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REGARDING CANNABIS QUALITY CONTROL TESTING
10/01/2021

WAC 314-55-101 Quality control sampling. (1) All licensed marijuana processors, producers, certified labs, and certified lab employees must comply with the sampling procedures described in this section, consistent with RCW 69.50.348. Noncompliance may result in disciplinary action as described in this chapter and applicable law.

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

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

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

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

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

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

(a) 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) For marijuana flower weighing up to 10 pounds, a minimum of 8 samples must be taken.

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

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

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

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

(4) **Sample retrieval and transportation.** Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab.

(5) Certified labs 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. [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.

(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.

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- (a) Certified labs must be certified to conduct the following fields of testing:
- (i) Moisture analysis;
 - (ii) Potency analysis;
 - (iii) Foreign matter inspection;
 - (iv) Microbiological screening;
 - (v) Mycotoxin screening;
 - (vi) Pesticide screening; and
 - (vii) Residual solvent screening.
- (b) Certified labs may be certified for heavy metal testing. Certified labs must comply with the guidelines for each quality control field of testing described in this chapter if they offer that testing service.
- (c) Certified labs may reference samples for mycotoxin, heavy metal, or pesticide testing by subcontracting for those fields of testing.
- (2) General quality control testing requirements for certified labs.

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- (a) Certified labs must record an acknowledgment of the receipt of samples from producers or processors. Certified labs must also verify if any unused portion of the sample is destroyed after the completion of required testing.
- (b) Certified labs must report quality control test results directly to the board in the required format.
- (c) Product must not be converted, transferred, or sold by the licensee until the required tests are reported to the board and the licensee.
- (d) Certified labs must fail a sample if the results for any limit test are above allowable levels regardless of whether the limit test is required in the testing tables in this chapter.
- (e) Certified labs must test samples on an "as is" or "as received" basis.
- (3) **Quality control analysis and screening.** The following analysis and screening are only required for samples that have not been previously tested, or that have failed quality control testing.

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(a) **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 x M CBDA).

(iii) Regardless of analytical equipment or methodology, certified labs must accurately measure and report the acidic

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(THCA and CBDA) and neutral (THC and CBD) forms of the
cannabinoids.

(b) **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:

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<u>Unprocessed Plant Material</u>	<u>Colony Forming Unit per Gram (CFU/g)</u>
<u>Bile Tolerant Gram Negative (BTGN)</u>	<u>1.0 * 10⁴</u>
<u>Shiga toxin-producing Escherichia coli (STEC)</u>	<u><1</u>
<u>Salmonella spp.</u>	<u><1</u>

<u>Processed Plant Material</u>	<u>Colony Forming Unit per Gram (CFU/g)</u>
<u>Bile Tolerant Gram Negative (BTGN)</u>	<u>1.0 * 10³</u>
<u>Shiga toxin-producing Escherichia coli (STEC)</u>	<u><1</u>
<u>Salmonella spp.</u>	<u><1</u>

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

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

(f) Residual solvent screening. Except as otherwise provided in this subsection, a sample and the related population fails quality control testing for residual solvents if the results exceed the limits provided in the table below. Residual solvent results of more than 5,000 ppm for class three solvents,

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50 ppm for class two solvents, and 2 ppm for any class one

solvents as defined in *United States Pharmacopoeia USP 30*

Chemical Tests / <467> - Residual Solvents (USP <467> not listed

in the table below fail quality control testing. When residual

solvent screening is required, certified labs must test for the

solvents listed in the table below at a minimum.

<u>Solvent</u>	<u>µg/g</u>	<u>ppm</u> <u>(simplified)</u>	<u>CAS #</u>
Acetone	$5.0 * 10^3$	5000	67-64-1
Benzene	2.0	2	71-43-2
<u>Butanes (Sum of Isomers)</u>	$5.0 * 10^3$	5000	
• n-butane			<u>106-97-8</u>
• 2-methylpropane (isobutane)			<u>75-28-5</u>
Cyclohexane	$3.9 * 10^3$	3880	<u>110-82-7</u>
Chloroform	2.0	2	<u>67-66-3</u>
Dichloromethane	$6.0 * 10^2$	600	<u>75-09-2</u>
Ethyl acetate	$5.0 * 10^3$	5000	<u>141-78-6</u>
<u>Heptanes (Single Isomer)</u>	$5.0 * 10^3$	5000	
• n-heptane			<u>142-82-5</u>
<u>Hexanes (Sum of Isomers)</u>	$2.9 * 10^2$	290	
• n-hexane			<u>110-54-3</u>
• 2-methylpentane			<u>107-83-5</u>
• 3-methylpentane			<u>96-14-0</u>
• 2,2-dimethylbutane			<u>75-83-2</u>
• 2,3-dimethylbutane			<u>79-29-8</u>
Isopropanol (2-propanol)	$5.0 * 10^3$	5000	<u>67-63-0</u>
Methanol	$3.0 * 10^3$	3000	<u>67-56-1</u>
<u>Pentanes (Sum of Isomers)</u>	$5.0 * 10^3$	5000	
• n-pentane			<u>109-66-0</u>

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• <u>methylbutane</u> (isopentane)			<u>78-78-4</u>
• <u>dimethylpropane</u> (neopentane)			<u>463-82-1</u>
<u>Propane</u>	<u>5.0 * 10³</u>	<u>5000</u>	<u>74-98-6</u>
<u>Toluene</u>	<u>8.9 * 10²</u>	<u>890</u>	<u>108-88-3</u>
<u>Xylenes (Sum of Isomers)</u>	<u>2.2 * 10³</u>	<u>2170</u>	
• <u>1,2-dimethylbenzene</u> (ortho-)			<u>95-47-6</u>
• <u>1,3-dimethylbenzene</u> (meta-)			<u>108-38-3</u>
• <u>1,4-dimethylbenzene</u> (para-)			<u>106-42-3</u>

(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.

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

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

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

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

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

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

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

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

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

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

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

<u>Intermediate Product Type</u>	<u>Tests Required</u>
<u>Marijuana mix</u>	<u>1. Moisture content</u> <u>2. Potency analysis</u> <u>3. Foreign matter inspection</u> <u>4. Microbiological screening</u> <u>5. Mycotoxin screening</u> <u>6. Pesticide screening</u>
<u>Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases</u>	<u>1. Potency analysis</u> <u>2. Mycotoxin screening</u> <u>3. Residual solvent test</u> <u>4. Pesticide screening</u>

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<u>Intermediate Product Type</u>	<u>Tests Required</u>
<u>approved by the board of at least 99% purity)</u>	
<u>Concentrate or extract made with a CO₂ extractor like hash oil</u>	<ol style="list-style-type: none"> <u>1. Potency analysis</u> <u>2. Mycotoxin screening</u> <u>3. Residual solvent test</u> <u>4. Pesticide screening</u>
<u>Concentrate or extract made with ethanol</u>	<ol style="list-style-type: none"> <u>1. Potency analysis</u> <u>2. Mycotoxin screening</u> <u>3. Residual solvent test</u> <u>4. Pesticide screening</u>
<u>Concentrate or extract made with approved food grade solvent</u>	<ol style="list-style-type: none"> <u>1. Potency analysis</u> <u>2. Microbiological screening</u> <u>3. Mycotoxin screening</u> <u>4. Residual solvent test</u> <u>5. Pesticide screening</u>
<u>Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash</u>	<ol style="list-style-type: none"> <u>1. Potency analysis</u> <u>2. Microbiological screening</u> <u>3. Mycotoxin screening</u> <u>4. Pesticide screening</u>
<u>Infused cooking oil or fat in solid form</u>	<ol style="list-style-type: none"> <u>1. Potency analysis</u> <u>2. Microbiological screening</u> <u>3. Mycotoxin screening</u> <u>4. Pesticide screening</u>

(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).

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(5) 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) **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.

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(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;

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- (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) **Referencing.** Certified labs may reference samples for mycotoxins, heavy metals, and pesticides testing to other certified labs by subcontracting for those fields of testing. Labs must record all referencing to other labs on a chain-of-custody manifest that includes, but is not limited to, the

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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-

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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 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.

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(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 board to certify laboratories for marijuana testing, approve PT programs, and perform on-site assessments of laboratories.

(2) The 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 the board or the board's vendor prior to conducting PT. The 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

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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

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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 board or the board's vendor upon request.

(8) Laboratories are responsible for obtaining PT samples from vendors approved by the board or the board's vendor.

Laboratories are responsible for all costs associated with obtaining PT samples and rounds of PT.

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

(11) The 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 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 the board.

(13) (a) The board will suspend a laboratory's certification if the laboratory fails to maintain a passing score on an

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ongoing basis in two out of three successive PT studies. The board may reinstate a laboratory's suspended certification if the laboratory successfully analyzes PT samples from the board or 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 board will suspend a laboratory's certification if the laboratory fails two consecutive rounds of PT. The board may reinstate a laboratory's suspended certification once the laboratory conducts an investigation, provides the board a deficiency report identifying the root cause of the failed PT, and successfully analyzes PT samples from a 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

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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.]

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