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. 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 disciplinary action as described in this chapter and applicable law.
- (2) Sampling protocols for all marijuana product lots and batches: Sample collection. All samples of marijuana, usable marijuana, or marijuana-infused products must be submitted to a certified lab for testing consistent with this chapter.
- (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: All samples must be deducted, stored, and transported in a way that prevents contamination and degradation.

- (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

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

- (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. Each quality control sample container must be clearly marked "quality control sample" and labelled 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 sample.
- (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. Sampling and analysis requirements apply to all marijuana products regulated by the board.

- (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.

- (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

  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. For marijuana flower weighing up to 10 pounds, a minimum of 8 samples must be taken.
- (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 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) <u>Sample retrieval and transportation</u>. Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab. <del>Certified labs</del> 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.

[Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 17-12-032, § 314-55-101, filed 5/31/17, effective 8/31/17; WSR 16-11-110, § 314-55-101, filed 5/18/16, effective 6/18/16.]

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.

and accreditation for quality control 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

sereening. 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 sereening in that field of testing, regardless of whether the test is required under this section. 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) Potency analysis. Certified labs must be certified to conduct the following fields of testing:
- (i) Certified labs must test and report the following cannabinoids to the WSLCB when testing for potency: Moisture analysis;
  - (A) THCA;
  - (B) THC;
  - (C) Total THC;
  - (D) CBDA;

- (E) CBD; and
- (F) Total CBD.
- (ii) Calculating total THC and total CBD. Potency analysis;
- (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 +  $(0.877 \times M \text{ delta-9 THCA})$ .
- (B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD +  $(0.877 \times M \text{ CBDA})$ .
- (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. Foreign matter inspection;
  - (iv) Microbiological screening;
  - (v) Mycotoxin screening;
  - (vi) Pesticide screening; and
  - (vii) Residual solvent screening.
- (b) Potency analysis for flower lots. Certified labs may be certified for heavy metal testing. Certified labs must comply

#### THIS IS NOT A RULE PROPOSAL

### THESE ARE CONCEPTUAL DRAFT RULES DESIGNED FOR DISCUSSION REGARDING CANNABIS QUALITY CONTROL TESTING 10/01/2021

with the guidelines for each quality control field of testing described in this chapter if they offer that testing service.

(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 +  $(0.877 \times M \text{ CBDA})$ .

- (c) Certified labs may combine in equal parts multiple

  samples from the same flower lot for the purposes of the

  following tests after the individual samples described in WAC

  314-55-101(3) have been tested for potency analysis. Certified

  labs may reference samples for mycotoxin, heavy metal, or

  pesticide testing by subcontracting for those fields of testing.
- (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:

#### THIS IS NOT A RULE PROPOSAL

### THESE ARE CONCEPTUAL DRAFT RULES DESIGNED FOR DISCUSSION

#### REGARDING CANNABIS QUALITY CONTROL TESTING

	$\sim 1$
10/0	

	- / - /	
	Enterobacteria (bile-tolerant gram- negative bacteria)	E. coli (pathogenic strains) and Salmonella spp.
Unprocessed Plant Material	104	Not detected in 1g
Extracted or processed Botanical Product	103	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.
- 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&gt; Residual Solvents (USP <467&gt;) not listed in the table below fail quality assurance testing. When residual solvents arecening is required, certified labs must test for the solvents listed in the table below at a minimum.

#### THIS IS NOT A RULE PROPOSAL

#### THESE ARE CONCEPTUAL DRAFT RULES DESIGNED FOR DISCUSSION REGARDING CANNABIS QUALITY CONTROL TESTING

#### 10/01/2021

10/01/2021		
Solvent*	<del>ppm</del>	
Acetone	5,000	
Benzene	2	
Butanes	5,000	
Cyclohexane	<del>3,880</del>	
Chloroform	2	
Dichloromethane	600	
Ethyl acetate	5,000	
Heptanes	5,000	
Hexanes	<del>290</del>	
<del>Isopropanol</del> <del>(2-propanol)</del>	5,000	
Methanol	3,000	
Pentanes	5,000	
Propane	5,000	
Toluene	890	
Xylene**	<del>2,170</del>	

<sup>\*</sup>And isomers thereof.

(c) Heavy metal screening batch fail quality assurance testing for heavy metals if the

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

imits provided in the table below.

Quality assurance testing required. General quality control testing requirements for certified labs. The following quality assurance tests are the minimum required tests for each of the following marijuana products, respectively. Licensees and

results exceed

<sup>\*\*</sup>Usually 60% m-xylene, 14% p-xylene, 9% o-xylene with 17% ethyl

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. 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.
- (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:

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

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

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

  Product must not be converted, transferred, or sold by the

  licensee until the required tests are reported to the board and
  the licensee.
- (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	1. Potency analysis 2. Mycotoxin screening* 3. Residual solvent test

#### THIS IS NOT A RULE PROPOSAL

#### THESE ARE CONCEPTUAL DRAFT RULES DESIGNED FOR DISCUSSION REGARDING CANNABIS QUALITY CONTROL TESTING

#### 10/01/2021

	Test(s) Required
<b>Product</b>	Intermediate Products
solvents or gases approved by the board of	
at least 99% purity)	
Concentrate or extract	1. Potency analysis
made with a CO <sub>2</sub>	2. Mycotoxin screening*
extractor like hash oil	3. Residual solvent test
Concentrate or extract	1. Potency analysis
made with ethanol	2. Mycotoxin screening*
	3. Residual solvent test
Concentrate or extract	1. Potency analysis
made with approved	2. Microbiological
food grade solvent	screening*
	3. Mycotoxin screening*
	4. Residual solvent test
Concentrate or extract	1. Potency analysis
(nonsolvent) such as	2. Microbiological screening
kief, hash, rosin, or	3. Mycotoxin screening
<del>bubble hash</del>	
Infused cooking oil or fat	1. Potency analysis
<del>in solid form</del>	2. Microbiological
	screening*
	3. Mycotoxin screening*

<sup>\*</sup> 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

concentrates, marijuana mix packaged, and products, marijuana from a processor to a retailer following quality assurance tests:

#### THIS IS NOT A RULE PROPOSAL THESE ARE CONCEPTUAL DRAFT RULES DESIGNED FOR DISCUSSION

### REGARDING CANNABIS QUALITY CONTROL TESTING 10/01/2021

10/01/2021	1
	Test(s)
	Required
	End
Product	Products
Infused solid edible	Potency
	analysis
Infused liquid (like a soda	Potency
or tonic)	analysis
Infused topical	Potency
	analysis
Marijuana mix packaged	Potency
(loose or rolled)	analysis
Marijuana mix infused	Potency
(loose or rolled)	analysis
Concentrate or marijuana	Potency
infused product for inhalation	analysis

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) End products consisting of only one intermediate product that has not been changed in any way are not subject to potency analysis. Certified labs must test samples on an "as is" or "as received" basis.
- 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:

  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) 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 Cannabinoid concentration 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 +  $(0.877 \times M CBDA)$ .
- (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) 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. Moisture analysis. The sample fails quality control testing for moisture analysis if the results exceed the following limits:
- (i) Water activity rate of more than 0.65 aw for usable marijuana;
  - (ii) Moisture content more than fifteen percent.
- (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 3mm 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	1.0 * 104
(BTGN)	
Shiga toxin-producing	<1
Escherichia coli (STEC)	
Salmonella spp.	<1

Processed Plant Material	Colony	Forming Unit per	Gram
		(CFU/g)	
Bile Tolerant Gram Negative		1.0 * 103	
(BTGN)	X		
Shiga toxin-producing	<b>&gt;</b>	<1	
Escherichia coli (STEC)		<del></del>	
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.	
<ul> <li>Aflatoxin B1</li> </ul>		<u>1162-65-8</u>
<ul> <li>Aflatoxin B2</li> </ul>		<u>7220-81-7</u>
<ul> <li>Aflatoxin G1</li> </ul>		<u>1165-39-5</u>
<ul> <li>Aflatoxin G2</li> </ul>		<u>7241-98-7</u>
Ochratoxin A	20.	<u>303-47-9</u>

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 (USF <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	CAS #
		(simplified)	
Acetone	$5.0 * 10^3$	5000	67-64-1
Benzene	2.0	2	71-43-2
Butanes (Sum of	$5.0 * 10^3$	5000	
<pre>Isomers)</pre>			
• n-butane			106-97-8
• 2-methylpropane			75-28-5
(isobutane)			
Cyclohexane	3.9 * 10 <sup>3</sup>	3880	110-82-7
Chloroform	2.0	2	67-66-3
Dichloromethane	6.0 * 10 <sup>2</sup>	600	75-09-2
Ethyl acetate	5.0 * 10 <sup>3</sup>	5000	141-78-6
Heptanes (Single Isomer)	$5.0 * 10^3$	5000	
• n-heptane			142-82-5
Hexanes (Sum of Isomers)	2.9 * 10 <sup>2</sup>	290	

### THIS IS NOT A RULE PROPOSAL

#### THESE ARE CONCEPTUAL DRAFT RULES DESIGNED FOR DISCUSSION REGARDING CANNABIS QUALITY CONTROL TESTING 10/01/2021

• 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
<pre>Isopropanol (2-propanol)</pre>	5.0 * 10 <sup>3</sup>	5000	<u>67-63-0</u>
Methanol	3.0 * 103	3000	67-56-1
Pentanes (Sum of Isomers)	5.0 * 10 <sup>3</sup>	5000	
• n-pentane			<u>109-66-0</u>
<pre>methylbutane   (isopentane)</pre>			78-78-4
<pre>dimethylpropane   (neopentane)</pre>			463-82-1
Propane	5.0 * 10 <sup>3</sup>	5000	74-98-6
Toluene	8.9 * 102	890	108-88-3
Xylenes (Sum of Isomers)	$2.2 * 10^3$	2170	
• 1,2-dimethylbenzene (ortho-)			<u>95-47-6</u>
• 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.

(i) 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.

<u>Metal</u>	<u>пб/б</u>
Arsenic	2.0
<u>Cadmium</u>	0.82
Lead	<u>1.2</u>
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.
- testing. 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) 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. Marijuana flower. Marijuana flower requires the following quality control tests:

<b>Product</b>	Test(s) Required
Marijuana flower	1. Moisture analysis 2. Potency analysis
	3. Foreign matter inspection 4. Microbiological screening
	5. Mycotoxin screening
	6. Pesticide screening

- (b) Retesting. At of the producer or processor, <del>validate a failed test</del> basis. All costs of the retest will be result on a case borne by the producer or the processor requesting the retest. Potency retesting will generally not be authorized. If marijuana flower will be sold as usable flower, no further testing is required.
- (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; retailer carrying marijuana products derived from harvest, lot, or batch; or consumer upon request. The entire harvest, lot, or batch the failed sample(s) deducted from must be remediated using the same remediation technique. No remediated harvest, lots or batches may be sold or transported successful passage of quality assurance until the completion and testing as required in this section. 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;

(ii) 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. Moisture content 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 <sub>2</sub> 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

Intermediate Product Type	Tests Required
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

- (v) Intermediate products that pass the required quality control testing may be sold or added to an end product, with no further testing of the intermediate product required. A single serving may not exceed ten milligrams active tetrahydrocannabinol (THC) consistent with WAC 314-55-095(1)(a).
- Certified labs may reference samples for (5) Referencing. and pesticides testing to other mycotoxin, heavy metal certified labs by subcontracting for those fields of testing. referencing to other labs on a chain-offest 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. Usable flower, batch of marijuana concentrate, or 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) 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) 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. 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 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 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

  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 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 marijuana is not remediated or
  reprocessed in any way, 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) 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, for other quality assurance tests deemed necessary 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-ofcustody 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 or investigatory compliance checks. Samples may be randomly screened and used for other quality control tests deemed necessary by the board.

[Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 17-12-032, § 314-55-102, filed 5/31/17, effective 8/31/17; WSR 16-11-110, § 314-55-102, filed 5/18/16, effective 6/18/16; WSR 15-11-107, § 314-55-102, filed 5/20/15, effective 6/20/15; WSR 14-07-116, § 314-55-102, filed 3/19/14, effective 4/19/14. Statutory Authority: RCW 69.50.325, 69.50.331, 69.50.342, 69.50.345. WSR 13-21-104, § 314-55-102, filed 10/21/13, effective 11/21/13.]

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-the board or WSLCB's 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 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)  $\pm$  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-board or WSLCB's the board's vendor upon request.

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

pass or fail, to the laboratory and the board, or the board's vendor.

- (11) The WSLCB board may require the laboratory to submit raw data and all photographs of plated materials along with the report of analysis of PT samples. The laboratory must keep and maintain all raw data and all photographs of plated materials from PT for a period of three years.
- (12) The WSLCB board may waive proficiency tests for certain fields of testing if PT samples or PT programs are not readily available or for other valid reasons as determined by WSLCB the board.
- (13) (a) The WSLCB-board will suspend a laboratory's certification if the laboratory fails to maintain a passing score on an ongoing basis in two out of three successive PT studies. The WSLCB-board may reinstate a laboratory's suspended certification if the laboratory successfully analyzes PT samples from a WSLCB-the board or WSLCB's the 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 board or WSLCB's 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. [Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 17-12-032, § 314-55-1025, filed 5/31/17, effective 8/31/17.]