**QUALITY ASSURANCE**

**WAC 314-55-101 Quality assurance sampling protocols.** (1) Quality assurance samples submitted to certified third-party laboratories (certified labs) must be representative of the lot or batch from which they were sampled as required by RCW 69.50.348. Licensed producers, licensed processors, certified labs, and their employees must comply with the minimum sampling protocols as provided in this section.

(2) **Sampling protocols for all marijuana product lots and batches:**

(a) Samples must be deducted in a way that is most representative of the lot or batch and maintains the structure of the marijuana sample. Licensees, certified labs, and their employees must not adulterate or change the representative sample from a lot or batch before submitting the sample to certified labs. Examples of adulterating or changing the sample to inflate the level of potency, or to hide any microbiological contaminants from the required microbiological screening include, but are not limited to:

(i) Adulterating the sample with kief, concentrates, or other extracts;

(ii) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This subsection does not prohibit the treatment of failed lots or batches with methods approved by the board; or

(iii) Pregrinding a flower lot sample.

(b) All samples must be taken in a sanitary environment using sanitary practices. Facilities must be constructed, and maintained in a clean and sanitary condition in accordance with rules and as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.

(c) Persons collecting samples must wash their hands prior to collecting a sample from a lot or batch, wear appropriate gloves while preparing or deducting the lot or batch for sample collection, and must use sanitary utensils and storage devices when collecting samples.

(d) Samples must be placed in a sanitary plastic or glass container, and stored in a location that prevents the propagation of pathogens and other contaminants, such as a secure, low-light, cool and dry location.

(e) The licensee must maintain the lot or batch from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the marijuana from becoming contaminated or losing its efficacy.

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

(i) The identification number generated by the traceability system;

(ii) The license number and name of the certified lab receiving the sample;

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

(iv) The date the sample was collected; and

(v) The weight of the sample.

(3) **Additional sampling protocols for flower lots:**

(a) Licensees or certified labs must collect a minimum of four separate samples from each marijuana flower lot up to ten pounds. Licensees or certified labs may collect more samples than this minimum, but must not collect less. The samples must be of roughly equal weight not less than one gram each.

(b) The four separate samples must be taken from different quadrants of the flower lot. A quadrant is the division of a lot into four equal parts. Dividing a lot into quadrants prior to collecting samples must be done in a manner that ensures the samples are collected from four evenly distributed areas of the flower lot and may be done visually or physically.

(c) The four samples may be placed together in one container conforming to the packaging and labeling requirements in subsection (2) of this section for storage and transfer to a certified lab.

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

(5) Certified labs may reject or fail a sample if the lab believes the sample was not collected in the manner required by this section, adulterated, contaminated with known or unknown solvents, or manipulated in a manner that violates the sampling protocols, limit tests, or action levels.

(6) The board 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.** An independent lab must be certified by the board or the board's designee as meeting the board's certification and accreditation requirements consistent with WAC 314-55-0995 and other requirements prior to conducting quality assurance tests required under this section.

(1) **Quality assurance fields of testing.** Labs certified by the board must be certified to the following fields of testing by the board or its designee and must adhere to the guidelines for each quality assurance field of testing listed below. Field of testing is only required if using lots of marijuana flower that has not been previously tested, or that has failed QA testing. Certified labs may reference samples for mycotoxin, heavy metals, and pesticides testing to other certified labs by subcontracting for those fields of testing during until (FUTURE DATE).

 (a) **Potency analysis.**

(i) Certified labs must test and report the following cannabinoids to the board when testing for potency:

(A) THCA;

(B) THC;

(C) Total THC;

(D) CBDA;

(E) CBD; and

(F) Total CBD.

(ii) Calculating total THC and total CBD.

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

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD + (0.877 x M CBDA).

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

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

(b) **Potency analysis for flower lots.**

(i) Certified labs must test and report the results for the required flower lot samples as described in WAC 314-55-101(3) for the following required cannabinoids:

(A) THCA;

(B) THC;

(C) Total THC;

(D) CBDA;

(E) CBD; and

(F) Total CBD.

(ii) Calculating total THC and total CBD.

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

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD + (0.877 x M CBDA).

(c) Certified labs may combine in equal parts multiple samples from the same flower lot for the purposes of the following tests after the individual samples described in WAC 314-55-101(3) have been tested for potency analysis:

(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 aw; and

(B) Moisture content more than fifteen percent.

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

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

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

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

|  | **Enterobacteria (bile-tolerant gram-negative bacteria)** | ***E. coli* (pathogenic strains) and *Salmonella spp.*** |
| --- | --- | --- |
| **Unprocessed Plant Material** | 104 | Not detected in 1g |
| **Extracted or processed Botanical Product** | 103 | Not detected in 1g |

(iv) **Mycotoxin screening.** For purposes of mycotoxin screening, a sample shall be deemed to have passed if it meets the following standards:

|  |  |
| --- | --- |
| **Test** | **Specification** |
| The total of aflatoxin B1, aflatoxin B2, aflatoxin G1 and aflatoxin G2 | <20 μg/kg of substance |
| Ochratoxin A | <20 μg/kg of substance |

(d) **Residual solvent screening.** Except as otherwise provided in this subsection, a sample and related lot or batch fail quality 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 solvent screening is required, certified labs must test for the solvents listed in the table below at a minimum.

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

|  |  |
| --- | --- |
| \* | And isomers thereof. |
| \*\* | Usually 60% *m*-xylene, 14% *p*-xylene, 9% *o*-xylene with 17% ethyl benzene. |

(e) **Heavy metal screening.** For purposes of heavy metal screening, a sample shall be deemed to have passed if it meets the following standards:

| **Metal** |  | **μ/daily dose (5 grams)** |
| --- | --- | --- |
| Arsenic |  | 10.0 |  |
| Cadmium |  | 4.1 |  |
| Lead |  | 6.0 |  |
| Mercury |  | 2.0 |  |

(f) **Pesticide screening.** For purposes of the pesticide screening, a sample shall be deemed to have passed if it meets the standards described in WAC 314-55-108 and applicable department of agriculture rules.

(g) **Terpenes**. Testing for terpene presence and concentration is required if:

(i) The producer or processor states terpene content on any product packaging, labeling, or both; or

(ii) The producer or processor adds or removes terpenes from their product.

(2) **Quality assurance testing required.** The following quality assurance tests are the minimum required tests for each of the following marijuana products, respectively. Licensees and certified labs may elect to do multiple quality assurance tests on the same lot or testing for mycotoxin, pesticides, and heavy metals consistent with this section.

(a) **General quality assurance testing requirements for certified labs.**

(i) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the board 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 board 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 .** Marijuana flower lots require the following quality assurance tests:

| **Product** | **Test(s) Required** |
| --- | --- |
| Lots of marijuana flowers or other material that will not be extracted | 1.analysis2. Potency analysis3. Foreign matter inspection4. Microbiological screening5. Mycotoxin screening6. Pesticide screening7. Heavy metals screening |

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

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

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

(iii) A batch of marijuana mix may not exceed ten 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 analysis\*2. Potency analysis3. Foreign matter inspection\*4. Microbiological screening5. Mycotoxin screening6. Pesticide screening7. Heavy metals screening |
| Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity) | 1. Potency analysis2. Mycotoxin screening\*3. Residual solvent test4. Pesticide screening5. Heavy metals screening |
| Concentrate or extract made with a CO2 extractor like hash oil | 1. Potency analysis2. Mycotoxin screening\*3. Residual solvent test4. Pesticide screening5. Heavy metals screening |
| Concentrate or extract made with ethanol | 1. Potency analysis2. Mycotoxin screening\*3. Residual solvent test4. Pesticide screening5. Heavy metals screening |
| Concentrate or extract made with approved food grade solvent | 1. Potency analysis2. Microbiological screening\*3. Mycotoxin screening\*4. Residual solvent test5. Pesticide screening6. Heavy metals screening |
| Concentrate or extract (nonsolvent) such as kief, hash, rosin, or bubble hash | 1. Potency analysis2. Microbiological screening3. Mycotoxin screening4. Pesticide screening5. Heavy metals screening |
| Infused cooking oil or fat in solid form | 1. Potency analysis2. Microbiological screening\*3. Mycotoxin screening\*4. Pesticide screening5. Heavy metals screening |

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

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

| **Product** | **Test(s) Required****End Products** |
| --- | --- |
| Infused solid edible | Potency analysis |
| Infused liquid (like a soda or tonic) | Potency analysis |
| Infused topical | Potency analysis |
| Marijuana mix packaged (loose or rolled) | Potency analysis |
| Marijuana mix infused (loose or rolled) | Potency analysis |
| Concentrate or marijuana-infused product for inhalation | Potency analysis |

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

(3) No lot of usable flower, batch of marijuana concentrate, or batch of marijuana-infused product may be sold or transported until the completion and successful passage of required quality assurance testing, except:

(a) Business entities with multiple locations licensed under the same UBI number may transfer marijuana products between the licensed locations; and

(b) Licensees may wholesale and transfer batches or lots of flower and other material that will be extracted and marijuana mix and nonsolvent extracts for the purposes of further extraction prior to completing required quality assurance testing. Licensees may wholesale and transfer failed lots or batches to be extracted pursuant to subsection (5) of this section.

(4) **Failed test samples.**

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

(b) **Retesting.** 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. Potency retesting will generally not be authorized.

(c) **Remediation.** Remediation is a process or technique applied to marijuana harvests, lots, or batches to remove pesticides, solvents, or both. Remediation may occur after the first failure of the lot, batch, or both depending on the failure, or if a retest process results in a second failure.

(i) Producers and processors may remediate failed lots, batches, or both so long as the remediation method does not impart any toxic or harmful substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to:

(A) A licensed processor;

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

(C) A licensed retailer carrying marijuana products derived from the remediatedlot or batch; or

(D) a consumer upon request.

(ii) The entire lot obatch from whichthe failed sample(s) were deductedmust be remediated..

(iii) No remediated lots,batches, or both may be sold or transported until quality assurance testing consistent with the requirements of this section is completed. ~~the completion and successful passage of quality assurance testing as required in this section~~.

(5) **Referencing.** Certified labs may reference samples for mycotoxin, heavy metals, and pesticides testing to other certified labs by subcontracting for those fields of testing. Labs must record all referencing to other labs on a chain-of-custody manifest that includes, but is not limited to, the following information: Lab name, certification number, transfer date, address, contact information, delivery personnel, sample ID numbers, field of testing, receiving personnel.

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

(7) Upon the request of the board or its designee, a licensee or a certified lab must provide an employee of the board or their designee samples of marijuana or marijuana products or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened for pesticides and chemical residues, unsafe levels of heavy metals, and used for other quality assurance 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, 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 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 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 certified for and provide proof of the successful PT results prior to initial certification.

(5)(a) A certified laboratory must participate in a minimum of two rounds of PT per year for each field of testing to maintain its certification.

(b) To maintain certification, the laboratory must achieve a passing score, on an ongoing basis, in a minimum of two out of three successive rounds of PT. At least one of the scores must be from a round of PT that occurs within six months prior to the laboratory's certification renewal date.

(6) If the laboratory fails to achieve a passing score on at least eighty percent of the analytes in any proficiency test, the test is considered a failure. If the PT provider provides a pass/fail on a per analyte basis but not on the overall round of PT the lab participates in, the pass/fail evaluation for each analyte will be used to evaluate whether the lab passed eighty percent of the analytes. If the PT provider does not provide individual acceptance criteria for each analyte, the following criteria will be applied to determine whether the lab achieves a passing score for the round of PT:

(a) +/- 30% recovery from the reference value for residual solvent testing; or

(b) +/- 3 z or 3 standard deviations from the reference value for all other fields of testing.

(7) If a laboratory fails a round of PT or reports a false negative on a micro PT, the laboratory must investigate the root cause of the laboratory's performance and establish a corrective action report for each unsatisfactory analytical result. The corrective action report must be kept and maintained by the laboratory for a period of three years, available for review during an on-site assessment or inspection, and provided to the board or 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.

(9) The laboratory must manage, analyze and report all PT samples in the same manner as customer samples including, but not limited to, adhering to the same sample tracking, sample preparation, analysis methods, standard operating procedures, calibrations, quality control, and acceptance criteria used in testing customer samples.

(10) The laboratory must authorize the PT provider to release all results used for certification and/or remediation of failed studies to 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 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 a board or board's vendor approved PT provider, so long as the supplemental PT studies are performed at least fifteen days apart from the analysis date of one PT study to the analysis date of another PT study.

(b) The 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 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.]