PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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FILED

DATE: May 27, 2020
TIME: 11:19 AM

WSR 20-12-026

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 (effective until February 28, 2021); New Section WAC 314-55-1021 – Quality Assurance and Quality Control (Effective March 1, 2021 until August 31, 2021; New Section WAC 314-55-1022 – Quality Assurance and Quality Control (Effective September 1, 2021); 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:**
July 8, 2020	10:00 am	1025 Union Avenue, Olympia, WA 98501	

Date of intended adoption: August 5, 2020 (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) July 8, 2020

Assistance for persons with disabilities:

Contact Claris 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) June 24, 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 also provides that as of September 2021, in addition to the currently required suite of tests, all marijuana products produced, processed, and sold in Washington State be tested for pesticides and heavy metals. This is accomplished by revising and updating existing WAC 314-55-102 by way of a phase-in plan, as follows:

- The first proposed revisions, if adopted, would be effective until February 28, 2021.

- On March 1, 2021, WAC 314-55-102 would be repealed, and WAC 314-55-1021 would become effective until August 31, 2021, adding pesticide testing to the current suite of required product testing for all marijuana products produced and sold in Washington State.
- Finally, on September 1, 2021, WAC 314-55-1021 would be repealed, and 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.

Need for Withdrawal of Original CR102 Proposal

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.

On March 23, 2020, Governor Inslee issued the first Stay Home, Stay Healthy proclamation. Because there were no viable options for the Board to hold a public hearing that complied with the Stay Home, Stay Healthy proclamation and subsequent updates, the Board was unable to hold a public hearing on the proposed rules on April 1, 2020. On March 27, 2020, and consistent with RCW 34.05.335 and WAC 1-21-060, the Board withdrew its proposed rulemaking filed on March 11, 2020 as WSR 20-07-052 as a continuance of proposed rulemaking filed on January 22, 2020 as WSR 20-03-076.

The Board's intention in taking this action was to refile a new CR102 regarding proposed marijuana quality control rules as soon as reasonably possible, and once virtual stakeholder engagement options became available. It was clearly articulated at the March 27 meeting that the Board was *not* redrafting rules for this project. The only change to the re-filed CR102 rule package would be the hearing date, potentially the forum for the public hearing, and timelines regarding phase in. The purpose of the withdrawal was to merely place the project on pause until venue and method for holding a public hearing were solidified and available. The substance of the rule proposal would not change, and has not changed.

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:	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? ☐ 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: Katherine Hoffman
Address: 1025 Union Avenue, Olympia WA 98502
Phone: 360-664-1622
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)(d): WAC 314-55-101; 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 314-55-102, 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:

Type of Business	# of Businesses In Washington	Percentage of Businesses Considered Small[3]	Average Annual Revenues[4,5]	Minor Cost Threshold (0.3% Average Annual Revenues)
Marijuana Producer, Processor	341[1]	98%	$1,418,224	$4,255
Cannabis Testing Laboratory	14[2]	100%	$1997000	$5,990

Notes:
[1] Represents the number of Marijuana producer/processors that reported revenue, lab tests, and employment between 2018-05 and 2019-04
[2] Represents the number of labs certified to conduct testing on cannabis products in Washington State.
[3] Defined as having 50 or fewer employees. Producer/processor employment information provided by the Employment Security Department for the 3rd quarter of 2018. Laboratory businesses employment determined through interviews with labs and LinkedIn business profiles accessed 2019-04 and 2020-01
[4] Average annual revenues for producer/processors based on total sales divided by the number of business that reported sales, lab tests, and employment.
[5] For testing laboratories, minor cost threshold based on average annual revenues from the 2010 Economic census of the U.S. for businesses in the "Testing Laboratories" category (NAICS 541380)(WA State Auditor's Office 2019)

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 incremental phase-in period that contemplates full compliance by March, 2021; 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 15 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: May 27, 2020	**Signature:** 
Name: Jane Rushford	
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~~)) 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.~~))

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 August 31, 2020)

(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 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) 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 total CBD = M CBD + (0.877 x M CBDA).

(iii) Any psychoactive cannabinoids intentionally added to the formula of a product must be tested for potency including, but not limited to, delta-8-THC.

(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 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.~~)) 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)	***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.~~)) 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

Solvent*	ppm
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.**~~))

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 ((~~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~~)) analysis 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening

((~~(c)~~)) (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*~~)) analysis 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((*)) - Field of testing is only required if using lots of marijuana flower that have not passed QA testing 3. Residual solvent test
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

Product	Test(s) Required Intermediate Products
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
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
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((*)) - 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

((* ~~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
Other	Potency analysis

((~~(c)~~)) (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) **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)~~)) (8) 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~~)) (9) 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.

NEW SECTION

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

(Effective September 1, 2020, until February 28, 2021)

(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 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) Any psychoactive cannabinoids intentionally added to the formula of a product must be tested for potency including, but not limited to, delta-8-THC.

(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 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 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)	***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.** 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

Solvent*	ppm
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 or other material that will not be extracted	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 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 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
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) **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.

(8) 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.

(9) 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.

NEW SECTION

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

(Effective March 1, 2021)

(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 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) Any psychoactive cannabinoids intentionally added to the formula of a product must be tested for potency including, but not limited to, delta-8-THC.

(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 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 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)	***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.** 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

Solvent*	ppm
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 or other material that will not be extracted	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 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 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
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

Product	Test(s) Required Intermediate Products
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) **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.

(8) 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.

(9) 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.

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 sol-

vent, 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 release all results used for certification and/or remediation of failed studies to ((~~WSLCB or WSLCB's~~)) the board or 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.