PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
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DATE: December 08, 2021
TIME: 11:26 AM

WSR 22-01-055

Agency: Washington State Liquor and Cannabis Board

☒ **Original Notice**

☐ **Supplemental Notice to WSR _____**

☐ **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; WAC 314-55-102 – Quality assurance testing; and WAC 314-55-1025 – Proficiency testing. The Washington State Liquor and Cannabis Board (WSLCB) proposes amendments to current marijuana product testing standards to require pesticide testing for all marijuana produced, processed, and sold in Washington State, and randomized or investigation driven testing of marijuana for heavy metals.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
February 2, 2022	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 Microsoft Teams 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: Not earlier than February 16, 2022 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Jeff Kildahl
Address: 1025 Union Avenue SE, Olympia, WA 98501
Email: rules@lcb.wa.gov
Fax: 360-664-9689
Other:
By (date) February 2, 2022

Assistance for persons with disabilities:

Contact Anita Bingham, ADA Coordinator, Human Resources
Phone: 360-664-1739

Fax: 360-664-9689
TTY: 7-1-1 or 1-800-833-6388
Email: anita.bingham@lcb.wa.gov
Other:
By (date) January 26, 2022

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposed rules is to require that all marijuana products produced and sold in Washington State are tested for pesticides. The proposed rules also allow the Washington State Liquor and Cannabis Board (WSLCB) to conduct random or investigation driven testing for heavy metals in marijuana products. It is anticipated that the effect of these rules will be to promote the overarching goal of the WSLCB to protect public health and safety, and to assure that all products sold within the I-502 market are safe for all consumers.

Changes in existing rules include increasing the maximum amount of marijuana flower that may be represented by a single I-502 panel of tests and updating the number of one-gram flower samples required; revised sample collection and storage procedures; elimination of the ability of certified labs to return unused portions of samples to licensees; revised guidance to labs regarding when to reject or fail a sample; updated lab testing requirements and procedures; updated and expanded information regarding testing levels for water activity, potency analysis, foreign matter inspection, microbial screening, mycotoxin screening, and residual solvent screening; addition of required pesticide screening and randomized or investigation driven testing for heavy metals; updated rule language regarding product retesting, remediation of failed lots, expiration of certificates of analysis, and referencing of samples; and updated reporting requirements for lab proficiency testing.

This proposal also 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 WAC 314-55-101 and WAC 314-55-102.

Reasons supporting proposal: Existing testing requirements for adult use marijuana are intended to safeguard products for sale and list potency levels. However, Washington recreational marijuana products are currently not required to be tested for pesticides or 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 mandatory pesticide testing for all marijuana products produced, processed, and sold in Washington State is necessary, and that random or investigation driven heavy metal testing conducted by the WSLCB is also needed.

There is no product testing 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.

With the recent increase in hemp-derived delta-8, delta-9, and other unregulated products entering the I-502 market, it is important at this time to require pesticide testing and random or investigation driven heavy metal testing for adult use marijuana products to protect public health and safety.

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?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

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

Name of proponent: (person or organization) Washington State Liquor and Cannabis Board

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Jeff Kildahl, Policy and Rules Coordinator	1025 Union Avenue SE, Olympia WA, 98501	360-664-1781
Implementation:	Kendra Hodgson, Marijuana Examiners Unit Manager	1025 Union Avenue SE, Olympia, WA. 98501	360-664-4555
Enforcement:	Chandra Brady, Director of the Enforcement and Education	1025 Union Avenue SE, Olympia, WA, 98501	360-664-1726

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Jeff Kildahl
Address: 1025 Union Avenue SE, Olympia WA 98501
Phone: 360-664-1781
Fax: 360-664-9689
TTY:
Email: rules@lcb.wa.gov
Other:

☐ 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):

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

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

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

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

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☒ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4): 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 314-55-101 and WAC 314-55-102 will likely result in additional compliance costs. This includes the requirement to test all marijuana products for pesticides, in addition to the current required suite of tests for adult use products.

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?

As of July 2021, there were 1,306 licensed marijuana producers and processers in the State of Washington. Of those businesses, nine employ more than 50 individuals, indicating that 99.3 percent of the businesses in this industry are considered small. Any licensed business producing marijuana flower and/or intermediate products for which existing regulations require testing would incur costs under the proposed rule. Licensed business that are not currently operating, or that produce only flower marked for extraction would not be affected by this rule.

"Minor 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 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 revenues of business entities in the affected industries. The minor cost threshold is $3,466 (2020$) per business within the industry, based on the average annual revenues reported for calendar years 2018 through 2020 and the number of licensed producers and/or processors as of August 2021.

TYPE OF BUSINESS[1]	# OF BUSINESSES IN WASHINGTON[2]	PERCENTAGE OF BUSINESSES CONSIDERED SMALL[3]	AVERAGE ANNUAL REVENUES (2020$)[4]	MINOR COST THRESHOLD = 0.3% AVERAGE ANNUAL REVENUES (2020$)
Cannabis Producer and/or Processor	1,306	99.3%	$1,155,374	$3,466

Notes:

1. Relevant North American Industry Classification System (NAICS) codes for this industry include the following:
   111998 – All Other Miscellaneous Crop Farming, including Marijuana Grown in an Open Field
   111419 – Other Food Crops Grown Under Cover, including Marijuana Grown Under Cover
   115112 – Soil Preparation, Planting, and Cultivating
   325411 – Medicinal and Botanical Manufacturing
   311812 – Commercial Bakeries
   311991 - Perishable Food Manufacturing

424590 – Other Farm Product Raw Material Merchant Wholesalers, including Marijuana Merchant wholesalers
2. Represents the total number of cannabis producer, producer/processor, and processor licenses as of July 2021 (Email communications from WSLCB August 24, 2021).
3. Number of businesses with <50 employees of all producer/processor license holders (9) provided by the Employment Security Division (ESD) via email on September 20, 2021.
4. Average annual revenues for all licensees that reported revenues between 2018 and 2020, provided by WSLCB on October 22, 2021.

[7] Email communications from WSLCB to IEc, August 24, 2021. Licensed businesses include holders of three license types – Producer, Processor, and Producer/Processor. This report refers to this group of businesses collectively as "producers and processors".

[8] Number of large businesses provided by the Employment Security Division (ESD) via email on September 20, 2021.

Does the rule have a disproportionate impact on small businesses?

When proposed rule changes cause more than minor costs to small businesses, the RFA (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. Over 99 percent of the regulated businesses in this industry are small. As a result, the rule is found to disproportionately impact small businesses, and this SBEIS accordingly identifies and documents cost mitigation strategies.

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

RCW 19.85.030 requires that, when a rule is expected to disproportionately impact small businesses, the agency consider several methods for reducing the impact of the rule on small businesses. The proposed rule itself includes several provisions that are intended to reduce the compliance costs for small businesses.

RULE PROVISION	DESCRIPTION	MECHANISM OF COST REDUCTION
Addition of random or investigation-driven heavy metals screening.	WSLCB may conduct investigation-driven or random spot testing of flower and intermediate product for heavy metals.	Businesses do not have to incur the costs of heavy metals testing on all amounts of flower or batches of intermediate product.
Increase in maximum amount of marijuana flower that may be represented by a single I-502 panel of tests.	Increasing the amount of flower that can be tested using a single I-502 test panel from one test panel per five-pound lot to a single test panel per amounts up to 50 pounds.	Businesses that are able to prepare larger quantities of flower for testing can reduce the number of pesticides tests required under the proposed rule, as well as reduce the number of I-502 test panels currently required, which reduces their testing costs.
Change in number of one-gram flower samples required.	For amounts of flower greater than five pounds, reducing the number of one-gram samples required per pound of tested flower.	On a per pound basis, reduces the amount of flower diverted to testing, instead allowing that flower to be sold, and reducing lost revenues associated with diverted flower.

During development of the proposed rule, through an amendment to WAC 314-55-075, WSLCB increased the allowable canopy size for Tier 1 producers to allow for larger harvests, increasing the ability of those producers to take advantage of the proposed rule provision that allows for amounts of flower up to 50 pounds to be tested with a single panel of tests.
In addition, WSLCB considered a range of suggestions from industry representatives as to how the costs of the rule could be reduced, including:

1. Reduce the number of existing mandatory I-502 tests to accommodate pesticide testing without increasing costs to businesses.
2. Reduce the amount of flower necessary to divert for testing (i.e., maintaining the same four-gram requirement for five-pound lots).
3. Reduce the total number and frequency of pesticides tests required, for example:
    - Regular third-party testing periodically (e.g., quarterly or once a month), funded by the industry.
    - Allowing for more than one strain to be tested together as a single lot, so long as strains are grown in the same indoor room, or receive the same outdoor treatment.
4. Implement measures that might facilitate an ability for producers and processors to raise the price of their products:
    - 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 revisions to the structure of the industry in which producers may pass costs of testing onto retailers.

5. Shift testing requirements from flower and intermediate products to end products.
6. Consider having WSLCB test flower at the retailer level, rather than having flower tested by producers.
    - Consider increased enforcement through increased random sampling by LCB to ensure those acting fairly are not disadvantaged.

WSLCB considered these and other cost reduction options presented by the industry. However, LCB has determined they cannot be included for multiple reasons, including that they didn't meet the intended goals of the rule (e.g., testing end products after they were already placed on retail shelves), did not meaningfully reduce the costs of the rule (e.g., eliminating existing I-502 panel tests identified by the industry), were not feasible due to constraints (e.g., reducing the number of one-gram samples of flower required to test a five-pound amount of flower), or were outside of the bounds of the rule.

The regulating agency must consider delaying compliance timetables as a potential cost mitigation option. During this rulemaking, WSLCB did consider delaying the timeframe for compliance with the heavy metals testing requirement at the request of the industry. As heavy metals testing is no longer required under the proposed rule, WSLCB is no longer considering a delay in compliance timing.

Other types of cost mitigation strategies that must be considered are not relevant to this rulemaking:

- Reducing the frequency of inspections: This rule does not change the rate at which inspections carried out by WSLCB would occur.
- Simplifying, reducing, or eliminating recordkeeping and reporting requirements: The rule does not impose any additional reporting or recordkeeping requirements on the industry.
- Reducing or modifying fine schedules for non-compliance: This rule does not affect fines for noncompliance.

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

Throughout the rule-development process, the WSLCB has engaged with small businesses likely to be affected by the rule. In 2019, WSLCB hosted two "listen and learn" sessions, inviting industry discussion and feedback on the proposed rules. 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.

In 2021, WSLCB hosted a series of three Deliberative Dialog Sessions to allow the regulated community an opportunity to voice their perspectives on cannabis quality assurance testing. The three sessions focused on the perspectives of three distinct elements of the supply chain affected by changes to cannabis quality assurance testing – consumers, producers and processors, and testing labs, respectively. Information collected during these sessions further informed development of the proposed rule.

The proposed rule went through several stages of edits, review, discussion, and then further refinement before arriving at the final proposal. The end result of this process is a proposed rule that would provide 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, and offered as part of this rule proposal.

To support development of this SBEIS, WSLCB invited licensed businesses to participate in a one-hour interview with the authors of the SBEIS. WSLCB selected 25 producers and/or processors representing a range of business types, producer tiers, business sizes, and geographies to participate in the interviews. WSLCB's contractor contacted prospective interviewees via email or phone call to schedule interviews. Potential interviewees were given several options within a one-month window for an interview, with additional times and dates offered if those originally proposed were not compatible with interviewee schedules. In the case that prospective interviewees did not respond after the first contact, they were contacted two to three times in additional attempts to schedule an interview. Ultimately, interviews were conducted with 14 producer/processors and 4 processors. Additional opportunity for public comment will be available when the proposed rule is published.

To solicit information to support this SBEIS from as broad a sample of licensed businesses as possible, WSLCB also worked with its contractor to design an online survey targeted to collecting key data points and business thoughts regarding potential provisions of the proposed rule. WSLCB invited all licensed businesses to participate in this survey, which was distributed by email on September 17, 2021. Of the 4,820 email recipients representing license holders to whom the survey was provided, 116 (2 percent) provided a response by the September 24, 2021 deadline.

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

The impacts to individual producers and processors would depend on their ability to limit their increased costs by increasing the amount of flower that is tested per testing panel, and to pass on increased testing costs (in the form of higher prices to retailers). However, the proposed rule is not expected to affect the amount of cannabis produced. Thus, the proposed rule is unlikely to affect the overall (i.e. industry-wide) number of employees of producer/processors. For example, if increased testing costs lead some smaller entities to cease production, other entities may produce larger volumes. While the additional testing costs may cause some small businesses to close if they are unable to pass on the increased testing costs, the likelihood of this occurring is unknown.

The extent to which employment may change within an individual business would depend on the specific costs incurred by that business and its ability to absorb those costs by reducing costs in other areas, raising prices, or reducing profits, for example. Several interviewees suggested that the increased costs of pesticide testing may be substantial enough to result in reduction of staff hours or release of staff. One interviewee noted that there are substantial operating costs associated with marijuana production and processing, and that modifications to employment is oftentimes the only available option for reducing costs. Conversely, at least one interviewee anticipated that compliance with the new regulations may require him to hire an additional employee. Overall, given the relatively low costs of the rule compared to revenues reported for these businesses, it seems unlikely that the costs of the rule would result in widespread reductions in employment across these businesses.

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

Name: Jeff Kildahl
Address: 1025 Union Avenue SE, Olympia, WA 98501
Phone: 360-664-1781
Fax: 360-664-9689
TTY:
Email: rules@lcb.wa.gov
Other:

Date: December 8, 2021	**Signature:** 
Name: David Postman	
Title: Chair	

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

WAC 314-55-101 Quality ((~~assurance sampling protocols~~)) control sampling. (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 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.~~)) All licensed marijuana processors, producers, certified labs, and certified lab employees must com-

ply with the sampling procedures described in this section, consistent with RCW 69.50.348. Noncompliance may result in disciplinary action as described in this chapter and applicable law.

(2) **Sample collection.** All samples of marijuana, useable marijuana, or marijuana-infused products must be submitted to a certified lab for testing consistent with this chapter.

(a) All samples must be deducted, stored, and transported in a way that prevents contamination and degradation.

(b) To maximize sample integrity, samples must be placed in a sanitary container and stored in a location that prevents contamination and degradation.

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

(i) The certificate number and name of the certified lab receiving the sample;

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

(iii) The date the sample was collected; and

(iv) The weight of the marijuana, useable marijuana, or marijuana-infused product the sample was collected from.

(d) Sampling and analysis requirements apply to all marijuana products regulated by the board.

(3) **Additional sampling protocols for ((~~flower lots~~)) quantities of marijuana flower:**

(a) ((~~Licensees or certified labs must collect a minimum of four separate samples from each marijuana flower lot up to five pounds. Licensees or certified labs may collect more samples than this minimum, but must not collect less. The~~)) Samples must be of roughly equal weight not less than one gram each. Each sample must be deducted from a harvest as defined in WAC 314-55-010(14).

(b) ((~~The four separate samples 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 are collected from four evenly distributed areas of the flower lot and may be done visually or physically.~~

~~(c) The four samples 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.~~)) For marijuana flower weighing up to 10 pounds, a minimum of eight samples must be taken.

(c) For marijuana flower weighing 10 pounds or more but less than 20 pounds, a minimum of 12 samples must be taken.

(d) For marijuana flower weighing 20 pounds or more but less than 30 pounds, a minimum of 15 samples must be taken.

(e) For marijuana flower weighing 30 pounds or more but less than 40 pounds, a minimum of 18 samples must be taken.

(f) For marijuana flower weighing 40 pounds or more but not more than 50 pounds, a minimum of 19 samples must be taken.

(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 any unused portion of the samples.~~))

(5) Certified labs ((~~may~~)) must reject or fail a sample if the lab has reason to believe 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.~~))

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. ((~~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 conducting quality assurance 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 designee 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) **Potency analysis.**~~

~~(i) Certified labs must test and report the following cannabinoids to the WSLCB 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 total CBD = M CBD + (0.877 x M CBDA).~~

~~(iii) 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 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 total CBD = M CBD + (0.877 x M 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.

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

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

(B) Moisture content more than fifteen percent.

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

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

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

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

	Enterobacteria (bile-tolerant gram-negative bacteria)	***E. coli* (pathogenic strains) and *Salmonella spp.***
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 µg/kg of substance; and

(B) 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 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 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

Solvent*	ppm
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.

(c) **Heavy metal screening.** A sample and related lot or batch fail quality assurance 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.** The following quality assurance tests are the minimum required tests for each of the following marijuana products, respectively. Licensees and certified labs may elect to do multiple quality assurance 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 tests:

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

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

(i) All intermediate products must be homogenized prior to quality assurance 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 tests:

Product	Test(s) Required Intermediate Products
Marijuana mix	1. Moisture content* 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* 3. Residual solvent test
Concentrate or extract made with a CO_2 extractor like hash oil	1. Potency analysis 2. Mycotoxin screening* 3. Residual solvent test
Concentrate or extract made with ethanol	1. Potency analysis 2. Mycotoxin screening* 3. Residual solvent test
Concentrate or extract made with approved food grade solvent	1. Potency analysis 2. Microbiological screening* 3. Mycotoxin screening* 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
Infused cooking oil or fat in solid form	1. Potency analysis 2. Microbiological screening* 3. Mycotoxin screening*

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

(d) **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 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

Product	Test(s) Required End Products
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

(c) 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 usable flower, batch of marijuana concentrate, or batch of marijuana-infused product may be sold or transported until the completion and successful passage of quality assurance 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 testing. Licensees may wholesale and transfer failed lots or batches to be extracted pursuant to subsection (5) of this section.

(4) **Samples, lots, or batches that fail quality assurance testing.**

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

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

(c) **Remediation.** Producers and processors may remediate failed harvests, lots, or batches so long as the remediation method does not impart any toxic or deleterious 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 licensed processor the producer or producer/processor transfers the products to; a licensed retailer carrying marijuana products derived from the remediated harvest, lot, or batch; or consumer upon request. The entire harvest, lot, or batch the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated harvest, lots or batches may be sold or transported until the completion and successful passage of quality assurance testing as required in this section.

(5) **Referencing.** Certified labs may reference samples for mycotoxin, 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) 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.~~

~~(7) Upon the request of the WSLCB or its designee, a licensee or a certified lab must provide an employee of the WSLCB 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 for pesticides and chemical residues, unsafe levels of heavy metals, and used for other quality assurance tests deemed necessary by the WSLCB.~~)) (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 conduct the following fields of testing:

(i) Water activity;

(ii) Potency analysis;

(iii) Foreign matter inspection;

(iv) Microbiological screening;

(v) Mycotoxin screening;

(vi) Pesticide screening; and

(vii) Residual solvent screening.

(b) Certified labs may be certified for heavy metal 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 mycotoxin, heavy metal, or pesticide 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. Certified labs must also verify if any unused portion of the sample is destroyed after the completion of required testing.

(b) Certified labs must report quality control test results directly to the board in the required format.

(c) Product must not be converted, transferred, or sold by the licensee 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.

(f) For the purposes of this section, limits have been written to the number of significant digits that laboratories are expected to use when reporting to the board and on associated certificates of analysis.

(3) **Quality control analysis and screening.** The following analysis and screening are only required for samples 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)

Cannabinoid	Lower Limit of Quantitation (mg/g)	CAS #
CBD	1.0	13956-29-1
CBDA	1.0	1244-58-2
Δ^9-THC	1.0	1972-08-3
Δ^9-THCA	1.0	23978-85-0

(B) Total THC;

(C) 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 × 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 total CBD = M CBD + (0.877 × M CBDA).

(iii) 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) **Water activity testing.** The sample fails quality control testing for water activity if the results exceed the following limits:

(i) Water activity rate of more than 0.65 a_w for useable marijuana;

(ii) Water activity rate of more than 0.85 a_w for solid edible products.

(c) **Foreign matter screening.** The sample fails quality control testing for foreign matter screening if the results exceed the following limits:

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

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

(iii) One insect fragment, one hair, or one mammalian excreta in sample.

(d) **Microbiological screening.** The sample and the related population fails quality control testing for microbiological screening if the results exceed the following limits:

Unprocessed Plant Material	Colony Forming Unit per Gram (CFU/g)
Bile Tolerant Gram Negative bacteria (BTGN)	$1.0 * 10^4$
Shiga toxin-producing Escherichia coli (STEC)	≤1
Salmonella spp.	≤1

Processed Plant Material	Colony Forming Unit per Gram (CFU/g)
Bile Tolerant Gram Negative bacteria (BTGN)	$1.0 * 10^3$
Shiga toxin-producing Escherichia coli (STEC)	≤1
Salmonella spp.	≤1

(e) **Mycotoxin screening.** The sample and the related population fails quality control testing if the results exceed the following limits:

Mycotoxin	µg/kg	CAS #
Aflatoxins (Sum of Isomers)	20.	
• Aflatoxin B1		1162-65-8
• Aflatoxin B2		7220-81-7
• Aflatoxin G1		1165-39-5
• Aflatoxin G2		7241-98-7
Ochratoxin A	20.	303-47-9

(f) **Residual solvent screening.** Except as otherwise provided in this subsection, a sample and the related population fails 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 any 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	µg/g	ppm (simplified)	CAS #
Acetone	$5.0 * 10^3$	5000	67-64-1
Benzene	2.0	2	71-43-2
Butanes (Sum of Isomers)	$5.0 * 10^3$	5000	
• n-butane			106-97-8
• 2-methylpropane (isobutane)			75-28-5
Cyclohexane	$3.9 * 10^3$	3880	110-82-7
Chloroform	2.0	2	67-66-3
Dichloromethane	$6.0 * 10^2$	600	75-09-2
Ethanol	$5.0 * 10^3$	5000	64-17-5
Ethyl acetate	$5.0 * 10^3$	5000	141-78-6
Heptanes (Single Isomer)	$5.0 * 10^3$	5000	
• n-heptane			142-82-5
Hexanes (Sum of Isomers)	$2.9 * 10^2$	290	
• n-hexane			110-54-3
• 2-methylpentane			107-83-5
• 3-methylpentane			96-14-0
• 2,2-dimethylbutane			75-83-2
• 2,3-dimethylbutane			79-29-8
Isopropanol (2-propanol)	$5.0 * 10^3$	5000	67-63-0
Methanol	$3.0 * 10^3$	3000	67-56-1
Pentanes (Sum of Isomers)	$5.0 * 10^3$	5000	
• n-pentane			109-66-0
• methylbutane (isopentane)			78-78-4
• dimethylpropane (neopentane)			463-82-1
Propane	$5.0 * 10^3$	5000	74-98-6

Solvent	µg/g	ppm (simplified)	CAS #
Toluene	$8.9 * 10^2$	890	108-88-3
Xylenes (Sum of Isomers)	$2.2 * 10^3$	2170	
• 1,2-dimethylbenzene (ortho-)			95-47-6
• 1,3-dimethylbenzene (meta-)			108-38-3
• 1,4-dimethylbenzene (para-)			106-42-3

(g) **Heavy metal screening.** Heavy metal screening is required for all DOH compliant product as described in chapter 246-70 WAC. Heavy metal screening is optional for non-DOH compliant product; however, heavy metal limits provided below apply to all products. Any product exceeding the provided limits is subject to recall and destruction. The board may conduct random or investigation driven heavy metal screening for compliance. A sample and related quantity of product 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

(h) **Pesticide screening.** For purposes of pesticide screening, a sample and the related quantity of marijuana is considered to have passed if it meets the standards described in WAC 314-55-108 and applicable department of agriculture rules.

(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 sample.

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

Product	Test(s) Required
Marijuana flower	1. Water activity testing 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening 6. Pesticide screening

(b) If marijuana flower will be sold as useable flower, no further testing is required.

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

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

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

(iii) Marijuana mix must be chopped or ground so no particles are greater than 3 mm; and

(iv) Intermediate products require the following quality assurance tests:

Intermediate Product Type	Tests Required
Marijuana mix	1. Water activity testing 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening 6. Pesticide 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 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 3. Residual solvent test 4. Pesticide screening
Concentrate or extract made with ethanol	1. Potency analysis 2. Mycotoxin screening 3. Residual solvent test 4. Pesticide screening
Concentrate or extract made with approved food grade solvent	1. Potency analysis 2. Microbiological screening 3. Mycotoxin screening 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 3. Mycotoxin screening 4. Pesticide screening

(d) **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 tests:

End Product Type	Tests Required
Infused solid edible	1. Potency analysis 2. Water activity testing
Infused liquid (like a soda or tonic)	1. Potency analysis
Infused topical	1. Potency analysis
Marijuana mix packaged (loose or rolled)	1. Potency analysis
Marijuana mix infused (loose or rolled)	1. Potency analysis
Concentrate or marijuana-infused product for inhalation	1. Potency analysis

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

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

(a) Licensees may wholesale and transfer batches or quantities of marijuana 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.

(b) 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 control testing.

(c) Licensees may wholesale and transfer failed batches or quantities of marijuana flower to be extracted pursuant to subsection (6) of this section, unless failed for tests that require immediate destruction.

(6) **Failed test samples.**

(a) Upon approval by the board, failed quantities of marijuana 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 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 quantities of marijuana flower, lots, or batches. Remediation may occur after the first failure, 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 marijuana flower, lots, or batches so long as the remediation method does not impart any toxic or harmful substance to the useable 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 marijuana flower, lot, or batch; or

(D) The consumer upon request.

(ii) The entire quantity of marijuana from which the failed sample(s) were deducted must be remediated.

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

(iv) If a failed quantity of remediated marijuana is not remediated or reprocessed in any way after a first failure, it cannot be retested. Any subsequent certificates of analysis produced without remediation or reprocessing of the failed quantity of marijuana will not supersede the original compliance testing certificate of analysis.

(7) **Referencing.** Certified labs may reference samples for mycotoxins, 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, de-

livery personnel, sample ID numbers, field of testing, and receiving personnel.

(8) Certified labs are not limited in the amount of useable 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.

(9) 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 12 calendar months after issuance.

(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 or investigatory compliance checks. Samples may be randomly screened and used for other quality control tests deemed necessary by the board.

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~~)) chapter, 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 the 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~~)) 80 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~~)) 80 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 the board's vendor upon request.

(8) Laboratories are responsible for obtaining PT samples from vendors approved by ((~~WSLCB or WSLCB's~~)) the board or the 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 release all results ((~~used for certification and/or remediation of failed studies to WSLCB or WSLCB's~~)) at the same time, 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 ongo-

ing 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~~)) the board or the board's vendor approved PT provider, so long as the supplemental PT studies are performed at least ((~~fifteen~~)) 15 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~~)) 15 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.