

AMENDATORY SECTION (Amending WSR 22-14-111, filed 7/6/22, effective 8/6/22)

WAC 314-55-0995 Laboratory certification (~~(and accreditation)~~) requirements. The following requirements apply to third-party (~~(labs)~~) laboratories seeking certification by the (~~(WSLCB or its designee to do)~~) LCB to conduct quality assurance testing on cannabis and cannabis products in Washington state, and for certified third-party laboratories (certified (~~(labs)~~) laboratories) to remain certified by the (~~(WSLCB)~~) LCB. The requirements provided in this section are continuing requirements, and must be adhered to and maintained for a third-party (~~(lab)~~) laboratory to remain certified. The (~~(WSLCB)~~) LCB may summarily suspend a (~~(lab's)~~) laboratory's certification if a certified (~~(lab)~~) laboratory is found out of compliance with the requirements of this chapter.

(1) A third-party laboratory must be certified by the (~~(WSLCB or their vendor as meeting the WSLCB's)~~) LCB and meet WSDA accreditation (~~(and other)~~) requirements under chapter 16-310 WAC prior to conducting quality assurance tests required under this chapter. Certified (~~(labs)~~) laboratories must conspicuously display the

certification letter received by the ((~~WSLCB~~)) LCB upon certification at the ((~~lab's~~)) laboratory's premises in a conspicuous location where a customer may observe it unobstructed in plain sight.

(2) Licensed producers or processors may not have a financial interest in a certified laboratory. A person with financial interest in a certified lab may not have direct or indirect financial interest in a licensed cannabis producer or processor for whom they are conducting required quality assurance tests. A person with direct or indirect financial interest in a certified ((~~lab~~)) laboratory must disclose to the ((~~WSLCB~~)) LCB by affidavit any direct or indirect financial interest in a licensed cannabis producer or processor.

(3) The following provisions are conditions of certification for third-party testing ((~~labs~~)) laboratories. Failure to adhere to the below requirements may result in the suspension or revocation of certification.

(a) Each lab must employ a scientific director responsible to ensure the achievement and maintenance of quality standards of practice. The scientific director must possess the ((~~following~~)) minimum qualifications ((~~+~~

~~(i) A doctorate in the chemical or microbiological sciences from a college or university accredited by a national or regional~~

~~certifying authority with a minimum of two years' post-degree laboratory experience;~~

~~(ii) A master's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of four years' of post-degree laboratory experience; or~~

~~(iii) A bachelor's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of six years of post-education laboratory experience)) as described in chapter 16-309 WAC.~~

(b) Certified (~~(labs)~~) laboratories must follow the analytical requirements (~~(most current version of the Cannabis Inflorescence and Leaf Monograph published by the American Herbal Pharmacopoeia or~~ notify the WSLCB or its designee what alternative scientifically valid testing methodology the lab is following for each quality assurance test. Third-party validation by the WSLCB or its designee is required for any monograph or analytical method followed by a certified lab to ensure the methodology produces scientifically accurate results prior to use of alternative testing methods to conduct required quality assurance tests.

~~(c) The WSLCB may require third-party validation and ongoing monitoring of a certified lab's basic proficiency to correctly execute the analytical methodologies employed by the certified lab. The WSLCB may contract with a vendor to conduct the validation and ongoing monitoring described in this subsection. The certified lab must pay all vendor fees for validation and ongoing monitoring directly to the WSLCB's vendor.~~

~~(4) Certified labs)) under chapter 16-309 WAC.~~

(c) Certified laboratories must be accredited by WSDA under chapter 16-310 WAC.

(d) A laboratory must provide the following documentation to the LCB when applying for certification:

(i) Their most recent audit report issued to them by the WSDA;

(ii) The scope of accreditation listing the accredited parameters;

(iii) Proof of current accreditation with the WSDA;

(iv) Their contact information including: Email, phone number, and physical and mailing addresses.

(e) LCB will provide a certification letter to laboratories applying for certification to indicate whether certification is approved or denied. Letters that issue certification approval will

include approved fields of testing, requirements for maintaining certification, and the date of expiration for certification.

(f) LCB certification of a laboratory is valid for one year.

Laboratories must apply for certification renewal each year to maintain their certification. Laboratories applying for a renewal of certification must submit required certification documentation to the LCB at least 30 days prior to their certification expiration date.

(g) Certified laboratories must allow the ((WSLCB or the WSLCB's vendor)) LCB to conduct physical visits and inspect ((related)) the laboratory and equipment, testing and ((other)) related records during normal business hours without advance notice.

~~((5) As a condition of certification, labs must adopt and follow minimum good lab practices (GLPs) as provided in WAC 314-55-103, and maintain internal standard operating procedures (SOPs), and a quality control/quality assurance (QC/QA) program as specified by the WSLCB. The WSLCB or authorized third-party organization (WSLCB's designee) may conduct audits of a lab's GLPs, SOPs, QC/QA, and inspect all other related records.))~~ (h) Certified laboratories must report all test

results directly into LCB's traceability system within 24 hours of completion. Laboratories must also record in the traceability system an acknowledgment of the receipt of samples from producers or

processors and verify if any unused portion of the samples provided to them for testing was destroyed in compliance with WAC 314-55-097 Cannabis waste disposal or returned to the customer.

(i) A certified laboratory must notify the LCB of any change or potential change in their WSDA accreditation status within 48 hours of the change or notice of a potential change. This includes any notices received from WSDA which identify a potential change to accreditation status including, but not limited to, notices to correct, notices of intent, or other administrative notices of potential action for any or all accredited testing parameters.

(j) The board may suspend a laboratory's certification if the WSDA revokes or suspends a laboratory's accreditation under chapter 16-310 WAC or if the laboratory conducts testing under this chapter outside of their approved scope of accreditation.

((6)) (4) The ((~~WSLCB or its designee~~)) LCB will take immediate disciplinary action against any certified ((~~lab~~)) laboratory that fails to comply with the provisions of this chapter, chapter 314-55 WAC, or chapter 16-309 WAC, or falsifies records related to this section or chapter 16-309 WAC including, without limitation, revoking the certification of the certified ((~~lab~~)) laboratory.

[Statutory Authority: RCW 69.50.342 and 2022 c 16 § 168. WSR 22-14-111, § 314-55-0995, filed 7/6/22, effective 8/6/22. Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 17-12-032, § 314-55-0995, filed 5/31/17, effective 8/31/17.]

AMENDATORY SECTION (Amending WSR 24-21-051, filed 10/9/24, effective 1/7/25)

WAC 314-55-102 Quality assurance and quality control. (1)

Certified laboratory 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. Cannabis licensees must use a laboratory certified by the board (certified laboratory) to conduct quality control testing required under this chapter. Prior to becoming certified, laboratories must be accredited by the WSDA as specified in chapter (~~16-309~~) 16-310 WAC.

(a) Licensees must use LCB certified laboratories to conduct testing on cannabis and cannabis products in the following required fields of testing:

- (i) Water activity;
- (ii) Cannabinoid concentration analysis;
- (iii) Foreign matter inspection;
- (iv) Microbiological ~~((screening))~~ testing;
- (v) Mycotoxin ~~((screening))~~ testing;
- (vi) Pesticide ~~((screening))~~ testing; and
- (vii) Residual solvent ~~((screening))~~ testing.

(b) ~~((Certified labs may be certified for heavy metal testing.))~~

Certified labs must comply with the guidelines for ~~((each))~~ quality control fields of testing described in this chapter and chapter 16-309 WAC if they offer ~~((that))~~ testing services to other certified laboratories.

(c) Certified labs may reference samples for ~~((mycotoxin, heavy metal, or pesticide))~~ testing by subcontracting for ~~((these))~~ fields of testing to other laboratories certified by the LCB.

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

(a) Certified labs must record an acknowledgment of the receipt of samples from producers or processors. Certified labs must also verify if any unused portion of the sample is destroyed after the completion of required testing.

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

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

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

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

(f) For the purposes of this section, ~~limits have been written to the number of significant digits that~~ certified laboratories are expected to use ~~when reporting~~ two significant figures for all test parameters except foreign matter when reporting test results to the board and on associated certificates of analysis.

(3) **Quality control analysis and ((~~screening~~)) testing.** The following analysis and ((~~screening~~)) testing are only required for samples that have not been previously tested, or that have been authorized by the LCB to retest following failed quality control testing.

(a) **Cannabinoid concentration analysis.**

(i) A cannabinoid concentration analysis is required to determine the concentration of cannabinoid compounds present in cannabis and cannabis products. The results of the cannabinoid concentration analysis must be reported to the board in the state's traceability system in the required format. The cannabinoid concentration analysis must include testing for at least the following cannabinoids:

(A)

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

(B) Any THC compound that is labeled, advertised, or marketed as part of the product;

(C) Total delta-9 THC;

(D) Total THC for tetrahydrocannabinol compounds other than delta-9 THC;

(E) Total CBD.

(ii) Calculating total THC and total CBD.

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

(B) Total THC for tetrahydrocannabinol compounds other than delta-9 that are present in an amount greater than 0.2 mg/g must be calculated as follows, where M is the mass or mass fraction of the neutral (THC) or acidic form (THCA) of the tetrahydrocannabinol compound: $M \text{ total THC} = M \text{ THC} + [(molar \text{ mass of THC} / molar \text{ mass of THCA}) \times M \text{ THCA}]$.

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

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

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

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

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

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

- (i) Five percent of stems 3 mm or more in diameter; or
- (ii) Two percent of seeds or other foreign matter; or
- (iii) One insect fragment, one hair, or one mammalian excreta in sample.

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

Unprocessed Plant Material	Colony Forming Unit per Gram (CFU/g)
Bile Tolerant Gram Negative bacteria (BTGN)	((1.0 * 10⁴)) <u>10,000</u>
Shiga toxin-producing Escherichia coli (STEC)	<1
Salmonella spp.	<1
Processed Plant Material	Colony Forming Unit per Gram (CFU/g)
Bile Tolerant Gram Negative bacteria (BTGN)	((1.0 * 10³)) <u>1,000</u>
Shiga toxin-producing Escherichia coli (STEC)	<1
Salmonella spp.	<1

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

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

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

Solvent	((µg/g))	µg/g (ppm) (((simplified)))	CAS #
Acetone	((5.0 * 10³))	5000	67-64-1
Benzene	((2.0))	((2)) <u>2.0</u>	71-43-2
Butanes (Sum of Isomers)	((5.0 * 10³))	5000	
• n-butane			106-97-8
• 2-methylpropane (isobutane)			75-28-5
Cyclohexane	((3.9 * 10³))	3880	110-82-7
Chloroform	((2.0))	((2)) <u>2.0</u>	67-66-3
Dichloromethane	((6.0 * 10²))	600	75-09-2
Ethanol	((5.0 * 10³))	5000	64-17-5
Ethyl acetate	((5.0 * 10³))	5000	141-78-6
Heptanes (Single Isomer)	((5.0 * 10³))	5000	
• n-heptane			142-82-5
Hexanes (Sum of Isomers)	((2.9 * 10²))	290	
• n-hexane			110-54-3
• 2-methylpentane			107-83-5
• 3-methylpentane			96-14-0
• 2,2-dimethylbutane			75-83-2

Solvent	(($\mu\text{g/g}$))	$\mu\text{g/g}$ (ppm) ((simplified))	CAS #
• 2,3-dimethylbutane			79-29-8
Isopropanol (2-propanol)	(($5.0 * 10^3$))	5000	67-63-0
Methanol	(($3.0 * 10^3$))	3000	67-56-1
Pentanes (Sum of Isomers)	(($5.0 * 10^3$))	5000	
• n-pentane			109-66-0
• methylbutane (isopentane)			78-78-4
• dimethylpropane (neopentane)			463-82-1
Propane	(($5.0 * 10^3$))	5000	74-98-6
Toluene	(($8.9 * 10^2$))	890	108-88-3
Xylenes (Sum of Isomers)	(($2.2 * 10^3$))	2170	
• 1,2-dimethylbenzene (ortho-)			95-47-6
• 1,3-dimethylbenzene (meta-)			108-38-3
• 1,4-dimethylbenzene (para-)			106-42-3

(g) **Heavy metal** (~~(**screening**)~~) testing. Heavy metal (~~(**screening**)~~) testing is required for all DOH compliant product as described in chapter 246-70 WAC. Heavy metal (~~(**screening**)~~) testing 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**)~~) testing for compliance. A sample and related quantity of product fail quality control testing for heavy metals if the results exceed the limits provided in the table below.

Metal	$\mu\text{g/g}$
Arsenic	2.0
Cadmium	0.82
Lead	1.2
Mercury	0.40

(h) **Pesticide** (~~(screening)~~) testing. For purposes of pesticide (~~(screening)~~) testing, a sample and the related quantity of cannabis 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 cannabis products described below. Licensees and certified labs may opt to perform (~~(additional)~~) optional quality control tests on the same sample.

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

Product	Test(s) Required
Cannabis flower	1. Water activity testing 2. Cannabinoid concentration analysis 3. Foreign matter inspection 4. Microbiological ((screening)) <u>testing</u> 5. Mycotoxin ((screening)) <u>testing</u> 6. Pesticide ((screening)) <u>testing</u>

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

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

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

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

(iii) Cannabis 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
Cannabis mix	1. Water activity testing 2. Cannabinoid concentration analysis 3. Foreign matter inspection 4. Microbiological ((screening)) <u>testing</u> 5. Mycotoxin ((screening)) <u>testing</u> 6. Pesticide ((screening)) <u>testing</u>
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. Cannabinoid concentration analysis 2. Mycotoxin ((screening)) <u>testing</u> 3. Residual solvent ((test)) <u>testing</u> 4. Pesticide ((screening)) <u>testing</u>
Concentrate or extract made with a CO ₂ extractor like hash oil	1. Cannabinoid concentration analysis 2. Mycotoxin ((screening)) <u>testing</u> 3. Residual solvent ((test)) <u>testing</u> 4. Pesticide ((screening)) <u>testing</u>
Concentrate or extract made with ethanol	1. Cannabinoid concentration analysis 2. Mycotoxin ((screening)) <u>testing</u> 3. Residual solvent ((test)) <u>testing</u> 4. Pesticide ((screening)) <u>testing</u>
Concentrate or extract made with approved food	1. Cannabinoid concentration analysis

Intermediate Product Type	Tests Required
grade solvent	2. Microbiological (<u>screening</u>) <u>testing</u> 3. Mycotoxin (<u>screening</u>) <u>testing</u> 4. Residual solvent (<u>test</u>) <u>testing</u> 5. Pesticide ((<u>screening</u>)) <u>testing</u>
Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash	1. Cannabinoid concentration analysis 2. Microbiological (<u>screening</u>) <u>testing</u> 3. Mycotoxin (<u>screening</u>) <u>testing</u> 4. Pesticide ((<u>screening</u>)) <u>testing</u>
Infused cooking oil or fat in solid form	1. Cannabinoid concentration analysis 2. Microbiological (<u>screening</u>) <u>testing</u> 3. Mycotoxin (<u>screening</u>) <u>testing</u> 4. Pesticide ((<u>screening</u>)) <u>testing</u>

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

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

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

(5) Useable flower, a batch of cannabis concentrate, or a batch of cannabis-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 cannabis flower and other material that will be extracted, and cannabis mix and nonsolvent extracts, for the purposes of further extraction prior to completing required quality control testing.

(b) Business entities with multiple locations licensed under the same UBI number may transfer cannabis products between the licensed locations under the same UBI number prior to quality control testing.

(c) Licensees may wholesale and transfer failed batches or quantities of cannabis 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 cannabis 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 heavy metal or pesticide tests that require immediate destruction.

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

(c) Remediation. Remediation is a process or technique applied to quantities of cannabis 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 cannabis flower, lots, or batches so long as the remediation method does not impart any toxic or harmful substance to the useable cannabis, cannabis concentrates, or cannabis-infused product. Remediation solvents or methods used on the cannabis product must be disclosed to:

(A) A licensed processor;

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

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

(D) The consumer upon request.

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

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

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

(7) **Referencing.** Certified laboratories may reference samples for (~~mycotoxins, heavy metals, and pesticides~~) testing to other certified labs by subcontracting for (~~these~~) fields of testing. Laboratories may not reference samples for conducting retesting of samples for fields of testing they have already analyzed.

(a) Laboratories 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.

(b) All test results (fields of testing) that were subcontracted to other certified laboratories must be clearly indicated on the certificate of analysis including the name and certification number of the laboratory that tested the sample.

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

(9) A certificate of analysis issued by a certified laboratory for any cannabis product subject to the requirements of this chapter and chapter 246-70 WAC that has not already been transferred to a retail location expires 12 calendar months after issuance.

(10) The board, or its designee, may request that a licensee or a certified lab provide an employee of the board or their designee samples of cannabis or cannabis 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.

(11) All cannabis products produced, processed, distributed, or sold after the effective date of these rules, must comply with these rules and this chapter; however, postharvest products in the possession of or being processed by a licensee that do not comply with these rules as of their effective date may be sold, distributed, or both within a reasonable period of time, determined by the board.

[Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 24-21-051, s 314-55-102, filed 10/9/24, effective 1/7/25. Statutory Authority: RCW 69.50.342 and 2022 c 16 § 168. WSR 22-14-111, § 314-55-102, filed 7/6/22, effective 8/6/22. Statutory Authority: RCW 69.50.345 and 69.50.348. WSR 22-06-097, § 314-55-102, filed 3/2/22, effective 4/2/22. 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.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

AMENDATORY SECTION (Amending WSR 22-14-111, filed 7/6/22, effective 8/6/22)

WAC 314-55-1035 Laboratory certification—Suspension and revocation. (1) The board may summarily suspend or revoke the certification of any lab certified under WAC 314-55-0995 for any of the following reasons:

(a) The laboratory owner or science director violates any of the requirements of chapter 314-55 WAC relating to the operations of the laboratory.

(b) The laboratory owner or science director aids, abets, or permits the violation of any provision of chapters 314-55 WAC, 69.50 RCW, 69.51A RCW, or Title 9 or 9A RCW related to the operations of the laboratory, or the laboratory owner or science director permits laboratory staff to do so.

(c) Evidence the certificate holder or owner made false statements in any material (~~regard~~) including, but not limited to:

- (i) On the application for certification;
- (ii) In submissions to the board relating to receiving or maintaining certification; or

(iii) Regarding any testing performed or results provided to ~~((WSLCB))~~ LCB or the cannabis licensee by the certificate holder or owner pursuant to WAC 314-55-102.

(d) The laboratory owner or science director is convicted of any crime substantially related to the qualifications or duties of that owner and related to the functions of the laboratory, including a conviction for falsifying any report of or that relates to a laboratory analysis. For purposes of this subsection, a "conviction" means a plea or finding of guilt regardless of whether the imposition of sentence is deferred or the penalty is suspended.

(e) The laboratory submits proficiency test sample results generated by another laboratory as its own.

(f) The laboratory staff denies entry to any employee of the ~~((WSLCB or WSLCB's vendor))~~ LCB during normal business hours for an on-site assessment or inspection, as required by ~~((WAC 314-55-0995, 314-55-102, 314-55-1025, or 314-55-103))~~ chapter 314-55 WAC.

(2) (a) The following violations are subject to the penalties as provided in (b) of this subsection:

(i) The laboratory fails to submit an acceptable corrective action report in response to a deficiency report, and failure to

implement corrective action related to any deficiencies found during a laboratory assessment.

(ii) The laboratory fails to (~~report proficiency testing results pursuant to WAC 314-55-1025~~) notify the LCB of changes in accreditation status with the WSDA as required under WAC 314-55-0995. This includes failure to notify the LCB of any notices received from WSDA which identify a potential for future change to accreditation status for any or all fields of testing as required under WAC 314-55-0995.

(iii) (~~The laboratory fails to remit certification fees within the time limit established by a certifying authority.~~

~~(iv))~~) The laboratory fails to meet recordkeeping requirements as required by chapter 314-55 WAC unless the failure to maintain records is substantial enough to warrant a suspension or revocation under subsection (1) of this section.

(b) The penalties for the violations in (a) of this subsection are as follows:

(i) First violation: Ten-day suspension of the lab's certification or until the lab corrects the violation leading to the suspension, whichever is longer.

(ii) Second violation within a three-year period: Thirty-day suspension of laboratory certification or until the laboratory corrects the violation leading to the suspension, whichever is longer.

(iii) Third violation within a three-year period: Revocation of the lab's certification.

~~(3) ((A certified lab may also be subject to a suspension of certification related to proficiency testing requirements under WAC 314-55-1025.~~

~~(4))~~ A laboratory that has its certification suspended or revoked under this section may request an administrative hearing to contest the suspension or revocation as provided in chapter 34.05 RCW. [Statutory Authority: RCW 69.50.342 and 2022 c 16 § 168. WSR 22-14-111, § 314-55-1035, filed 7/6/22, effective 8/6/22. Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 17-12-032, § 314-55-1035, filed 5/31/17, effective 8/31/17.]

AMENDATORY SECTION (Amending WSR 24-21-051, filed 10/9/24, effective 1/7/25)

WAC 314-55-109 Cannabinoid additives—Requirements, restrictions, and quality assurance testing. (1) As provided in RCW

69.50.326 Licensed cannabis producers and licensed cannabis processors may use a cannabidiol (CBD) product obtained from a source not licensed under this chapter, provided the CBD product:

(a) Is not cannabis or a cannabis product, as defined in chapter 69.50 RCW; and

(b) Has been tested for contaminants and toxins by a testing laboratory (~~(accredited)~~) certified under this chapter and in accordance with testing standards established in this section.

(2) Licensed cannabis producers and licensed cannabis processors may use a CBD product obtained from a source not licensed under this chapter and chapter 69.50 RCW as an additive for the purpose of enhancing the CBD concentration of any product authorized for production, processing, and sale under this chapter. However, useable cannabis, except cannabis that is an intermediate product that will be converted into a cannabis-infused product or a cannabis concentrate, may not be treated or otherwise adulterated in any way including the addition of a CBD product consistent with the rules of this chapter. Except as allowed under this section, CBD product additives must be lawfully produced by, or purchased from, a producer or processor licensed under this chapter. The testing requirements for CBD products derived from cannabis produced by cannabis licensees are provided in

WAC 314-55-102. The testing requirements in this section are required in addition to quality assurance testing otherwise required under this chapter for cannabis products.

(3) **Traceability requirements.** A licensee must enter CBD products obtained from a source not licensed under this chapter into the state traceability system and keep the information in the traceability system completely up to date, consistent with cannabis and cannabis product recordkeeping and traceability requirements in WAC 314-55-083. A licensee must keep CBD products obtained from a source not licensed under this chapter labeled and quarantined in an area separate from cannabis and cannabis products under video surveillance consistent with the requirements for controlled areas in WAC 314-55-083(3) until the CBD products successfully pass quality assurance testing or are destroyed due to failure of tests as provided in this section. At no time during the quarantine period can the product be handled or moved under any circumstances, except for purposes of deducting samples as required under this section, and is subject to auditing by the LCB or its designee(s). CBD products obtained from a source not licensed under this chapter that fail quality assurance testing as provided in this section must not be added to any cannabis product and must be

disposed of consistent with WAC 314-55-097 and the disposal logged into the traceability system consistent with WAC 314-55-083.

(4) **Testing requirements.** The following sample deduction and testing requirements apply to CBD products obtained from a source not licensed under this chapter. Such products must successfully pass quality assurance testing prior to being added to any cannabis product. Samples that fail quality assurance testing and the corresponding products that the samples were deducted from must be disposed of consistent with WAC 314-55-097.

(a) **Sample size and deduction requirements.** Licensed producers, licensed processors, certified labs, and their employees must adhere to the minimum sampling protocols as provided in this section. Samples must be deducted in a way that is most representative of the product the sample is deducted from. The minimum sample size for the testing requirements under this section for CBD products is one percent of the product as packaged by the manufacturer of the CBD product but in no case shall the sample be less than two grams. Licensees, certified labs, and their employees may not adulterate or change in any way the representative sample before the sample is tested.

(i) All samples must be collected/deducted 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.

(ii) Persons collecting samples must wash their hands prior to collecting a sample, wear appropriate gloves, and must use sanitary utensils and storage devices when collecting samples.

(iii) 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.

(iv) The licensee must maintain the CBD products from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the products from becoming contaminated or degraded prior to the CBD products being added or incorporated into cannabis products after successful passage of testing requirements.

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

(A) The unique identifier for the product generated by the state traceability system;

(B) The name of the certified lab receiving the sample;

(C) The license number and business or trade name of the licensee sending the sample;

(D) The date the sample was collected; and

(E) The weight of the sample.

(vi) Certified labs may retrieve samples from a cannabis licensee's licensed premises and transport the sample(s) directly to the lab. Certified labs may also return any unused portion of the sample(s).

(b) **Required fields of testing.**

(i) **Cannabinoid concentration analysis.** Cannabinoid concentration analysis is required to confirm the product is not cannabis or a cannabis product, as defined in chapter 69.50 RCW, contains detectable levels of CBD, and to measure the levels of THC, THC-A, CBD, and CBD-A in the product, as provided in WAC 314-55-102. Synthetic cannabinoids as defined in RCW 69.50.204 are prohibited under RCW 69.50.401 and any test result that suggests the presence of a synthetic cannabinoid must be immediately reported to the board in the required format. The cannabinoid concentration analysis must be conducted consistent with the requirements under WAC 314-55-102. The following cannabinoid concentration analysis results fail quality control and assurance testing for the purposes of this section and the sample and

corresponding product from which the sample was deducted must be disposed of consistent with this section and WAC 314-55-097:

(A) The CBD product is cannabis or a cannabis product, as defined in chapter 69.50 RCW;

(B) The CBD product does not contain any detectable levels of CBD or CBD-A; and

(C) The sample test results indicate that a substance is present that is not THC, CBD, or inert substance which the THC or CBD is dissolved into.

(ii) **Pesticide** (~~(screening)~~) testing.

(A) Licensees must use a certified laboratory to (~~screen~~) test for any pesticides that are not allowed and are designated as having the potential for misuse on a list created, maintained, and periodically updated by the department of health in consultation with the Washington state department of agriculture and the LCB.

(B) If the LCB, WSDA, other designee of the LCB, or certified lab identifies a pesticide that is not allowed for use or application on cannabis under this chapter and is above the action levels provided in WAC 314-55-108, that sample and corresponding product from which the sample was deducted has failed quality assurance testing. A sample that tests at or above the action levels for pesticides consistent

with WAC 314-55-108 fails pesticide testing requirements for the purposes of this section. A sample and corresponding product from which the sample was deducted that fails quality assurance testing under this section must be destroyed consistent with WAC 314-55-097.

(C) Cannabis licensees must also use certified laboratories to screen for pyrethrins and piperonyl butoxide (PBO) in samples of CBD products obtained from a source not licensed under this chapter. Certified laboratories may also screen for additional pesticides not specifically required under this section and per the DOH list, however, any sample that tests at or above the action level for any pesticide(s) as established in WAC 314-55-108 fails the testing requirements under this section and must be disposed of consistent with WAC 314-55-097.

(iii) **Heavy metal** (~~((screening))~~) **testing**. For the purposes of heavy metal (~~((screening))~~) **testing**, a sample fails quality assurance testing and must be disposed of consistent with WAC 314-55-097 if it meets or exceeds the (~~((following))~~) limits(~~((÷))~~) provided in WAC 314-55-102.

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

(iv) **Residual solvents** (~~(screening)~~) testing. Cannabis licensees must use a certified laboratory to test for the solvents listed in the table below at a minimum. Except as otherwise provided in this subsection, a sample and corresponding product from which the sample was deducted fail quality assurance testing for residual solvents and must be disposed of consistent with WAC 314-55-097 if the results meet or exceed the limits provided in ~~((the table below))~~ WAC 314-55-102. Residual solvent results of more than 5,000 ppm for class three solvents, 50 ppm for class two solvents, and 2 ppm for class one solvents as defined in *United States Pharmacopoeia, USP 30 Chemical Tests / <467> - Residual Solvents (USP <467>)* not listed in the table below fail quality assurance testing.

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

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

(v) **Microbiological ((~~screening~~)) testing**. The sample and corresponding product from which the sample was deducted fail quality assurance testing for microbiological screening and must be disposed of consistent with WAC 314-55-097 if the results exceed the ((~~following~~)) limits((~~÷~~)) provided in WAC 314-55-102.

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

(vi) **Mycotoxin ((~~screening~~)) testing**. The sample and corresponding product from which the sample was deducted fail quality assurance testing for mycotoxin ((~~screening~~)) testing and must be disposed of consistent with WAC 314-55-097 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 WAC 314-55-~~

102.

(5) **Test results reporting requirements.** Cannabis licensees must use ((~~a~~)) an LCB certified laboratory to report all test results as

required by this section into the state traceability system within 24 hours of completion of the tests.

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

(7) **Remediation.** Producers and processors may remediate failed products so long as the remediation method does not impart any toxic or deleterious substance to the CBD products obtained from a source outside the regulated system. Remediation solvents or methods used on the product must be disclosed to a licensed processor the producer or producer/processor transfers the products to; a licensed retailer carrying cannabis products derived from the remediated product; or consumer upon request. The product(s) the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated CBD products obtained from a source outside the regulated system may be sold, transported, or used in the processing of cannabis products until the completion and successful passage of quality assurance testing as required in this section.

(8) A licensee or certified lab that violates any of the provisions of this section is subject to disciplinary action, including possible summary suspension or revocation of the producer license, processor license, producer/processor license, or lab certification.

[Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 24-21-051, s 314-55-109, filed 10/9/24, effective 1/7/25. Statutory Authority: RCW 69.50.342 and 2022 c 16 § 168. WSR 22-14-111, § 314-55-109, filed 7/6/22, effective 8/6/22. Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 18-22-056, § 314-55-109, filed 10/31/18, effective 12/1/18.]