samples” as “subsamples;”
- Clarifying current language around retrieval and transportation for product quality control;
- Clarifying limitations on adulteration of product quality control samples that could circumvent contamination testing detection limits;
- Clearly stating under what circumstances a lab must reject or fail a sample; and
- Proposing to increase the sample collection for flower lot size from five pounds to ten pounds.

The WSLCB received a number of comments regarding current rule requirements, both in writing and orally, although these comments did not embody or represent broad licensee or lab agreement on any specific theme or themes. Comment regarding sampling protocol, lot size, increased cost to producers and processors, along with comments that did not pertain to this section of rule were gathered up to, during, and

after the first listen and learn session on April 9, 2019, the second listen and learn session on August 22, 2019 through the end of December, 2019. Comment on the rule proposal discussed at the public hearing on July 8, 2020 were also gathered and reviewed, resulting in this supplemental proposal.

As a result, the WSLCB maintained its original, proposed reorganized of this rule section, and in addition, proposes to increase the current minimum of four separate subsamples from each marijuana flower lot up to five pounds, to eight separate subsamples from each marijuana flower lot up to ten pounds on August 1, 2021 in conjunction with the addition of pesticide testing, and consistent with the phase in plan designed to implement these proposed rule revisions.

Certified labs may still retrieve samples from a marijuana licensee's premise and transport those samples. Labs may also continue to return any unused portion of the samples, and the proposal provides that labs may also destroy any unused portion of the samples, as well. Additionally, language regarding sampling and adulteration has been updated, simplified and reorganized without substantive impact on current requirements.

Cost/Benefit Analysis:

The proposed rules reaffirm existing sampling protocols designed to reduce, to the extent possible, product contamination during and after sample deduction.

The supplemental proposal increases the current sampling lot size from five pounds to ten pounds effective August 1, 2021. This increase in lot size is the triggering event for a supplemental proposal since this is a substantive change from the original proposal. The concept of expanding lot size to ten pounds or more was discussed during rule development and at both Listen and Learn sessions. No verifiable evidence or data was submitted to support the idea that a representative sample could be realized in larger lot sizes without increasing the number of representative samples, nor was there any consensus between any of the commenters regarding lot size before, during, or after these Listen and Learn sessions.

WSLCB considered the several initial comments during rule development that Washington State consider regulatory frameworks similar to California and Oregon standards, including an increase from a 5 pound lot size to a 50 pound lot size. The WSLCB offers that in both Oregon and California, only labs deduct samples substantially increasing cost and regulatory oversight. In Washington, licensees may deduct samples, and normally do. Additionally, there are other differences in the statutory and regulatory structures between these states that do not align with the Washington State framework. In other words, practices in other states align with a system of regulation that is shared by multiple agencies and different licensing structures consistent with enabling legislation. In contrast, I-502 placed all authority for marijuana regulation with the WSLCB, a licensing and enforcement agency. It is not

possible to simply “lift and shift” another state’s regulatory structure for product quality control and place it in Washington’s framework.

For example, in California, all products must be first held by a *licensed distributor* – not the producer or processor - while they are tested by an independent, *licensed* laboratory. Licensed testing laboratories do not publish their prices, and the costs of testing services are not publicly available. Testing prices depend on the number of samples to be tested, the type of product testing, and the specifics of the contract between the distributor and the laboratory, among other factors. Similarly, Oregon labs perform every step of testing, including collecting and processing samples, performing compliance tests, and reporting results. Oregon also requires that, among other things, individuals performing “sampler” functions must be employed by an Oregon accredited laboratory, provide proof of training, and be licensed to transport required quantities of “usable marijuana items. These additional layers of regulatory oversight add significant cost to testing requirements and highlight the differences in enabling statute design.

While both California and Oregon allow larger batch weights or lot sizes, the sample increments for each lot or batch are proportionate and similar to Washington’s proposed requirements.

One of the few common themes emerging from comments received during the July 8, 2020 public hearing was a request to increase lot size to at least ten pounds or more. In considering this adjustment, the WSLCB analyzed the trade-off between accuracy (or representativeness) in testing results and compliance costs. From one perspective, larger lot size eases regulatory burden and cost. Since sampled material cannot be sold, a large lot size decreases loss of unsellable marijuana. However, if there is a large amount of variation within an individual lot, and this is common with marijuana, a sample from within that lot might have drastically different properties than another part of the lot. If the sample does not pass testing requirements, then the entire lot must be destroyed, meaning that in the case of a 50 pound lot, loss of the entire lot. While some large producers would be able to absorb this loss and remain viable, the same would not be true for many licensees subject to these rules.

Since marijuana is a highly variable crop, the lot size must be small enough to recognize the unique makeup of a particular harvest. This adjusted lot size attempts to recognize the unique makeup of each harvest, while attempting to reduce variability, cost of testing and potential loss across all tiers. However, collecting the correct amount and quality of product sample remains the responsibility of the licensee.

Under this proposal, sampling frequency may decrease, offering a cost reduction and an additional pathway to compliance. Licensees have the option to sample up to ten pounds, since they are not precluded from continuing to sample five pound lots if this best fits their business model. This offers flexibility to adjust sample size to individual business model.

More importantly, these revisions to quality control rules provide public benefit at a time when public safety is not only critical, but necessary. As of September 25, 2020, the CoronaVirus Disease 2019, or COVID-19 respiratory illness has resulted in 2,175 deaths in Washington State alone, and over 200,000 deaths nationally. Assuring that all marijuana product aligns with stringent product quality standards supports efforts to increase consumer protection when it is most needed to align with ongoing statewide public safety and harm reduction efforts. WSLCB's mission is to promote public safety through trust and fair administration of enforcement of liquor, cannabis, tobacco and vapor laws. This proposal not only promotes, but supports currently public safety efforts by assuring that all product entering the I-502 marketplace is safe for human consumption when it is needed most. This greater public benefit of safe, appropriately tested marijuana product outweighs compliance costs.

2. WAC 314-55-102 – Quality control (formerly assurance) testing; new sections WAC 314-55-1021 (Effective August 1, 2021 until January 31, 2022) and WAC 314-55-1022 (Effective February 1, 2022).

Description of the proposed rule:

Originally entitled, “Quality assurance testing,” this section has been renamed “Quality assurance and quality control.” Previously, required quality control tests included five tests – moisture analysis, potency analysis, foreign matter screening, microbiological screening, and mycotoxin screening for most products. The proposed rules reaffirm these required tests, and add testing for pesticides and heavy metals for all product types through an incremental phase-in plan. The proposed rule also provides that testing for terpene presence or concentration is required if a processor or producer indicates or states terpene content on any product packaging, labeling or both.

The WSLCB contracted with Industrial Economics through the Governor's Office of Regulatory Innovation and Assistance (ORIA) in early 2019 to perform a preliminary small business economic impact statement (SBEIS) under the framework of chapter 19.85 RCW for this particular section of rule. In most circumstances, the SBEIS is not completed until the actual rule proposal is prepared. In this instance, however, a preliminary SBEIS was prepared to serve solely as a basis to understand estimated impact threshold only because data such as employment, revenue, and costs are not established in this particular industry as they are in other, more established industries. The preliminary SBEIS was drafted based on draft conceptual rules offered in April 2019, as well as on the best publicly available data at the time, and updated to consider lot size increase proposed in the supplemental CR 102. The best analogous industry types and associated NAICS coding have been used to update calculations, and the updated SBEIS analyzes the supplemental rule proposal.

It is critical to understand the differences between what an SBEIS does and is required for, and what a cost/benefit analysis does and is required for under RCW 34.05.328. The WSLCB intends to provide educational opportunities to interested parties regarding each of the processes and their very different purposes in the future. The WSLCB

encourages interested parties to review [ORIA's frequently asked questions](#) regarding SBEIS and significant analysis.

Analysis

A key objective of regulating marijuana is ensuring that products sold at retail are as safe as possible for consumption (Pacula, Kilmer, Wagenaar, Chaloupka & Caulkins, 2014). The use of pesticides on marijuana or cannabis crops is a complex and often confusing issue for a range of stakeholders, including cultivators, regulators, retailers, labs, consumers, and public health researchers. While marijuana growers are interested in pest management to defend crops (referring to pest in the broadest sense), invertebrates, weeds, pathogens, and insects, regulators are concerned with pesticide management and reducing potential for risk to public health, particularly consumers and workers (Ehler, 2006). No pesticide is currently registered in the US specifically for cannabis (Stone, 2014; Thomas & ElSohly, 2016).

Like most crops grown in the United States, marijuana is vulnerable to pests. However, unlike most crops, the Environmental Protection agency (EPA) has not approved any pesticides for use on marijuana plants, and 28 U.S.C § 136j(a)(2)(G) dictates that a pesticide may not be used inconsistently with its labeling. Therefore, application of any pesticide not approved for general use on marijuana plants violates federal law. This leaves marijuana producers with the options of either (1) using no pesticides; (2) using pesticides that do not require EPA approval for use on crops; or (3) illegally using pesticides approved for other crops.

The toxicological effects of pesticides, heavy metals, mycotoxins, and pathogenic microbes is well-documented in literature, including their carcinogenicity, neurotoxicity, and teratogenicity (Bennett & Klich, 2003; Damalas & Eleftherohorinos, 2011; Denkhaus & Salnikow, 2002; Derbalah et al., 2019; Duruibe et al., 2007; Gargani et al., 2011; Gud et al., 2018; Mostafalou & Abdollahi, 2013, 2017; Pham et al., 2010; Stone, 2014; Taylor et al., 1982; Ye et al., 2017). Exposure to these contaminants through consumption of marijuana products may lead to short- and long-term adverse effects. A number of pesticides have shown carcinogenic and mutagenic effects in humans and could be lethal when overdosed (Craven, Wawryk, Jiang, Liu & Li, 2019).

Of the 11 states that have legalized both medical and recreational marijuana, Washington is the only state that does not require pesticide and heavy metal testing for all product (Seltenrich, 2019; Taylor & Birkett, 2019; Feldman, 2015). Colorado, Oregon and California all require pesticide and heavy metal testing. States with only medical marijuana programs, such as Michigan, Rhode Island, and Maryland require testing for solvents, microbiological contaminants, as well as pesticides and heavy metals.

Currently, Washington marijuana testing requirements are more stringent for products identified as DOH compliant than they are for products considered recreational. While recreational and DOH compliant marijuana must be tested for microbiological contaminants, only DOH compliant product is tested for pesticides and heavy metals.

WSLCB must consider the implications for how the legal recreational cannabis market may best be regulated in the public health interest. From that perspective, the basic issue with substances or activities that may pose risk of harm is the need to limit harm (Room & Ornberg, 2019). Considering the various methods of marijuana consumption, marijuana treated with pesticides likely present more health hazards to consumers than food crops or tobacco. Both acute and long term exposure to certain contaminants can result in a range of adverse health effects.

For example,

- Exposure to the insecticide bifenthrin, which is part of the pyrethrinoid family, may be a carcinogen and ingestion can cause headaches, vomiting, and respiratory irritation.
- Exposure to pyrethrins can cause difficulty breathing, vomiting and diarrhea when inhaled, and over prolonged periods may cause tissue damage in respiratory passages, and tremors.
- Microbiological contaminants, such as salmonella, can cause serious infections in people with weakened immune systems.
- Heavy metals, such as chromium may be carcinogenic to humans (Kim, Kim & Seo, 2015). Lead has been found in marijuana in tests performed in Germany and has no level of safe exposure. Heavy metals can affect the nervous system, cause kidney damage, slow brain development, and cause miscarriages. Arsenic is present in some groundwater sources and fertilizers that could be used on marijuana. Long-term exposure to arsenic can cause cancer and skin lesions, and acute exposure may cause vomiting, diarrhea, and even death.

Additionally, in 2016, the Association of Public Health Laboratories published a report for state medical marijuana testing programs that recommended testing for heavy metals in addition to solvents, pesticides, and micro biological contaminants. According to the report, heavy metals may accumulate in the body; some are carcinogenic, and considered to cause a variety of diseases. Marijuana is efficient at absorbing and storing heavy metals and other pollutants found in soil and water, which increases the risk that marijuana users could ingest or inhale heavy metals.

The best way to avoid pesticide and heavy metal consumption would be to guarantee that pesticides are not on marijuana plants at all. Commercial growers abroad have grown marijuana in large quantities using “biocontrols” such as predatory insects and beneficial microorganisms. However, in the United States, marijuana cannot be classified as “organic” because the term is federally regulated, and the United States Department of Agriculture (USDA) does not recognize marijuana as a legal crop.

While the current rules represent the WSLCB’s efforts to assure that marijuana testing factors in some of the known dangers of pesticides and solvents, the proposed rules add testing requirements for pesticides and heavy metals to protect public health and

safety to the greatest extent possible. Existing language regarding remediation and retesting is reaffirmed and refined in the proposed rule text.

The proposed phase in plan for the addition of pesticides and heavy metals is provided as Attachment A to this significant analysis, and incorporated herein by reference. The proposed rules contemplate, and are written to support and control for this phase-in plan.

Cost/Benefit Analysis:

The WSLCB proposes to phase-in these requirements to provide additional time for impacted parties to adjust business models as needed. Attachment A provides a phase-in table. Attachment B describes estimated cost ranges if pesticide and heavy metals testing are added to the current suite of tests. Since this rule project began in August 2018, impacted parties have had in excess of two years to consider and prepare for this proposal. Under the proposed phase-in plan, licensees will have an additional extended period of time to adjust their self-selected business models.

The phase-in plan provides that upon the effective date of these proposed rules, should they be adopted, that existing levels of testing would remain the same, and only the technical revisions of the rule would go into immediate effect. At this time, the WSLCB anticipates a rule effective date of February 6, 2021. This would provide licensees six months after to prepare and adjust for the pesticide testing requirement and lot size increase, and for labs to prepare to offer the additional testing if they chose, with the pesticide testing requirement anticipated to go into effect on August 1, 2021. Then, licensees would have an additional six months to prepare for the addition of heavy metal testing, and it is anticipated that by February 1, 2022. There is currently more than one lab available and prepared to offer this testing, and it is anticipated that this number will increase by the final effective date.

As noted previously, the CR 101 was filed in this rule project in August of 2018, and it is anticipated that these proposed rules would be fully effective in February, 2022. Under that timeline, licensees will have had well over three years to adjust business models and plans in preparation for these rule revisions that align the state of Washington with national practice. The WSLCB anticipates that these rules will not result in any additional administrative costs to licensees for the following reasons:

- Sampling practices and requirements are essentially the same. The WSLCB does not anticipate that these rules will result in additional employee time to deduct or handle samples;
- Administrative tasks, such as completing laboratory forms or documents, travel, or other costs associated with moving product to labs for testing are the same, and will not result in additional cost.

The WSLCB recognizes that these rules may result in additional costs to producers/processors, and has sought to mitigate those costs through increasing lot

size and a phased in approach. However, product quality control testing is critical to ensuring that marijuana processed, produced, and sold in Washington State is free from harmful contaminants and safe for human consumption, regardless of the method by which that product is consumed.

As noted above, the use of pesticides on marijuana crops is complex, and no state “has it right” (Seltenrich, 2019). While producers are interested in pest management to defend crops (referring to pest in the widest sense as invertebrates, weeds, pathogens, and insects), regulators are interested in pesticide management and reducing possible risk to public health, and consumers in particular (Ehler, 2006; Subritzky, Pettigrew & Lenton, 2016). Also as noted above, no pesticide is currently registered in the US specifically for marijuana (Stone, 2014; Thomas & ElSohly, 2015). The WSLCB has an overarching responsibility to assure marijuana products are safe for human consumption. This proposal is a significant step toward assuring that all marijuana products produced and sold in Washington State meet stringent standards designed to protect the public health and safety.

More importantly, these revisions to quality control rules provide public benefit at a time when public safety is not only critical, but necessary. As of September 25, 2020, the CoronaVirus Disease 2019, or COVID-19 respiratory illness has resulted in 2,175 deaths in Washington State alone, and over 200,000 deaths nationally. Assuring that all marijuana product aligns with stringent product quality standards supports efforts to increase consumer protection when it is most needed to align with ongoing statewide public safety and harm reduction efforts. WSLCB’s mission is to promote public safety through trust and fair administration of enforcement of liquor, cannabis, tobacco and vapor laws. This proposal not only promotes, but supports currently public safety efforts by assuring that all product entering the I-502 marketplace is safe for human consumption when it is needed most. This greater public benefit of safe, appropriately tested marijuana product outweighs compliance costs.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the agency determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

Rule Development and Stakeholder Engagement Process

Virtually all of the comments received from licensees and labs focused on individual business viability. Fewer than five comments out of over 300 received during the initial stakeholder engagement process prioritized public health and safety, concentrated on ways to increase product purity or consumer confidence, or tied the production of safe products to existing business models.

In contrast, the majority of the comments from consumers received after the CR101 was filed concentrated on a presumption of recreational product safety. For example,

"As a long time consumer, I was shocked to learn that pot is not tested for pesticides! I learned this from one of the budtenders I recently spoke to in Maple Valley, which was funny because every other budtender I've ever talked to has sworn up and down that pot IS tested for pesticides. However, this budtender seemed incredibly well informed and assured me that no, pot is NOT tested for pesticides in Washington. I realize you guys probably have a lot to do and focus on, but this seems like a no brainer to me. Why wouldn't we require pot to be tested for pesticides? Considering we are concentrating the pot and then combusting it, literally changing the chemical make up of the flower, it seems irresponsible to not require pesticide testing in the legal market for all pot products. As a consumer I want to know that the product I'm purchasing is safe and thus pesticide testing seems imminent [sic]. Please do the right thing, make haste, and require mandatory pesticide testing for all legal pot products now!"

- Received in WSLCB rules in-box, September 14, 2018

The WSLCB's stakeholder engagement process encouraged parties to:

- Identify burdensome areas of existing and proposed rules;
- Propose initial or draft rule changes; and
- Refine those changes.

During the rule development process, the WSLCB hosted two public "Listen and Learn" sessions, and collected significant input from industry members, associations and other interested parties, representing processors and producers across tiers and many others. These meetings and comment periods were announced via GovDelivery and other media platforms, and open to the public, licensees, and any interested party to encourage community input. The WSLCB is aware that this is a topic of interest to many Washington State citizens, regardless of their positionality related to the regulatory structure.

It is important to note that these "Listen and Learn" sessions were among the first that the WSLCB offered to increase and enrich stakeholder engagement in the rule development process. Initially, and understandably, in person participation was somewhat guarded as the licensed community and others became familiar with the approach, and the concept of collaborative rule making. It is also important to note that few producers and processors attended the first meeting despite all licensees receiving notice of the meeting more than two weeks in advance. By the second session, attendees were better prepared to present and discuss ideas and solutions, and the conversation continued well beyond the scheduled session time, although again, few producers and processors attended in person even though messaging was broadly distributed to all licensees through several platforms. However, several of these entities provided written comment in the way of email to the rules coordinator during the meeting. These were shared at the meetings, and throughout the rule development process.

Additionally, agency staff visited the facilities of processors, producers, and labs who wished to participate in the process. To the extent possible, the qualitative and quantitative data presented in this significant analysis represent the multiple dimensions and broad spectrum of positions, as well as mitigation strategies offered by all participating parties. The WSLCB also coordinated rule development with staff the

Washington State Department of Health, the Washington State Department of Ecology, and the Washington State Department of Agriculture where possible and appropriate.

Although summarizing comments to provide brief descriptions of issues and themes related to the proposed rule set in general practice, doing so in this context was extremely challenging because over 300 comments were collected as a result of the two Listen and Learn sessions, and throughout the rule development process. These comments represented an extremely broad, often conflicting range of opinions and positions, along with multiple suggestions regarding draft conceptual rules. As a result, thematic organization was virtually impossible.

Despite criticism that the comments were not distilled and summarized when initially publicly shared, agency staff worked to preserve comments in their native form to assure not only transparency, but to make sure that each commenter was offered the opportunity to review and digest comments and thoughts of the entire community in their native form, as opposed to a curated, summarized version of comments interpreted by the WSLCB. The WSLCB intends to continue sharing comments in their native form, regardless of volume, moving forward.

Many of the suggestions offered required legislative or other action beyond the scope of the Board's regulatory authority. Other suggestions included creating new WSLCB programs, expanding on existing limited contracts, requesting rule changes that exceed the scope of the CR101 for this project, or suggesting internal operational changes that may exceed WSLCB available funding and capacity. Some of these suggestions included:

- WSLCB should create carve outs or exemptions from any additional product testing for Tier 1 producers and sun growers. Sampling frequency should be reduced for these Tier 1 producers.
- Sun growers should be "empowered" to select their own lot size. (Received December 29, 2019).
- Tier 1 exports of cannabis from Washington should be exempt from all cannabis sampling requirements. It was asserted that the receiving State or Country's testing requirements should dictate testing criteria.
- The WSLCB should immediately engage in emergency rulemaking for pesticide and heavy metal testing while simultaneously extending the period of the CR102, which at the time of the comment was not yet been presented to the Board or filed.
- The WSLCB should reduce the statutorily established tax rate on marijuana products from 37% to 20% to accommodate the increased cost of testing.

- The WSLCB should require the WSDA to perform 500 – 1000 random tests per month. WSLCB enforcement should collect random samples, and contract with “a lab for expanded testing.”
- WSLCB should not require “cannabis farmers to significantly increase spending with Washington’s cannabis labs until Washington State Department of Ecology accreditation is complete.” (Received December 29, 2019)
- Enterobacteria testing should be changed to an indicator test instead of a pass-fail test with follow up testing for pathogens, if high levels of enterobacteria are found (Received December 29, 2019).
- The WSLCB should remove pyrethrins and piperonyl butoxide from the list of pesticides with action levels prior to implementing additional testing requirements. (Received December 29, 2019).
- The WSLCB should not remove pyrethrins and piperonyl butoxide from the list of pesticides with action levels.
- The WSLCB should allow EPA Method 6200 to be self-performed at Tier 1 facilities for heavy metals compliance.
- The WSLCB should allow Tier 1 producers to combine samples and provide a single report for pesticide compliance. Tier 1 licensed farms would then be designated a quarantine facility and training developed to identify live pests and carcasses prior to combining samples. Tier 1 producers would be allowed to transport cannabis in Washington State prior to testing to accomplish this program.
- The WSLCB should allow Tier 1 producers to fundraise by selling directly to the public.
- Rather than adopt heavy metal testing, the WSLCB should develop a program to verify processors have the Material Safety Data Sheets (MSDS) for all raw materials used in their vape hardware and heavy metal testing results provided by their hardware distributor and/or manufacturer. WSLCB should perform random testing for heavy metals in vape cartridges. (Received December 29, 2019).
- Statistically representative samples should be taken from the lot for testing purposes and results should provide measures of variance so that potency can be reported and better represent the harvest population. (Received December 29, 2019).

- “Barely detectable levels” of pesticides or herbicides should trigger further investigation prior to the assessment of penalties, due to environmental contamination issues. (Received December 29, 2019).

Other concerns included:

- From processors/producers, concern that requiring tests for pesticides and heavy metals would negatively impact businesses, from both the producer/processor perspective:

“I own a 502 producer/processor and I just heard that there is discussion about adding mandatory heavy metal and pesticide testing for every 5-pound lot of product.

Well, if you want to finish the job of driving the small growers out of business, by all means proceed with the least cost-effective way of dealing with this "problem." The same effects can be obtained from a random testing program or from allowing harvest-sized batches, but hell, all those small growers are raking in the money, so they are ripe for a little more squeezing, right?

And by the way, do you know how many people have been killed by "contaminated" weed worldwide in the history of man? Zero. Do you know how many have been sickened? Zero confirmed. Good thing you are addressing this problem! I feel safer already!”

- From labs, general concern that increasing lot size would negatively impact business:

“Standardized testing is preferred. Most labs are barely making it. Doubling lot size, millions in equipment. Some labs are undercutting budget. Currently, charge \$90 for i502 testing (mycobio/potency/everything) and makes \$6 profit. Others charge \$70. Trace charges \$180 for the same tests. Time of service payments would help. Proposed rules would cut revenue in half.”

- Three processor/producers asserted that the public is disinterested in products tested for pesticides and heavy metals:

“At this time consumers have the option to buy product that has been tested for heavy metals and pesticides in the form of DOH compliant products. Legislation establishing DOH certified product type were adopted in 2015 however consumer demand for these product types has remained tepid. The public has clearly demonstrated a lack of interest in products tested for pesticides and heavy metals and the consumers that are interested in these standards are already served by the DOH certification. In response to the public’s lack of interest in DOH compliant products some producer and processor licensees have sought regulatory interference in the marketplace in the form of increased testing costs and standards to stymie market competition. Such calls to “level the playing field” amount to predation through regulation.”

- Comments from consumers expressed concern that recreational products were not tested for pesticides and heavy metals:

“It has come to my attention that cannabis is (still) not tested for pesticides in the adult use market. This seems like it is a necessary test that may have been overlooked by the Liquor and Cannabis Board. **I am writing you today to ask that you review your rule making on this issue and analyze whether requiring pesticide testing in the adult use market makes sense for consumer and patient health and safety.** I realize that the data and research are still out onto whether pesticides are "bad" for you, but I would anticipate that a conservative approach, considering your mission, would make sense. I also recall seeing a story in The Stranger a while ago, that showcased a random selection of retail cannabis of which a large portion failed a pesticide screening. Even with that article in 2016, it appears that the Liquor and Cannabis Board has hesitated to address illegal pesticide usage in the 502 market. I kindly ask that you review your rules and regulations around mandatory pesticide testing for adult use products, while taking into account the effect your rule changes will have on licensees. **Consumer safety should be the forefront of a state agencies concern, followed by making sure your rules do not overly burden the small businesses who are the backbone of the cannabis industry.**” – LCB Rules in-box, 9/13/18

Comments Received During the First Public Hearing held July 8, 2020

See Attachment C.

Alternative Versions of the Rule and Least Burdensome Alternative

Two versions of draft conceptual rules were offered for stakeholder comment before the initial CR 102 was filed. Only one stakeholder offered alternative language, or specific suggested revisions. To date, and even after the original CR 102 was filed and at public hearing, no alternative language was offered. Most comments were general concepts about rule revision rather than actual rule language, complaints regarding current rule, or assertions that WSLCB failed to appropriately develop rules, draft and vet draft conceptual rules, research, or understand the issue. As noted above, most comments spoke to the perceived effect a rule revision would have on businesses. Several attendees indicated that they would offer specific rule language, but at the time of original writing and as of this update on September 30, 2020, no specific language has been offered for consideration.

Summarized below are brief descriptions of issues related to the proposed rule set and how the agency collaborated with stakeholders to mitigate potential burden associated with rule compliance:

Issue	Potential Burden	Mitigation Strategy
Lot size	Producer/Processor: General consensus that lot size increase would decrease burden and reduce costs; others asserted that lot size should remain the same to assure a truly representative sample.	Proposal increases lot size to 10lb at Phase 2 of implementation.
Addition of pesticide and heavy metal testing to current suite of required I-502 tests	Producer/Processor: No consensus on whether this would increase or decrease burden. Some indicate, as they did in 2016, that additional tests will reduce business viability; others agreed that testing was necessary.	Proposal maintains addition of pesticides and heavy metals with an incremental 12-month phase period to allow licensees businesses to adjust.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take action that violates requirements of federal or state law.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The agency coordinated to the extent possible with the Department of Health, the Washington State Department of Ecology and the Washington State Department of Agriculture.

Attachment A

Phase-in of Required Quality Control Testing	Lots of marijuana flowers or other material that will not be extracted	Marijuana Mix	Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity)	Concentrate or extract made with a CO2 extractor like hash oil	Concentrate or extract made with ethanol	Concentrate or extract made with approved food grade solvent	Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash	Infused cooking oil or fat in solid form
February 6, 2021 (Effective Date)								
Moisture analysis	√	√						
Potency analysis	√	√	√	√	√	√	√	√
Foreign matter inspection	√	√						
Microbiological screening	√	√				√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Mycotoxin screening	√	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Residual solvent test			√	√	√	√		
August 1, 2021 (Ten pound lot size becomes effective)								
Moisture analysis	√	√						
Potency analysis	√	√	√	√	√	√	√	√
Foreign matter inspection	√	√						
Microbiological screening	√	√				√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Mycotoxin screening	√	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Residual solvent test			√	√	√	√		
Pesticides	√	√	√	√	√	√	√	√
February 1, 2022								
Moisture Content	√	√						
Potency analysis	√	√	√	√	√	√	√	√
Foreign matter inspection	√	√						
Microbiological screening	√	√				√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Mycotoxin screening	√	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing	√	√ Field of testing is only required if using lots of marijuana flower that has not passed QC testing
Residual solvent test			√	√	√	√		
Pesticides	√	√	√	√	√	√	√	√
Heavy metals	√	√	√	√	√	√	√	√

Attachment B

Scenario	Number of Samples Tested Annually	\$165 Per Sample ³	\$225 Per Sample ¹	\$400 Per Sample ¹
Low # of Samples	72 ¹	\$11,880	\$16,200	\$28,800
High # of Samples	2,080 ¹	\$343,200	\$468,000	\$832,000
Average # of Samples	184 ²	\$30,360	\$41,400	\$73,600
Median # of Samples	101 ²	\$16,665	\$22,725	\$40,400
Notes: ¹ Estimates based off of information collected in interviews by Industrial Economics Incorporated, Spring 2019 ² Figures based on traceability data, as of 1/2020 ³ Cost based on currently available pricing in Washington state, as of 1/2020				

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Small Business Economic Impact Statement

Chapter 314-55
Rules Concerning Marijuana Quality Assurance
Testing and Product Requirements

September 30, 2020
Supplemental CR 102

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.

In early 2018, several stakeholders, including medical marijuana patients, consumers, and licensees, urged WSLCB to require producers and processors to test recreational crops for pesticides and heavy metals. These partners asserted that such a move, already adopted in other states, would inspire confidence among consumers, increase access to medically compliant products, and bolster sales.

In August 2018, the WSLCB began the initial stages of rule development regarding marijuana quality control and product requirements. Among the rule changes being considered was whether all marijuana products be tested for pesticides and heavy metals.

The proposed rules are necessary to align current marijuana testing standards with the testing requirements described in existing Washington State Department of Health (DOH) Marijuana Product Compliance regulations, located in chapter 246-70 WAC. These proposed rule revisions are anticipated to increase testing efficiencies, safety and quality for all marijuana products produced and sold in Washington State.

WSLCB filed a CR101 on August 18, 2018 to consider rule changes to chapter 314-55 WAC regarding quality assurance testing and product requirements. The CR101 described the following topic areas to be considered for rule development and revision:

- Lot and batch sizes;
- Fields of testing and pass/fail level adjustments;
- Potency testing requirements;
- Pesticide testing requirements for all marijuana products;
- Heavy metals testing requirements;
- Sample deduction requirements;
- General testing rule adjustments;
- Product, THC (tetrahydrocannabinol) serving limits, and packaging requirements; and
- Other related rule changes that may be necessary or advisable.

While the supplemental proposed rules consist of substantive changes to both WAC 314-55-101 and WAC 314-55-102, the requirements determined most likely to result in costs to businesses are the inclusion of testing requirements for pesticides and heavy metals. Therefore, these proposed testing requirements are the focus of this analysis of potential impacts on small businesses as they are defined in RCW 19.35.030.

RCW 19.85.030 requires that the relevant agency prepare a small business economic impact statement (SBEIS) if the proposed rule “will impose more than minor costs on businesses in an industry.”¹ “Minor cost” cost is defined in RCW 19.85.020 as a cost per business that is less than 0.3 percent of annual revenue or income, or \$100, whichever is greater, or one percent of annual payroll.² These calculations are statutorily defined, and the agency is required to comply with these specific requirements, despite stakeholder suggestion to the contrary.

The guidelines for preparing an SBEIS are included in RCW 19.85.040.³ The WSLCB also utilized the more specific guidance and resources provided by Washington State’s Office for Regulatory Innovation and Assistance (ORIA).⁴ Consistent with SBEIS Frequently Asked Questions guidance, agencies are required to consider costs imposed on businesses and costs associated with compliance with the proposed rules.⁵ Agencies are not required under chapter 19.85 RCW to consider indirect costs that are not associated with compliance with the rule.

This document describes the WSLCB analysis of potential, estimated economic impacts of revisions to WAC 314-55-101 and WAC 314-55-102 on small businesses in Washington State as small business is defined in RCW 19.35.030. The sequence of this analysis below follows templates provided by ORIA, and generally, chapter 19.85 RCW.

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.

The proposed rules primarily affect two types of licensed businesses involved in the marijuana industry in Washington State: licensed producer/processors, who bear the direct costs of additional testing requirements; and accredited marijuana testing laboratories, who conduct testing of marijuana products.⁶ Table 1 presents the number of entities in Washington State for each of these types of businesses, and the actual number of licensed marijuana processors and producers.

Table 1

¹ RCW 19.85.030 Agency Rules – Small Business economic impact statement reduction of costs imposed by rule. Accessed September 25, 2020 at: <https://app.leg.wa.gov/RCW/default.aspx?cite=19.85.030>.

² RCW 19.85.020 Definitions. Accessed September 25, 2020 at: <https://app.leg.wa.gov/rcw/default.aspx?cite=19.85.020>.

³ RCW 19.85.040 Small business economic impact statement—Purpose—Contents. Accessed January 8, 2020 at: <https://app.leg.wa.gov/RCW/default.aspx?cite=19.85.040>.

⁴ ORIA. 2019. Regulatory Fairness Act Support. Accessed September 25, 2020 at: https://www.oria.wa.gov/site/alias_oria/934/regulatory-fairness-act-support.aspx.

⁵ WA Attorney General Office. 2019. Small Business Economic Impact Statements – Frequently Asked Questions. Accessed September 25, 2020 at: https://www.oria.wa.gov/Portals/_oria/VersionedDocuments/RFA/Regulatory_Fairness_Act/DRAFT_SBEIS_FAQ.pdf.

⁶ While retailers may be affected by some minor changes to packaging labeling requirements under the proposed rules, these costs are considered likely to be minimal (Personal communication with WSLCB staff, March 14, 2019); thus, impacts to retailers are not considered in this analysis.

Type of Business	# of Businesses In Washington	Percentage of Businesses Considered "Small" ³	Average Annual Sales ²	Minor Cost Threshold (0.3%) Average Annual Sales
Marijuana Producer, Processor	801 ¹	98%	\$1,466,109	\$4,398
Notes: ¹ Represents the number of Marijuana producer/processors reporting sales in LEAF between 2018/01 and 2020/08 ² Average annual sales for producer/processors based on total sales divided by the number of business that reported sales, lab tests, and employment.				

Note that for licensing purposes, different tiers of producers are defined in WAC 314-55-075;⁷ however, for purposes of the small business economic impact statement, under the RCW 19.85.030, small business is defined as "any business entity, including a sole proprietorship, corporation, partnership, or other legal entity, that is owned and operated independently from all other businesses, and that has 50 or fewer employees."⁸

Also note that this is an updated version of the original table offered in the first SBEIS project. The minor cost threshold, even when relying on annual sales, is similar to analogous revenue as noted below.

When this SBEIS was originally drafted in 2019, there was uncertainty regarding how to classify marijuana processors and producers within the NAICS nomenclature since there are no codes assigned to either of these business types. However, since that time, best practice guidance from ORIA indicates that for emerging and un-coded industries, the most analogous NAICS code are appropriate to conduct analysis consistent with chapter 19.35 RCW. To complete Table 2, the *estimated, probable cost* of compliance, is calculated in Table 2, and applied here, but with the following caveats:

- Interviews conducted in 2019 with a cross section of licensed processors and producers self-reported a wide range in the number of samples tested annually (72 on the low end, and 2,090 on the high end). Interview participants included a sun grower and several indoor processor/producers across all three tiers.
- In contrast, traceability data from January 2020 indicates the number of samples tested for 2019 averaged 184 annually.
- This disparity in self-reported sample testing and traceability data that to an extent, is also self-reported underscores the challenge of precisely estimating compliance cost impact at this time. *These are estimates.*
- Monthly compliance costs may vary based on the number of harvests, business model and size, and other factors that vary widely across tiers. For purposes of estimating an

⁷ See https://lcb.wa.gov/milicense/producer_license_descriptions_fees. Tier 1 allows for 2,000 square feet or less of dedicated plant canopy; Tier 2 allows for between 2,000 and 10,000 square feet or less of dedicated plant canopy; and, Tier 3 allows for between 10,000 and 30,000 square feet or less of dedicated plant canopy.

⁸ RCW 19.85.020 Definitions. Accessed September 25, 2020 at: <https://app.leg.wa.gov/rcw/default.aspx?cite=19.85.020>.

average compliance cost, these are represented in Table 1. Under this analysis, the *monthly* cost of compliance does not exceed any of the minor cost thresholds. However, in Table 3, *annual* costs exceed minor cost thresholds.

Table 2

2017 Industry NAICS Code	Estimated <u>Monthly</u> Cost of Compliance	Industry Description	NAICS Code Title	Minor Cost Estimate - Max of 1%Pay, 0.3%Rev, and \$100	1% of Avg Annual Payroll . (0.01*AvgPay)	0.3% of Avg Annual Gross Business Income (0.003*AvgGBI)
111 ⁹	\$ 3,450	Marijuana Producers	Crop Production	\$4,082.13	\$4,082.13 2018 Dataset pulled from ESD	\$2,993.38 2018 Dataset pulled from DOR
312 ¹⁰	\$ 3,450	Marijuana Processors	Beverage and Tobacco Product Manufacturing	\$5,766.61	\$5,342.91 2018 Dataset pulled from ESDS	\$5,766.61 2018 Dataset pulled from DOR

Table 3

2017 Industry NAICS Code	Estimated <u>Annual</u> Cost of Compliance	Industry Description	NAICS Code Title	Minor Cost Estimate - Max of 1%Pay, 0.3%Rev, and \$100	1% of Avg Annual Payroll . (0.01*AvgPay)	0.3% of Avg Annual Gross Business Income (0.003*AvgGBI)
111	\$ 41,400	Marijuana Producers	Crop Production	\$4,082.13	\$4,082.13 2018 Dataset pulled from ESD	\$2,993.38 2018 Dataset pulled from DOR
312	\$ 41,400	Marijuana Processors	Beverage and Tobacco Product Manufacturing	\$5,766.61	\$5,342.91 2018 Dataset pulled from ESDS	\$5,766.61 2018 Dataset pulled from DOR

Because labs are not required to comply with these rules, additional analysis was not conducted.

“Minor cost” is defined in RCW 19.85.020 as a cost per business that is less than three-tenths of one percent of annual revenue or income, or one hundred dollars, whichever is greater, or one percent of annual payroll. As revenue information is more readily available than payroll, the analysis calculates minor cost thresholds based on sales of business entities in the affected industries. The minor cost threshold is \$4,082 for producer and \$5,766.61 for processors, based on the total revenue reported by analogous industries. Since these are the most recent and publicly available data points, these were used for this calculation.

Because each of these values falls well above \$100, the statutory minimum threshold for “minor cost,” we utilize these values in the analysis that follows.

⁹ **111 Crop Production**

Industries in the Crop Production subsector grow crops mainly for food and fiber. The subsector comprises establishments, such as farms, orchards, groves, greenhouses, and nurseries, primarily engaged in growing crops, plants, vines, or trees and their seeds.

¹⁰ **312 Beverage and Tobacco Product Manufacturing**

Industries in the Beverage and Tobacco Product Manufacturing subsector manufacture beverages and tobacco products. The Tobacco Manufacturing industry group includes two types of establishments: (1) those engaged in redrying and stemming tobacco and (2) those that manufacture tobacco products, such as cigarettes and cigars.

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 sale or revenue.

Complying with the proposed rule changes requires that marijuana products be tested for pesticides and heavy metals, in addition to existing testing protocols. This analysis relies on information gathered through outreach to businesses, WSLCB data, and analogous industry data to estimate the potential costs of the proposed rule. It is anticipated that rather than increased administrative costs, compliance costs are associated with the initial increase in testing costs.

For producer/processors, each marijuana flower lot or batch of intermediate product (e.g., concentrate, extract, or oil) will require additional testing in the form of screening for pesticides and heavy metals. During initial interviews, producer/processors indicated that they would be unable to pass these additional testing costs on to retailers in the form of higher prices.¹¹ This was further expressed during the two Listen and Learn sessions occurring in April and August of 2019, as well as through written comment.

For purposes of this analysis it is assumed that these costs will not be passed on to retailers or consumers at this time. This is a conservative assumption, in that it will lead to greater estimated impacts on businesses. If producer/processors are able to pass on the costs of testing, then the impacts would more likely be borne by consumers.

When the original CR 102 was filed for this project, labs charged approximately \$120 to \$125 per sample for pesticides testing; per sample costs for testing for heavy metals was listed on one website at \$70 and another at \$120.¹² Based on interviews with a subset of producer/processors and prices available from labs, we estimate the potential range of testing costs per sample to add pesticides and heavy metals screening; these costs are expected to range from \$165 to \$400.¹³ These figures have not changed for purposes of supplemental proposal calculations, although with the added option to test up to ten pound lots, the annual cost of compliance may be reduced since testing frequency will decline. However, the proposed rules do not prevent or preclude licensees from continuing to test five pound lots.

In order to estimate annual compliance costs for producer/processors, information on the number of samples tested annually is needed. It is difficult to generalize the average number of

¹¹ Based on interviews with a subset of producer/processors. Significant additional research would be required to confirm or refute this assumption. For example, research might include the identification or development of elasticity estimates for this evolving market, as well as information about current profit margins in this industry. This information, if available, could be used to determine which actors (producers or consumers) are most likely to bear the costs of the rule changes.

¹² Personal communication with labs (April 2019) and WSLCB staff (March 2019, January and September 2020); also, online research from testing labs websites.

¹³ Costs vary depending on whether they are for individual tests or incremental costs for a suite of tests; this range includes producer/processors expected testing costs as well as prices posted by laboratories. We note that for the two labs for which testing costs were available, prices ranged from \$165 - \$240.

samples tested, as business models vary greatly. For example, the number of samples tested on an annual basis may vary based on factors such as the size of an operation or harvest, the type of production (such as outdoor grows that harvest once or twice per year), and testing choices in terms of batch/lot size (e.g. small producers may choose to test only once they have a ten pound lot). Based on information gathered through initial interviews, follow up discussions during Listen and Learn sessions, and staff research, we estimate annual low-end and high-end costs of additional testing per producer/processor.¹⁴ These estimates are presented in Table 4 below:

Table 4:

Scenario	Number of Samples Tested Annually	\$165 Per Sample ³	\$225 Per Sample ¹	\$400 Per Sample ¹
Low # of Samples	72 ¹	\$5,940	\$8,100	\$14,400
High # of Samples	2,080 ¹	\$171,600	\$234,000	\$416,000
Average # of Samples	184 ²	\$30,360	\$41,400	\$73,600
Notes: ¹ Estimates based off of information collected in interviews by Industrial Economics Incorporated, Spring 2019 under assumption of samples from a five pound lot. These figures have not been revised since increasing lot size is optional, will reduce sampling frequency, and could ultimately result in annual cost reduction. ² Figures based on traceability data, 1/2020 ³ Cost based on currently available pricing in Washington state, 9/2020				

Source: Estimates of number of tests, and costs for pesticide and heavy metals testing based on information collected in interviews with labs and producer/processors and online research into testing prices.

The cost estimates in Table 4 are subject to a variety of caveats, including the following:

- Some producer/processors are already testing for pesticides for various reasons (e.g., already producing medically compliant products, consumer/retailer demand, and interest in pesticide-tested products). To the extent producers are already incurring pesticide testing costs, the overall incremental compliance costs of the proposed rule would be lower.
- Prices that will be charged for pesticide and heavy metals testing once these tests are required are uncertain. As more labs begin offering testing, pricing could change. Labs continue to indicate that there is a race to the bottom for pricing for marijuana testing, and labs have recently cut their prices for testing for the suite of quality control tests currently required under WAC 314-55-102.
- Licensees are not precluded from drawing four samples from a five pound lot. This estimate assumes that increasing the lot size to ten pounds, from which a minimum of

¹⁴ We note that while our interviews provided an understanding of the likely range of samples tested annually by Tier 1 and Tier 2 producer/processors in a variety of settings, including indoor and sun grown, due to the limited number of interviews and lack of response from Tier 3 producers/processors, we lack similar information for larger producer/processor operations.

eight samples must be drawn may result in cost reduction since testing would occur less frequently.

The proposed rules do not require labs to offer testing of pesticides or heavy metals. However, to remain viable under the proposal, labs may need to obtain the equipment needed for these additional tests, and seek certification for them. If they chose not to obtain pesticides and heavy metals certifications, they may experience a loss in business as customers opt for testing with other labs offering the full suite of required tests. Currently, four labs are certified to test for pesticides, and one is currently certified to test for the required pesticides and heavy metals. Through discussions with industry representatives, it appears many of the existing labs are considering purchasing the necessary equipment and becoming certified to perform the additional tests. This decision suggests that those labs believe offering these tests is a good business decision, and they will be able to recoup the costs of certification through the fees they will charge for conducting testing over time.¹⁵

Given the nascent status and current competitive nature of the marijuana industry, it is unclear how the market will react to new testing requirements. For example, in the short run some labs appear to be charging prices that do not likely cover incremental operating costs. This business strategy is likely not sustainable.

WSCLB is not required under RCW 19.85 to consider indirect costs potentially resulting from the proposed regulation. Costs of certification, and/or any loss in sales to testing labs as a result of the proposed rule are considered an indirect impact of the rulemaking, not a direct compliance cost. However, given that all of the marijuana testing labs are small businesses, we present these costs in context for purposes of this analysis.

Additionally, the proposed rules do not change or alter the laboratory accreditation process, revise any testing method or methodology development or validation processes, or require the acquisition, upgrade or purchase of any equipment. Currently, the WSLCB's authority to regulate marijuana testing labs is limited solely to accreditation which will eventually be a function of the Department of Ecology; however, **WSLCB remains statutorily required to establish and maintain standards for product testing, even after accreditation is transferred.** Further, testing labs in Washington State independently select and utilize various business and operating models. While the proposed rules increase required testing for marijuana **products**, they *do not* require testing labs to offer the full suite of proposed tests. As noted previously, whether or not the proposed full suite of tests is offered by a testing lab is a business decision to be made by each testing lab.

Costs associated with testing laboratories efforts to become certified to perform pesticides and heavy metals testing include a range of one-time and ongoing additional costs for the labs. The majority of the costs associated with a lab becoming certified to perform pesticides and heavy metals testing are related to the investment in equipment. Laboratories report that estimated costs for equipment needed to perform pesticides and heavy metals tests range from \$500,000 to \$1.3 million per business entity. In addition, there are a variety of other potential costs related to becoming certified for pesticides and heavy metals testing, including but not limited to:

- Rent or costs to purchase additional space to house equipment and store supplies;
- Improvements to space (e.g., duct work, electrical work);
- Operational costs including increased electricity costs, waste containers, consumables (e.g., solvents, standards);
- Payroll and benefits for additional scientists;
- Preventative maintenance contracts for equipment;
- Auditing costs (for certification); and,
- Miscellaneous (vibration proof benches).

SECTION 4:

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

Given the minor cost thresholds calculated in Section 2, and the compliance costs presented in Section 3, this rule is likely to impose more than minor costs on licensees. Based on the high-end costs of pesticide and heavy metals testing, if producer/processors perform more than five tests a year they will experience greater than minor costs; based on low-end testing cost estimates, producer/processors who perform more than 10 tests per year would exceed the minor cost threshold. The cost of equipment that labs would need to purchase to conduct testing would also exceed the minor cost threshold.

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.

When proposed rule changes cause more than minor costs to small businesses, the RCW 19.85.040 requires an analysis that compares the cost of compliance for small business with the cost of compliance for the ten percent of businesses that are the largest businesses required to comply with the proposed rules to determine whether the costs are considered

disproportionate.¹⁶ Data limitations prevent the identification of per entity compliance costs needed for this comparison. Specifically, we lack the detailed information needed to estimate average annual per entity costs, or a reasonable range of costs.

In particular, in order to calculate annual costs, we require information on a per entity basis describing the number of samples being tested per year. While we have some limited anecdotal information on the numbers of samples tested per year by individual producer/processors, we lack information on the myriad business models that could lead to a wide range in the number of samples tested per year, and thus a wide range of per entity compliance costs per year.

Developing reliable estimates would require a comprehensive survey with a *reasonable* response rate, and even then, given the wide variability of business models and documented inconsistency in responses from licensees, per entity costs is difficult to determine.

It is important to note that nearly all of the businesses affected by the rule changes are considered small under chapter 19.85 RCW (i.e., businesses with fewer than 50 employees). In addition, small businesses may experience the effects of the rule differently than large businesses in terms of cost.

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.

The proposed rule changes include provisions that are intended to reduce the compliance costs for small businesses. These include:

- An incremental phase-in period that contemplates full compliance by February 1, 2022;
- Increasing lot size from five pounds to ten pounds, although licensees are not precluded from continuing to sample from five pound lotes; and
- Allowing labs to subcontract pesticide and heavy metals testing for a period of time.

It is difficult to accurately assess if small businesses will be disproportionately impacted by this rule proposal when there is both significant overlap and variance between the groups evaluated. As noted above, and throughout this SBEIS, most of the businesses impacted are small as defined by RCW 19.85.030.

In addition, WSLCB considered a range of suggestions from industry representatives, licensees, and others, including:

¹⁶ The RFA provides several options for comparing costs, including: (a) Cost per employee; (b) Cost per hour of labor; (c) Cost per one hundred dollars of sales (RCW 19.85.040(1)). In the absence of sufficient data to calculate disproportionate impacts, an agency whose rule imposes more than minor costs must mitigate the costs to small businesses, where legal and feasible, as defined in this chapter (RCW 19.85.030(4)).

- Testing by lot system that is currently in place for other types of testing does not make sense. They suggested a range of other options including:
 - Regular third-party testing periodically (e.g. quarterly or once a month). Could have the producer/processors pay for this system.
 - For pesticides and heavy metals, allow processors to conduct one test of the concentrate for each harvest from each producer. This could reduce impacts because these testing costs get passed on to the producer and if the testing costs are increased significantly it may cause small businesses to choose not to make concentrates, and processors will lose business.
- Consider exemption for indoor growers for heavy metals testing; heavy metals should not be an issue for indoor growers because they are only using nutrients that have been approved and previously screened.
- Consider an exemption for new product development. Testing costs could make it cost prohibitive to grow small lots of new strains.
- Consider changes to the pesticide standards being proposed. Ensure that the limits are reasonable and science-based; need to consider different limits for different types of uses (e.g. ingestion vs. inhalation). Interviewees and commenters mentioned concerns about the pesticide standards being proposed being too stringent and the costs of failure for small businesses who then may lose the value of an entire lot.
- Consider an education campaign to inform retailers and consumers of the benefits of pesticides and heavy metals testing; could help increase prices to allow for producer/processors to pass on some of the increased cost of testing.
- Consider testing soil for heavy metals as opposed to plants;
- Create carve-outs, exemptions, and specialized criteria for sun growers who engage in “sustainable farming practices.”
- Recalculate costs based on methods other than those required by chapter 19.85 RCW.
- Revise rules outside of the rule development process and chapter 34.05 RCW; consider “intangibles,” such as when “...a farmer can no-longer earn a living off their land and when a small business owner who is passionate about what they do can longer do the thing they love for work. The world is a better place when more people get to follow their dreams & passion.”
- Keep lot size the same. Doing so will impact Tier 1 producers less.
- Consider only end product testing.
- Consider graduated lot sizes.
- Consider using WSDA lab for random pesticide and heavy metal testing.

SECTION 7:

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

Throughout the rule development process, the WSLCB has engaged with businesses likely to be affected by the rule, and who volunteered to participate in the process. To support development of the SBEIS, a subset of six producer/processors spanning a range of both tiers and types of producers was contacted; interviews were conducted with two producers, one processor, and one producer/processor. In addition, interviews were conducted with three testing laboratories. Additional opportunity for public comment will be available when the proposed rule is published. Indoor and outdoor farmers, including sun growers, were included in the interviews.

During the rule development process, the WSLCB hosted two “Listen and Learn” sessions, one in April 2019 and the second in August 2019, inviting industry discussion and feedback on the proposed rules, and discuss potential mitigation strategies. The WSLCB’s stakeholder process encouraged interested parties and industry partners to:

- Identify burdensome areas of existing and proposed rules;
- Proposed initial or draft rule changes; and
- Refine those changes.

Although the WSLCB broadly messaged these sessions (messaging went directly to *all* licensees, as well as over 10,000 GovDelivery subscribers), few processors and producers attended the sessions. This rule project was the first employing the “Listen and Learn” model, and attendees were initially unfamiliar with not only the model, but the process, although detailed agendas were provided well in advance of each meeting.

These heavily facilitated sessions followed two thought streams: the first asked attendees to review draft conceptual rules offered well in advance of the meeting and provide feedback or specific rule language, specifically indicating what they liked, didn’t like, and what they proposed in the way of a solution. No rule language revisions were offered by attendees at either session. Solutions ranged from suggesting that figures and language be more concise in general without offering example, to unsupported assertions that adding pesticides and heavy metals to the suite of required tests would put certain producers out of business.

All comments received during these sessions were curated to the extent possible, although developing themes from sessions was difficult based on the broad range of comments. The proposed rules went through several stages of edits, review, discussion, and then further refinement before arriving at the initial proposal. The end result of this process are proposed rules that are offered as a framework and guidance for testing marijuana products that supports the overarching WSLCB goal of public health and safety.

A summary of the description of issues related to the proposed rule set and how the agency collaborated with stakeholders and industry partners to mitigate potential burden associated with rule compliance is more fully described in the Significant Analysis prepared consistent with RCW 34.05.328, including a phase-in plan, and offered as part of this initial rule proposal.

SECTION 8:

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

While the impacts to individual producer processors may depend on their ability to pass on increased testing costs (in the form of higher prices to retailers), the proposed rule is not expected to affect the amount of marijuana produced. Thus, the proposed rule is unlikely to affect the overall number of employees of producer/processors or retailers. For example, if increased testing costs lead some smaller entities to cease production, other entities may produce larger volumes.

While it would be an indirect effect, the proposed rule may result in some limited additional employment in the labs conducting testing. In order to conduct the testing, a lab adding this testing capability may need to hire one or two additional scientists or technicians to operate equipment and conduct tests. The extent of potential employment gains are uncertain, but given the small number of labs in the industry (currently 14 certified labs) any employment gains would likely be limited.