Washington State
Liquor and Cannabis Board

Date: November 30, 2016

To: Jane Rushford, Board Chair
Ollie Garrett, Board Member

From: Joanna Eide, Policy and Rules Coordinator

Copy: Rick Garza, Agency Director
Peter Antolin, Agency Deputy Director
Justin Nordhorn, Chief of Enforcement
Becky Smith, Licensing Director
Karen McCall, Agency Rules Coordinator
Marijuana Examiners Unit

Subject: **Approval for filing proposed rules (CR 102) to amend rules in Chapter 314-55 WAC relating to certified labs, testing, and quality assurance.**

Rule changes are needed regarding laboratory certification requirements, proficiency testing, pesticide action levels, requirements to promote lab accuracy and consistency, and quality assurance requirements. The Board approved a CR-101 to initiate permanent rulemaking on this subject on April 20, 2016. Several CR-101s are combined into this CR-102, including CR-101s for lab certification and proficiency testing and pesticide action levels. WSLCB staff also held several meetings with industry members, certified labs, and other state agencies to inform the proposed rule changes in this CR-102.

Process

The Rules Coordinator requests approval to file the proposed rules (CR-102) for the rule making described above. An issue paper on these rule was presented at the Board meeting on November 30, 2016, and is attached to this order.

If approved for filing, the tentative timeline for the rule making process is outlined below:

April 20, 2016	Board approved filing the pre-proposal statement of inquiry (CR 101)
November 30, 2016	Board is asked to approve filing the proposed rules (CR 102 filing)
December 21, 2016	Code Reviser publishes notice, LCB sends notice to rules distribution list
January 11, 2016	Public Hearing
January 11, 2016	End of written comment period

January 25, 2017	Board is asked to adopt rules
January 25, 2017	Agency sends notice to those who commented both at the public hearing and in writing.
January 25, 2017	Agency files adopted rules with the Code Reviser (CR 103)
February 26, 2017	Rules are effective (31 days after filing)

_____ Approve _____ Disapprove _____ _____
Jane Rushford, Chair Date

_____ Approve _____ Disapprove _____ _____
Ollie Garrett, Board Member Date

Attachment: Issue Paper

Washington State Liquor and Cannabis Board

Issue Paper
Lab QA Rules

Date: November 30, 2016
Presented by: Joanna Eide, Policy and Rules Coordinator

Description of the Issue

The purpose of this Issue Paper is to request approval from the Board to file proposed rules (CR 102) for new rules and amendments to rules in Chapter 314-55 WAC Marijuana Licenses, Application Process, Requirements, and Reporting regarding laboratory certification requirements, proficiency testing, pesticide action levels, requirements to promote lab accuracy and consistency, and quality assurance requirements.

Why is rule making necessary?

Rule changes are needed regarding laboratory certification requirements, proficiency testing, pesticide action levels, requirements to promote lab accuracy and consistency, and quality assurance requirements. The Board approved a CR-101 to initiate permanent rulemaking on this subject on April 20, 2016. Several CR-101s are combined into this CR-102, including CR-101s for lab certification and proficiency testing and pesticide action levels. WSLCB staff also held several meetings with industry members, certified labs, and other state agencies to inform the proposed rule changes in this CR-102.

Rule changes are needed to protect consumer safety through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. Creating proficiency testing requirements to achieve and maintain certification and parameters for laboratories will promote accuracy and accountability in marijuana testing by certified laboratories. Additionally, current permanent rules provide how a laboratory may be certified by the WSLCB, but do not contain provisions on what a laboratory must do to remain certified or how the WSLCB may suspend or revoke the certification of a laboratory. WSLCB needs the authority to suspend or revoke the certification of a laboratory that does not follow rule requirements for testing or for those laboratories that do not consistently achieve accurate testing results.

Rules for pesticide action levels are needed for pesticide action levels for pesticides not allowable for use in the production of marijuana. Currently, permanent rules contain a zero tolerance for disallowed pesticides, which is unworkable and virtually untestable. The WSLCB needs action levels for pesticides to determine when a sample should fail quality assurance testing and when a recall should be initiated.

What changes are being proposed?

New Section. WAC 314-55-0995, Laboratory certification and accreditation requirements.

This section pulls lab certification requirements out of WAC 314-55-102 to create a stand-alone section. Labs will more easily be able to locate these requirements. Some adjustments and clarifications were made to the certification requirements, including clarification on education requirements for laboratory personnel, and language added to clearly state that the certification requirements are continuing requirements for maintaining certification. Additional changes were made to reduce redundancy.

Amendatory Section. WAC 314-55-101, Sampling protocols.

Sample labeling requirements are adjusted to clearly mark samples with all necessary information for identification.

The changes include adjustments to how lots may be accumulated to increase flexibility, as well as the number of samples that need to be collected for each lot to try to ensure sufficient minimum sample sizes while aiming to reduce the amount of material required. Adjustments are intended to reduce self-selection bias with sample deduction. Requirements for each sample to be packaged in a separate container to increase accurate assessment of lots and batches. Labs may collect samples if they choose.

Technical changes to accommodate other changes within the rule and to increase rule clarity and organization.

Amendatory Section. WAC 314-55-102, Quality assurance testing.

Editing for clarity, consistency, and organization. Removed lab certification requirements for placement in a new separate section to increase rule organizational logic and clarity.

Adjustments to how potency is calculated to increase accurate reporting and labeling of potency levels. Instead of a single result, potency analysis must be performed by testing 3 separate samples from the lot or batch and averaging the result. Direction on calculating potency, both THC and CBD, is included in the rule language.

Moisture analysis and microbiological testing changes. Changes include testing and reporting for water activity rate, which is a more accurate indicator of the risk of growth of microbes, mold, etc. Moisture content testing changes were made making a sample with more than 15% moisture content fail quality assurance testing. Microbiological screening was changed to test for

enterobacteria. Many of these changes to when these tests are required are offset by the addition of testing for aflatoxins and ochratoxin (under mycotoxin screening).

Residual solvent screening was changed heavily and mirrored after the standards used in the United States Pharmacopea. Only the solvents that are classified as having the least risk are allowed to be used in marijuana processing. The solvent levels correlate to the level of risk they pose for consumption. 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 Pharmacopea, USP 30 Chemical Tests / <467> - Residual Solvents* (USP <467>) not listed in the table in the rule fail quality assurance testing. (Similar construct as pesticide action levels). Labs must test for the residual solvents listed in the rule at a minimum. Labs and licensees may choose to test for additional solvents. The construct is aimed at identifying those solvents that have the highest risk for misuse.

Adjustments to when testing must be performed are proposed to allow for greater flexibility while still ensuring the proper tests are performed prior to products being sold at retail. There is also a requirement that concentrates be tested after production. Allowances for remediating failed lots or batches are made under certain conditions.

Technical changes to accommodate other changes within the rule and to increase rule clarity and organization.

New Section. WAC 314-55-108, Pesticide action levels.
This new section incorporates the pesticide action levels previously established by the Board through emergency rule. It adds direction for testing and retesting, conditions for remediation techniques (currently unknown, but this will be a placeholder if there are techniques developed in the future), and destruction requirements for harvest, lots, or batches that test above the pesticide action levels established in this section. The action levels in this draft mirror the action levels established by Oregon and to provide action levels for those disallowed pesticides beyond those that appear on the list. These action levels are supported by a report issued by the Oregon Health Authority.

New Section. WAC 314-55-1025, Proficiency testing.
This new section incorporates the proficiency testing requirements for labs previously established by the Board through emergency rule. The rule creates requirements for proficiency testing for laboratories seeking certification, and for certified laboratories to maintain certification. Laboratories may only use proficiency testing programs that are approved by the WSLCB or WSLCB's vendor. Laboratories seeking certification must complete one successful round of

proficiency testing and provide proof of the successful completion prior to receiving certification, and certified laboratories must complete a minimum of two successful rounds of proficiency testing for each field of testing per year to maintain certification. The rule also provides requirements for laboratories that fail proficiency testing, as well as the ability of WSLCB to suspend a certification should the laboratory fail to successfully complete proficiency testing. Lastly, the rules detail an avenue for laboratories to remediate if the laboratory fails proficiency testing so that the laboratory's suspended certification may be reinstated.

New Section. WAC 314-55-1035, Laboratory certification – Suspension and revocation.

This rule provides the ways in which the WSLCB may suspend or revoke the certification of laboratories that do not follow rule requirements for laboratories or testing of marijuana. The rule provides two separate levels of suspensions:

1. A summary suspension or revocation applying to more egregious and substantial violations, and
2. A graduated suspension and revocation approach for less serious violations.

The language also references suspensions for failing proficiency testing requirements under proposed WAC 314-55-1025. Lastly, the rule recognizes the right of a laboratory that receives a suspension or revocation to receive an administrative hearing if they choose under the provisions of the Administrative Procedure Act (Chapter 34.05 RCW).

Amendatory Section. WAC 314-55-103, Good laboratory practice checklist.

Changes and enhancements to this section are made to incorporate portions of ISO 17025 5.4 instead of requiring ISO 17025 accreditation for WSLCB certified labs. WSLCB staff worked with our laboratory certifying and auditing vendor, RJ Lee, to incorporate the changes proposed. Incorporating the new requirements in this section is intended to increase lab accuracy and consistency and are proposed as a cost savings measure as ISO 17025 accreditation is costly to achieve and maintain. The WSLCB will continue to look into ISO 17025 accreditation for certified labs as a requirement for achieving and maintaining WSLCB certification and may revisit this issue at a later date. The WSLCB believes that incorporating these changes will achieve the desired outcomes of ISO accreditation, such as accuracy and consistency, without the high costs of ISO accreditation.

NOTE: Additional adjustments to other rules to accommodate the changes in this rulemaking will be made in the Technical/Clarifying Changes to Chapter 314-55 WAC Rulemaking.

NEW SECTION

WAC 314-55-108 Pesticide action levels. (1) Only pesticides allowed under WAC 314-55-084 may be used in the production of marijuana, and they must be registered by the Washington state department of agriculture (WSDA) under chapter 15.58 RCW.

(2) Pursuant to WAC 314-55-102, if the WSLCB, WSDA, other designee of the WSLCB, or certified lab identifies a pesticide that is not allowed under subsection (1) of this section and is above the action levels provided in subsection (3) of this section, that lot or batch from which the sample was deducted has failed quality assurance testing and may be subject to a recall as provided in WAC 314-55-225.

(3) The action levels for pesticides are provided in the table below. The action level for all other pesticides that are not allowed under subsection (1) of this section or listed in the table below is 0.1 ppm.

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins*	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins**	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

*Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

**Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-1-2 respecitvely).

(4) Except as otherwise provided in this section, licensed marijuana producer or processor that provided a sample that fails quality assurance testing must dispose of the entire lot or batch from which the sample was taken as provided by marijuana waste disposal requirements in WAC 314-55-097 and document the disposal of the sample pursuant to traceability requirements in WAC 314-55-083(4) and record-keeping requirements in WAC 314-55-087.

(5) Except as otherwise provided in this section, a licensed marijuana producer or processor which provided a sample that fails quality assurance testing must dispose of the entire lot or batch from which the sample was taken as provided by marijuana waste disposal re-

quirements in WAC 314-55-097 and document the disposal of the sample pursuant to traceability requirements in WAC 314-55-083(4) and record-keeping requirements in WAC 314-55-087.

(6) Pursuant to WAC 314-55-102, at the request of the producer or processor, the WSLCB 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.

(7) Producers and processors may remediate failed harvests, lots, or batches so long as the remediation method does not impart any toxic or deleterious substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to a licensed retailer or consumer upon request. The entire harvest, lot, or batch the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated harvest, lots or batches may be sold or transported until the completion and successful passage of quality assurance testing as required in this section and WAC 314-55-102.

(8) Pursuant to WAC 314-55-102, upon request a marijuana licensee must disclose and make available all quality assurance tests and retest results for the lot or batch of usable marijuana, marijuana concentrates, or marijuana-infused products to the marijuana licensee or retail customer who is considering purchasing the usable marijuana, marijuana concentrates, or marijuana-infused products.

NEW SECTION

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

(2) The WSLCB or its vendor determines the sufficiency of PTs and maintains a list of approved PT programs. Laboratories may request authorization to conduct PT through other PT programs but must obtain approval for the PT program from WSLCB or WSLCB's vendor prior to conducting PT. The WSLCB may add the newly approved PT program to the list of approved PT programs as appropriate.

(3) As a condition of certification, laboratories must participate in PT and achieve a passing score for each field of testing for which the lab will be or is certified.

(4) A laboratory must successfully complete a minimum of one round of PT for each field of testing the lab seeks to be certified for and provide proof of the successful PT results prior to initial certification.

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

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

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

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

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

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

(8) Laboratories are responsible for obtaining PT samples from vendors approved by WSLCB or WSLCB's vendor. Laboratories are responsible for all costs associated with obtaining PT samples and rounds of PT.

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

(10) The laboratory must authorize the PT provider to release all results used for certification and/or remediation of failed studies to WSLCB or WSLCB's vendor.

(11) The WSLCB may require the laboratory to submit raw data and all photographs of plated materials along with the report of analysis of PT samples. The laboratory must keep and maintain all raw data and all photographs of plated materials from PT for a period of three years.

(12) The WSLCB may waive proficiency tests for certain fields of testing if PT samples or PT programs are not readily available or for other valid reasons as determined by WSLCB.

(13)(a) The WSLCB will suspend a laboratory's certification if the laboratory fails to maintain a passing score on an ongoing basis in two out of three successive PT studies. The WSLCB may reinstate a laboratory's suspended certification if the laboratory successfully analyzes PT samples from a WSLCB or WSLCB's vendor approved PT provider, so long as the supplemental PT studies are performed at least fifteen days apart from the analysis date of one PT study to the analysis date of another PT study.

(b) The WSLCB will suspend a laboratory's certification if the laboratory fails two consecutive rounds of PT. WSLCB may reinstate a laboratory's suspended certification once the laboratory conducts an investigation, provides the WSLCB a deficiency report identifying the root cause of the failed PT, and successfully analyzes PT samples from a WSLCB or WSLCB'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.

NEW SECTION

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:

(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 or the marijuana 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 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.

(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.

(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.

N E W S E C T I O N

WAC 314-55-0995 Laboratory certification and accreditation requirements.

The following requirements apply to third-party labs seeking certification by the WSLCB or its designee to do quality assurance testing on marijuana and marijuana products in Washington State, and for certified third-party laboratories (certified labs) to remain certified by the WSLCB. The requirements provided in this section are continuing requirements, and must be adhered to and maintained for a third-party lab to remain certified. The WSLCB may summarily suspend a lab's certification if a certified lab 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 accreditation and other requirements prior to conducting quality assurance tests required under this chapter. Certified labs must conspicuously display the certification letter re-

ceived by the WSLCB upon certification at the lab's premises in a conspicuous location where a customer may observe it unobstructed in plain sight.

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

(3) The following provisions are conditions of certification for third-party testing labs. 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; or

(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.

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

(5) 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.

(6) The WSLCB or its designee will take immediate disciplinary action against any certified lab that fails to comply with the provisions

of this chapter or falsifies records related to this section including, without limitation, revoking the certification of the certified lab.

WAC 314-55-101 Quality assurance ~~S~~ssampling protocols. (1)~~(a)~~ To ensure ~~that~~ quality assurance samples submitted to certified third-party ~~labs~~laboratories (certified labs) are representative from the lot or batch from which they were sampled as required in RCW 69.50.348, licensed producers, licensed processors, certified ~~third-party laboratories~~labs, and their employees must adhere to the ~~following~~ minimum sampling protocols as provided in this section.

~~(b)~~ (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 ~~third-party laboratories~~labs, and their employees may not adulterate or change in any way the representative sample from a lot or batch before submitting the sample to certified ~~third-party laboratories~~labs. This includes adulterating or changing the sample in

any way as to inflate the level of potency, or to hide any microbiological contaminants from the required microbiological screening such as, but not limited to:

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

(ii) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This ~~is not meant to be construed as prohibiting~~subsection does not prohibit the treatment of failed lots or batches with methods approved by the WSLCB; ~~and~~or

(iii) Pregrinding a flower lot sample.

~~(2) **Sampling protocols for all marijuana product lots and batches:** The deduction of all quality assurance samples must adhere to the following sampling protocols:~~

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

~~(b)~~(c) Persons ~~taking~~ collecting samples must wash their hands prior to ~~deducting samples~~collecting a sample from a lot or batch, wear

sterile gloves while preparing or deducting the lot or batch for ~~sampling~~sample collection, and must use ~~sanitary~~ sterile utensils and storage devices when collecting samples.

~~(c)~~(d) Samples must be placed in a sterile ~~plastic or glass~~ container, and stored in a location that prevents the propagation of pathogens and other contaminants~~. This includes low light levels, mild temperatures, and low humidity environments~~, such as a secure, low-light, cool and dry location.

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

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

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

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

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

(iv) The date the sample was collected; and

(v) The weight of the sample.

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

(a) Licensees or certified ~~third-party~~ labs ~~are required to deduct four~~must collect a minimum of three separate samples from each marijuana flower lot ~~in order to ensure representativeness of the lot~~up to five pounds. An additional sample must be collected for every five pound increment in lot weight, up to a maximum lot size of fifteen pounds. Flower lots that are more than five pounds, but less than ten pounds, require four samples. Flower lots more than ten pounds up to fifteen pounds require five samples. Licensees or certified labs may collect more samples than this minimum, but must not collect less. The ~~four~~ samples must be of roughly equal weight~~,~~ not less than ~~one~~ two grams each~~, and the cumulative weight of the four samples may not be more than the maximum allowed in WAC 314-55-102~~.

(b) The ~~four separate~~ samples must be taken from different ~~quadrants~~ sections of the flower lot. A ~~quadrant~~ section is the division of a lot into ~~four~~ equal parts in the same number as the number of samples to be collected. ~~This may be done visually or physically, but~~ Dividing a lot into sections prior to collecting samples must be done in a manner that

ensures the samples ~~were deducted~~are collected from ~~four~~ evenly distributed areas of the flower lot and may be done visually or physically.

(c) The ~~four separate~~ samples ~~may~~ must be ~~placed together~~ packaged in ~~a~~separate containers ~~that conforms~~conforming to the packaging and labeling requirements in subsection (2) of this section for storage and transfer to a certified ~~third-party~~ 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 ~~third-party laboratories~~labs may reject or fail a sample if ~~they~~the lab has reason to believe the sample was not collected in the manner required by this section, ~~has been~~ adulterated in any way, contaminated with known or unknown solvents, or ~~was~~ manipulated in a ~~way~~ manner that violates the sampling protocols, limit tests, or action levels.

~~(5)~~(6) The WSLCB or its designee will take immediate disciplinary action against any licensee or certified ~~third-party~~ lab ~~which~~ that fails to comply with the provisions of this section or falsifies records related to this section including, without limitation, revoking the license ~~or certificate of~~ the licensed producer or processor, or certification of the certified ~~third-party~~ lab.

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

WAC 314-55-102 Quality assurance testing. ~~(1)~~ A third-party testing lab must be certified by the WSLCB or ~~their~~ the WSLCB's vendor as meeting the WSLCB's accreditation and other requirements prior to conducting ~~required~~ quality assurance tests required under this section. ~~Certified labs will receive a certification letter from the WSLCB and must conspicuously display this letter in the lab in plain sight of the customers. The WSLCB can summarily suspend a lab's certification if a lab is found out of compliance with the requirements of this chapter.~~

~~(2) A person with financial interest in a certified third-party testing lab may not have direct or indirect financial interest in a licensed marijuana producer or processor for whom they are conducting required quality assurance tests. A person with direct or indirect financial interest in a certified third-party testing lab must disclose to the WSLCB by affidavit any direct or indirect financial interest in a licensed marijuana producer or processor.~~

~~(3) As a condition of certification, each lab must employ a scientific director responsible to ensure the achievement and maintenance of~~

~~quality standards of practice. The scientific director shall meet the following minimum qualifications:~~

~~(a) Has earned, from a college or university accredited by a national or regional certifying authority a doctorate in the chemical or biological sciences and a minimum of two years' post-degree laboratory experience; or~~

~~(b) Has earned a master's degree in the chemical or biological sciences and has a minimum of four years' of post-degree laboratory experience; or~~

~~(c) Has earned a bachelor's degree in the chemical or biological sciences and has a minimum of six years of post-education laboratory experience.~~

~~(4) As a condition of certification, labs must follow the most current version of the Cannabis Inflorescence and Leaf monograph published by the *American Herbal Pharmacopoeia* or notify the WSLCB what alternative scientifically valid testing methodology the lab is following for each quality assurance test. The WSLCB may require third-party validation of any monograph or analytical method followed by the lab to~~

~~ensure the methodology produces scientifically accurate results prior to them using those standards when conducting required quality assurance tests.~~

~~(5) As a condition of certification, the WSLCB may require third-party validation and ongoing monitoring of a lab's basic proficiency to correctly execute the analytical methodologies employed by the lab. The WSLCB may contract with a vendor to conduct the validation and ongoing monitoring described in this subsection. The lab shall pay all vendor fees for validation and ongoing monitoring directly to the vendor.~~

~~(6) The lab must allow the WSLCB or their vendor to conduct physical visits and inspect related laboratory equipment, testing and other related records during normal business hours without advance notice.~~

~~(7) Labs must adopt and follow minimum good lab practices (GLPs), 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 can conduct audits of a lab's GLPs, SOPs, QC/QA, and inspect all other related records.~~

~~(8) The WSLCB or its designee will take immediate disciplinary action against any certified third-party lab which fails to comply with the provisions of this chapter or falsifies records related to this section including, without limitation, revoking the certificate of the certified third-party lab.~~

~~(9) The general body of required quality assurance tests for marijuana flowers and infused products may include moisture content, potency analysis, foreign matter inspection, microbiological screening, pesticide and other chemical residue and metals screening, and residual solvents levels.~~

~~(10) Table of required quality assurance tests defined in the most current version of the *Cannabis Inflorescence and Leaf* monograph published by the American Herbal Pharmacopoeia.~~

(1) **Quality assurance fields of testing.** Certified labs must be certified to the following fields of testing by the WSLCB or its designee and must adhere to the guidelines for each quality assurance field of testing listed below. Labs may become certified by the WSLCB or its designee to test for heavy metal and pesticide residue screening, but must become certified in those fields of testing prior to conducting any testing or screening.

(a) **Potency analysis.**

(i) Certified labs must test and report the following cannabinoids to the WSLCB 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 (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 individual results and averages for the number of 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 a_w; and

(B) Moisture content more than fifteen percent (15%).

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(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 (5%) of stems 3mm or more in diameter; and

(B) Two percent (2%) 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	10^4	Not detected in 1 g
Extracted or processed Botanical Product	10^3	Not Detected in 1 g

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

(A) Total of Aflatoxin B1, B2, G1, G2: 20 µg/kg of substance; and

(B) Ochratoxin A: 20 µg/kg of substance.

(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 Pharmacopea, USP 30 Chemical Tests / <467> - Residual Solvents* (USP <467>) 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
Ethanol	2,500
Ethyl acetate	5,000
Heptanes	5,000
Hexanes	290

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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 nebzene.

(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 additional testing if desired.

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

(i) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the WSLCB seed to sale traceability system. Certified labs must also verify if any unused portion of the sample was destroyed or returned to the licensee after the completion of required testing.

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(ii) Certified labs must report quality assurance test results directly to the WSLCB traceability system when quality assurance tests for the field of testing are required within twenty-four hours of completion.

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

(b) **Marijuana flower lots and other material lots.** Marijuana flower lots or other material lots require the following quality assurance tests:

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Product	Test(s) Required	~~Maximum Sample Size~~
-	~~Flower Lots and Other Material Lots~~	-
Lots of marijuana flowers or other material that will not be extracted	1. Moisture content 2. Potency analysis 3. Foreign matter inspection 4. Microbiological screening 5. Mycotoxin screening	~~7 grams~~

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

(iii) A batch of marijuana mix may not exceed ~~five~~ fifteen 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	~~Maximum Sample Size~~
Marijuana mix	1. Moisture content* 2. Potency analysis 3. Foreign matter inspection* 4. Microbiological screening 5. Mycotoxin screening	~~7 grams~~
Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity)	1. Potency analysis 2. ~~Microbiological screening (only if using flowers and other plant material that has not passed QA testing)~~Mycotoxin screening* 3. Residual solvent test	~~2 grams~~
Concentrate or extract made with a CO_2 extractor like hash oil	1. Potency analysis 2. ~~Microbiological screening (only if using flowers and other plant material that has not passed QA testing)~~ Mycotoxin screening* 3. Residual solvent test	~~2 grams~~
Concentrate or extract made with ethanol	1. Potency analysis 2. ~~Microbiological screening (only if using flowers and other plant material that has not passed QA testing)~~ Mycotoxin screening* 3. Residual solvent test	~~2 grams~~
Concentrate or extract made with approved food grade solvent	1. Potency analysis 2. Microbiological screening ~~(only if using flowers and other plant material that has not passed QA testing)~~* 3. Mycotoxin screening* 4. Residual solvent test	~~2 grams~~
Concentrate or extract (nonsolvent) such as kief, hash~~ish~~, rosin, or bubble hash	1. Potency analysis 2. Microbiological screening 3. Mycotoxin screening	~~2 grams~~
Infused cooking oil or fat in solid form	1. Potency analysis 2. Microbiological screening ~~(only if using flowers and other plant material that has not passed QA testing)~~* 3. Mycotoxin screening*	~~2 grams~~

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

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~~(c)~~(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	~~Maximum Sample Size~~
Infused solid edible	~~1.~~ Potency analysis	~~1 unit~~
Infused liquid (like a soda or tonic)	~~1.~~ Potency analysis	~~1 unit~~
Infused topical	~~1.~~ Potency analysis	~~1 unit~~
Marijuana mix packaged (loose or rolled)	~~1.~~ Potency analysis	~~2 grams~~
Marijuana mix infused (loose or rolled)	~~1.~~ Potency analysis	~~2 grams~~
Concentrate or marijuana-infused product for inhalation	~~1.~~ Potency analysis	~~1 unit~~

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

~~(11) Certified third-party labs may request additional sample material in excess of amounts listed in the table in subsection (10) of this section for the purposes of completing required quality assurance tests. Labs certified as meeting the WSLCB's accreditation requirements may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab and return any unused portion of the samples.~~

~~(12) Labs certified as meeting the WSLCB's accreditation requirements are not limited in the amount of usable marijuana and marijuana products they may have on their premises at any given time, but they~~

~~must have records to prove all marijuana and marijuana-infused products only for the testing purposes described in WAC 314-55-102.~~

~~(13) At the discretion of the WSLCB, a producer or processor must provide an employee of the WSLCB or their designee samples in the amount listed in subsection (10) of this section 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 metals, and used for other quality assurance tests deemed necessary by the WSLCB. All costs of this testing will be borne by the producer or processor.~~

~~(14)~~(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 ~~all required~~ quality assurance testing~~.~~ as required in this section, except:

(a) Business entities with multiple locations licensed under the same UBI number may transfer marijuana products between the licensed locations under ~~their~~ the same UBI number prior to quality assurance testing~~.~~; and

(b) Licensees may wholesale and transfer batches or lots of flower and other material that will be extracted and marijuana mix and non-

solvent 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.

~~(15) Any usable marijuana or marijuana-infused product that passed the required quality assurance tests may be labeled as "Class A." Only "Class A" usable marijuana or marijuana-infused product will be allowed to be sold.~~

~~(16)~~(4) **Samples, lots, or batches that fail quality assurance testing.**

(a) Upon approval ~~of~~by the WSLCB, ~~a~~ failed lots ~~that fails a quality assurance test and the associated trim, leaf and other usable material~~ or batches may be used to create extracts ~~using hydrocarbon or CO_2 closed loop system~~. After processing, the ~~CO_2 or hydrocarbon based~~ extract must ~~still~~ pass all ~~required~~ quality assurance tests required in ~~WAC 314-55-102~~this section before it may be sold.

~~(17)~~(b) **Retesting.** At the request of the producer or processor, the WSLCB 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.

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~~(18) Labs must report all required quality assurance test results directly into the WSLCB's seed to sale traceability system within twenty-four hours of completion. Labs must also record in the seed to sale traceability system an acknowledgment of the receipt of samples from producers or processors and verify if any unused portion of the sample was destroyed or returned to the licensee.~~(c) **Lot Remediation**. Producers and processors may remediate failed harvests, lots, or batches so long as the remediation method does not impart any toxic or deleterious substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to a licensed processor the producer or producer/processor transfers the products to; a licensed retailer carrying marijuana products derived from the remediated harvest, lot, or batch; or consumer upon request. The entire harvest, lot, or batch the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated harvest, lots or batches may be sold or transported until the completion and successful passage of quality assurance testing as required in this section.

(5) **Referencing**. Certified labs may reference fields of testing to other certified labs by subcontracting fields of testing identified in this section. 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 they 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 WSLCB or its designee, a licensee or a certified lab must provide an employee of the WSLCB or their designee samples of marijuana or marijuana products or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened for pesticides and chemical residues, unsafe levels of heavy metals, and used for other quality assurance tests deemed necessary by the WSLCB.

[Statutory Authority: RCW 69.50.342 and 69.50.345. 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.]

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WAC 314-55-103 Good laboratory practice checklist. A third-party testing lab must be certified by the WSLCB or its vendor as meeting the WSLCB's accreditation and other requirements prior to conducting required quality assurance tests. The following checklist will be used by the WSLCB or its vendor to certify third-party testing labs:

ORGANIZATION: **Completed by:** **Reviewed by:**	**Document Reference**	**Y**	**N**	**NA**	**Comments**
1. The laboratory or the organization of which it is a part of shall be an entity that can be held legally responsible.	-	-	-	-	-
2. The laboratory conducting third-party testing shall have no financial interest in a licensed producer or processor for which testing is being conducted.	-	-	-	-	-
If the laboratory is part of an organization performing activities other than testing ~~and/or calibration~~, the responsibilities of key personnel in the organization that have an involvement or influence on the testing ~~and/or calibration~~ activities of the laboratory shall be defined in order to identify potential conflicts of interest.	-	-	-	-	-
3. The laboratory shall have policies and procedures to ensure the protection of its client's confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.	-	-	-	-	-
4. The laboratory is responsible for all costs of initial certification and ongoing site assessments.	-	-	-	-	-
5. The laboratory must agree to site assessments every ~~two years~~ year for the first three years to maintain certification. Beginning year four of certification, on-site assessments will occur every two years to maintain certification.	-	-	-	-	-
6. The laboratory must allow WSLCB staff or their representative to conduct physical visits and check I-502 related laboratory activities at any time.	-	-	-	-	-
7. The laboratory must report all test results directly into WSLCB's traceability system within twenty-four hours of completion. Labs 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 sample was destroyed or returned to the customer.	-	-	-	-	-

HUMAN RESOURCES **Completed by:** **Reviewed by:**	**Document Reference**	**Y**	**N**	**NA**	**Comments**
8a. Job descriptions for owners and all employees~~: Key staff~~. A written and documented system detailing the qualifications of each member of the staff including any specific training requirements applicable to analytical methods.	-	-	-	-	-
b. Specialized training such as by vendors, classes granting CEU's, etc. shall be documented in each training file.	-	-	-	-	-
9. Qualifications of owners and staff: CVs for staff on file.	-	-	-	-	-

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HUMAN RESOURCES **Completed by:** **Reviewed by:**	**Document Reference**	**Y**	**N**	**NA**	**Comments**
a. Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.	-	-	-	-	-
b. Documentation that the scientific director meets the requirements of WSLCB rules.	-	-	-	-	-
c. Chain of command, personnel organization/flow chart, dated and signed by the laboratory director.	-	-	-	-	-
d. Written documentation of delegation of responsibilities in the absence of the scientific director and management staff (assigned under chapter 314-55 WAC as related to quality assurance testing) ~~to qualified personnel, signed and dated by the laboratory director~~.	-	-	-	-	-
e. Documentation of employee competency (DOC): Prior to independently analyzing samples, and on an annual, ongoing basis, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls). Dated and signed by the laboratory director.	-	-	-	-	-
f. The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.	-	-	-	-	-
g. When using staff who are undergoing training, appropriate supervision shall be provided.	-	-	-	-	-
h. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as necessary.	-	-	-	-	-
i. The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.	-	-	-	-	-
j. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.	-	-	-	-	-
k. Successful training (in-house courses are acceptable) in specific methodologies used in the laboratory shall be documented.	-	-	-	-	-
~~f~~l. Designate a quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.	-	-	-	-	-
m. The laboratory shall delegate responsibilities for key managerial personnel to be acted upon in cases of absence or unavailability.	-	-	-	-	-
n. The laboratory shall provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;	-	-	-	-	-
~~10. Written and documented system detailing the qualifications of each member of the staff.~~	-	-	-	-	-
- ~~The need to require formal qualification or certification of personnel performing certain specialized activities shall be evaluated and implemented where necessary.~~	-	-	-	-	-

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HUMAN RESOURCES Completed by: Reviewed by:		Document Reference	Y	N	NA	Comments
~~11.~~10.	Standard operating procedure ~~manual that details records of internal training provided by facility for staff. Laboratory director must approve, sign and date each procedure.~~for the following:	-	-	-	-	-
a.	Instructions on regulatory inspection and preparedness.	-	-	-	-	-
b.	Instruction on law enforcement interactions.	-	-	-	-	-
c.	Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.	-	-	-	-	-
d.	Written and documented system of employee training on hazards (physical and health) of chemicals in the workplace, including prominent location of MSDS or SDS sheets and the use of appropriate PPE.	-	-	-	-	-
e.	Written and documented system on the competency of personnel on how to handle chemical spills and appropriate action; spill kit on-site and well-labeled, all personnel know the location and procedure.	-	-	-	-	-
f.	Information on how employees can access medical attention for chemical or other exposures, including follow-up examinations without cost or loss of pay.	-	-	-	-	-
g.	Biosafety at a minimum covering sterilization and disinfection procedures and sterile technique training.	-	-	-	-	-

STANDARD OPERATING PROCEDURES		Document Reference	Y	N	NA	Comments
~~12.~~11.	As appropriate, laboratory operations covered by procedures shall include, but not be limited to, the following:	-	-	-	-	-
a.	Environmental, safety and health activities;	-	-	-	-	-
b.	Sample shipping and receipt;	-	-	-	-	-
c.	Laboratory sample chain of custody and material control;	-	-	-	-	-
d.	Notebooks/logbooks;	-	-	-	-	-
e.	Sample storage;	-	-	-	-	-
f.	Sample preparation;	-	-	-	-	-
g.	Sample analysis;	-	-	-	-	-
h.	Standard preparation and handling;	-	-	-	-	-
i.	Postanalysis sample handling;	-	-	-	-	-
j.	Control of standards, reagents and water quality;	-	-	-	-	-
k.	Cleaning of glassware;	-	-	-	-	-
l.	Waste minimization and disposition.	-	-	-	-	-
~~13~~12.	The following information is required for procedures as appropriate to the scope and complexity of the procedures or work requested:	-	-	-	-	-
a.	Scope (e.g., parameters measured, range, matrix, expected precision, and accuracy);	-	-	-	-	-
b.	Unique terminology used;	-	-	-	-	-
c.	Summary of method;	-	-	-	-	-
d.	Interferences/limitations;	-	-	-	-	-
e.	Approaches to address background corrections;	-	-	-	-	-
f.	Apparatus and instrumentation;	-	-	-	-	-
g.	Reagents and materials;	-	-	-	-	-
h.	Hazards and precautions;	-	-	-	-	-
i.	Sample preparation;	-	-	-	-	-
j.	Apparatus and instrumentation setup;	-	-	-	-	-
k.	Data acquisition system operation;	-	-	-	-	-

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STANDARD OPERATING PROCEDURES		Document Reference	Y	N	NA	Comments
l.	Calibration and standardization;	-	-	-	-	-
m.	Procedural steps;	-	-	-	-	-
n.	QC parameters and criteria;	-	-	-	-	-
o.	Statistical methods used;	-	-	-	-	-
p.	Calculations;	-	-	-	-	-
q.	Assignment of uncertainty;	-	-	-	-	-
r.	Forms used in the context of the procedure.	-	-	-	-	-
s.	Document control with master list identifying the current revision status of documents	-	-	-	-	-

FACILITIES AND EQUIPMENT		Document Reference	Y	N	NA	Comments
~~14~~13.	Allocation of space: Adequate for number of personnel and appropriate separation of work areas.	-	-	-	-	-
~~15~~14.	Arrangement of space.	-	-	-	-	-
a.	Allows for appropriate work flow, sampling, lab space separate from office and break areas.	-	-	-	-	-
b.	Employee bathroom is separate from any laboratory area.	-	-	-	-	-
~~16~~15.	Adequate eyewash/safety showers/sink.	-	-	-	-	-
~~17~~16.	Procurement controls.	-	-	-	-	-
a.	The laboratory shall have procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures covering reagents and laboratory consumables shall exist for the purchase, receipt ~~and~~, storage ~~of reagents and laboratory consumable materials relevant for the tests and calibrations~~, and disposition of expired materials.	-	-	-	-	-
b.	The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned.	-	-	-	-	-
c.	Prospective suppliers shall be evaluated and selected on the basis of specified criteria.	-	-	-	-	-
d.	Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.	-	-	-	-	-
~~e.~~	~~When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.~~	-	-	-	-	-
17.	Subcontracting.	-	-	-	-	-
a.	The laboratory shall advise the customer of the subcontract arrangement in writing, including the subcontractors' accreditation credentials under chapters 69.50 RCW and 314-55 WAC.	-	-	-	-	-
b.	The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with chapter 314-55 WAC for the work in question.	-	-	-	-	-
c.	When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.	-	-	-	-	-
18.	Utilities. (Items verified upon on-site inspection)	-	-	-	-	-

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	FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
a.	Electrical:	-	-	-	-	-
i.	Outlets: Adequate, unobstructed, single-use, ~~no~~ multiplug adaptors with surge control;	-	-	-	-	-
ii.	~~No~~Single-use extension cords;	-	-	-	-	-
iii.	Ground fault circuit interrupters near wet areas.	-	-	-	-	-
b.	Plumbing:	-	-	-	-	-
i.	Appropriateness of sink usage: Separate sinks for work/personal use;	-	-	-	-	-
ii.	Adequate drainage from sinks or floor drains;	-	-	-	-	-
iii.	Hot and cold running water.	-	-	-	-	-
c.	Ventilation:	-	-	-	-	-
i.	Areas around solvent use or storage of solvents or waste solvents;	-	-	-	-	-
ii.	Vented hood for any microbiological analysis - Class II Type A biosafety cabinet as applicable.	-	-	-	-	-
iii.	Fume Hood with appropriate ventilation	-	-	-	-	-
d.	Vacuum: Appropriate utilities/traps for prevention of contamination (as applicable).	-	-	-	-	-
e.	Shut-off controls: Located outside of the laboratory.	-	-	-	-	-
19.	Waste disposal: Appropriate for the type of waste and compliant with WAC 314-55-097 Marijuana waste disposal—Liquids and solids.	-	-	-	-	-
20.	Equipment ~~list~~. Equipment and/or systems requiring periodic maintenance shall be identified and records of major equipment shall include:	-	-	-	-	-
-	~~Equipment and/or systems requiring periodic maintenance shall be identified and records of major equipment shall include:~~	-	-	-	-	-
a.	Name;	-	-	-	-	-
b.	Serial number or unique identification from name plate;	-	-	-	-	-
c.	Date received and placed in service;	-	-	-	-	-
d.	Current location;	-	-	-	-	-
e.	Condition at receipt;	-	-	-	-	-
f.	Manufacturer's instructions;	-	-	-	-	-
g.	Date of calibration or date of next calibration;	-	-	-	-	-
h.	Maintenance;	-	-	-	-	-
i.	History of malfunction.	-	-	-	-	-
21.	Maintenance.	-	-	-	-	-
a.	~~Regular~~ Documented evidence of routine preventive maintenance and calibration of equipment ~~demonstration in logbook~~ including, but not limited to: Thermometer ~~calibration~~, pipette ~~calibrations~~, analytical balances, and additional analytical equipment. ~~Documentation of a schedule and reviewed by the laboratory director.~~	-	-	-	-	-
i.	Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.	-	-	-	-	-
ii.	Before being placed into service, equipment, including equipment used for sampling, shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications.	-	-	-	-	-

FACILITIES AND EQUIPMENT		Document Reference	Y	N	NA	Comments
iii.	Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside of specified limits, shall be taken out of service. Such equipment shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.	-	-	-	-	-
b.	Documentation of a schedule and reviewed by the laboratory director.	-	-	-	-	-
i.	Calibration procedures shall specify frequency of calibration checks.	-	-	-	-	-
ii.	Instruments that are routinely calibrated shall be verified daily or prior to analyzing samples (as applicable).	-	-	-	-	-
iii.	Acceptance criteria shall be determined, documented and used.	-	-	-	-	-
iv.	When possible, any external calibration service (metrological laboratory) used shall be a calibration laboratory accredited to ISO/IEC 17025:2005 by a recognized accreditation body.	-	-	-	-	-
v.	Laboratories shall demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.	-	-	-	-	-
vi.	External calibration services shall, wherever possible, be obtained from providers accredited to ISO/IEC 17025 by an ILAC recognized signatory, a CIPM recognized National Metrology Institute (NMI), or a State Weights and Measures Facility that is part of the NIST Laboratory Metrology Program. Calibration certificates shall be endorsed by a recognized accreditation body symbol or otherwise make reference to accredited status by a specific, recognized accreditation body, or contain endorsement by the NMI. Certificates shall indicate traceability to the SI or reference standard and include the measurement result with the associated uncertainty of measurement.	-	-	-	-	-
vii.	Where traceability to the SI is not technically possible or reasonable, the laboratory shall use certified reference materials provided by a competent supplier	-	-	-	-	-
viii.	Calibrations performed in-house shall be documented in a manner that demonstrates traceability via an unbroken chain of calibrations regarding the reference standard/material used, allowing for an overall uncertainty to be estimated for the in-house calibration.	-	-	-	-	-
ix.	Calibrations shall be repeated at appropriate intervals, the length of which can be dependent on the uncertainty required, the frequency of use and verification, the manner of use, stability of the equipment, and risk of failure considerations	-	-	-	-	-
x.	Periodic verifications shall be performed to demonstrate the continued validity of the calibration at specified intervals between calibrations. The frequency of verifications can be dependent on the uncertainty required, the frequency of use, the manner of use, stability of the equipment, and risk of failure considerations.	-	-	-	-	-
~~b~~c.	Documentation of curative maintenance in logbook, signed and dated by laboratory director.	-	-	-	-	-
~~c~~d.	~~Temperature maintenance logbook for refrigerators.~~ Evidence of temperature monitoring for equipment requiring specific temperature ranges.	-	-	-	-	-
e.	Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	-	-	-	-	-
~~d~~f.	Decontamination and cleaning procedures for:	-	-	-	-	-
i.	Instruments;	-	-	-	-	-

FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
ii. Bench space; and	-	-	-	-	-
iii. Ventilation hood/microbial hood.	-	-	-	-	-
~~e~~g. Documentation of adequacy of training of personnel and responsibility for each maintenance task.	-	-	-	-	-
~~f~~h. The organization shall describe or reference how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems.	-	-	-	-	-
22. Computer systems. (Items verified upon on-site inspection)	-	-	-	-	-
a. Adequate for sample tracking.	-	-	-	-	-
b. Adequate for analytical equipment software.	-	-	-	-	-
c. Software control requirements applicable to both commercial and laboratory developed software shall be developed, documented, and implemented.	-	-	-	-	-
d. In addition, procedures for software control shall address the security systems for the protection of applicable software.	-	-	-	-	-
e. For laboratory-developed software, a copy of the original program code shall be:	-	-	-	-	-
i. Maintained;	-	-	-	-	-
ii. All changes shall include a description of the change, authorization for the change;	-	-	-	-	-
iii. Test data that validates the change.	-	-	-	-	-
f. Software shall be acceptance tested when installed, after changes, and periodically during use, as appropriate.	-	-	-	-	-
g. Software ~~T~~testing ~~may consist~~shall include of performing manual calculations or checking against another software product that has been previously tested, or by analysis of standards.	-	-	-	-	-
h. The version and manufacturer of the software shall be documented.	-	-	-	-	-
i. Commercially available software may be accepted as supplied by the vendor. For vendor supplied instrument control/data analysis software, acceptance testing may be performed by the laboratory.	-	-	-	-	-
23. Security.	-	-	-	-	-
a. Written facility security procedures during operating and nonworking hours.	-	-	-	-	-
b. Roles of personnel in security.	-	-	-	-	-
i. Reagents and standards shall be inspected, dated and initialed upon receipt, and upon opening.	-	-	-	-	-
ii. Calibration standards and analytical reagents shall have an expiration or reevaluation date assigned.	-	-	-	-	-
iii. Solutions shall be adequately identified to trace back to preparation documentation.	-	-	-	-	-
c. SOP for controlled access areas and personnel who can access.	-	-	-	-	-
~~d. Secured areas for log-in of sample, and for short and long-term storage of samples.~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~
24. Control of Records	-	-	-	-	-
a. The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.	-	-	-	-	-
b. All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.	-	-	-	-	-
c. Records must be retained for a period of three years	-	-	-	-	-

FACILITIES AND EQUIPMENT		Document Reference	Y	N	NA	Comments
d.	All records shall be held secure and in confidence.	-	-	-	-	-
e.	The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.	-	-	-	-	-
f.	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.	-	-	-	-	-
g.	The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.	-	-	-	-	-
h.	The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.	-	-	-	-	-
i.	Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.	-	-	-	-	-
j.	When mistakes occur in records, each mistake shall be lined out, not erased or made illegible or deleted, and the correct value entered alongside.	-	-	-	-	-
k.	All such alterations or corrections to records shall be signed or initialed and dated by the person making the correction.	-	-	-	-	-
l.	In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.	-	-	-	-	-
m.	All entries to hard copy laboratory records shall be made using indelible ink. No correction fluid may be used on original laboratory data records.	-	-	-	-	-
n.	Laboratories shall establish and maintain a data review process beginning at sample receipt and extending through the report process. The data review process shall be an independent review, conducted by a qualified individual other than the analyst.	-	-	-	-	-
o.	The review process shall be documented before data are reported.	-	-	-	-	-
~~24~~25.	Storage.	-	-	-	-	-
a.	Appropriate and adequate for sample storage over time. The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.	-	-	-	-	-
b.	Adequate storage of chemical reference standards.	-	-	-	-	-
c.	Appropriate storage of any reagents: Fireproof cabinet, separate cabinet for storage of any acids.	-	-	-	-	-
d.	Appropriate safe and secure storage of documents etc., archiving, retrieval of, maintenance of and security of data for a period of three years.	-	-	-	-	-

QA PROGRAM AND TESTING		Document Reference	Y	N	NA	Comments
25.	Sampling/sample protocols~~:~~ must be consistent with chapter 314-55 WAC, ~~W~~written and approved by the laboratory director, and must include documented training.	-	-	-	-	-

QA PROGRAM AND TESTING		Document Reference	Y	N	NA	Comments
a.	Demonstrate adequacy of the chain-of-custody, including: tracking upon receipt of sample including all personnel handling the sample and documenting condition of the sample through a macroscopic and foreign matter inspection.	-	-	-	-	-
~~b.~~	~~Sampling method (representative of an entire batch) including, but not limited to, homogenization, weighing, labeling, sample identifier (source, lot), date and tracking.~~	-	-	-	-	-
~~c~~b.	~~Condition of the sample:~~ Macroscopic and foreign matter inspection - Fit for purpose test. Scientifically valid testing methodology: Either AHP monograph compliant, other third-party validation.	-	-	-	-	-
~~d~~c.	Failed inspection of product: Tracking and reporting.	-	-	-	-	-
~~e~~d.	Return of failed product documentation and tracking.	-	-	-	-	-
~~f~~e.	Disposal of used/unused samples documentation.	-	-	-	-	-
~~g~~f.	Sample preparation, extraction and dilution SOP.	-	-	-	-	-
~~h~~g.	Demonstration of recovery for samples in various matrices (SOPs):	-	-	-	-	-
i.	Plant material - Flower;	-	-	-	-	-
ii.	Edibles (solid and liquid meant to be consumed orally);	-	-	-	-	-
iii.	Topical;	-	-	-	-	-
iv.	Concentrates.	-	-	-	-	-
26.	Data protocols.	-	-	-	-	-
a.	Calculations for quantification of cannabinoid content in various matrices - SOPs.	-	-	-	-	-
b.	Determination of the range for reporting the quantity (LOD/LOQ) data review or generation.	-	-	-	-	-
c.	Reporting of data: Certificates of analysis (CA) - Clear and standardized format for consumer reporting.	-	-	-	-	-
d.	Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:	-	-	-	-	-
i.	A title (e.g., "Test Report" or "Calibration Certificate");	-	-	-	-	-
ii.	The name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;	-	-	-	-	-
iii.	Unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;	-	-	-	-	-
iv.	The name and address of the customer;	-	-	-	-	-
v.	Identification of the method used;	-	-	-	-	-
vi.	A description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;	-	-	-	-	-
vii.	The date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;	-	-	-	-	-
viii.	Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;	-	-	-	-	-
ix.	The test or calibration results with, where appropriate, the units of measurement;	-	-	-	-	-
x.	The name(s), function(s) and signature(s) or equivalent identification of Person(s) authorizing the test report or calibration certificate; and	-	-	-	-	-
xi.	Where relevant, a statement to the effect that the results relate only to the items tested or calibrated.	-	-	-	-	-

QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
e. Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]", or an equivalent form of wording.	-	-	-	-	-
f. When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.	-	-	-	-	-
g. If the laboratory chooses to include a reference to their I-502 certification on their test report, any test results not covered under I-502 certification shall be clearly identified on the report.	-	-	-	-	-
~~d~~h. Documentation that the value reported in the CA is within the range and limitations of the analytical method.	-	-	-	-	-
~~e~~i. Documentation that qualitative results (those below the LOQ but above the LOD) are reported as "trace," or with a nonspecific (numerical) designation.	-	-	-	-	-
~~f~~j. Documentation that the methodology has the specificity for the degree of quantitation reported. Final reports are not quantitative to any tenths or hundredths of a percent.	-	-	-	-	-
~~g~~h. Use of appropriate "controls": Documentation of daily use of positive and negative controls that challenge the linearity of the curve; and/or an appropriate "matrix blank" and control with documentation of the performance for each calibration run.	-	-	-	-	-
27. Chemical assay procedure/methodology.	-	-	-	-	-
28. ~~Proficiency~~Quality Control (QC):	-	-	-	-	-
a. Documentation of use of an appropriate internal standard for any quantitative measurements as applicable to the method.	-	-	-	-	-
b. Appropriate reference standards for quantification of analytes, performing and documenting a calibration curve with each analysis.	-	-	-	-	-
i. Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked for accuracy as far as is technically and economically practicable.	-	-	-	-	-
ii. The laboratory shall create and follow procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.	-	-	-	-	-
iii. Reference materials shall have a certificate of analysis that documents traceability to a primary standard or certified reference material and associated uncertainty, when possible. When applicable, the certificate must document the specific NIST SRM® or NMI certified reference material used for traceability.	-	-	-	-	-
c. Demonstration of calibration curve r^2 value of no less than 0.995 with a minimum of four points ~~within~~ which bracket the expected sample concentration range.	-	-	-	-	-
~~d. Documentation of any proficiency testing as it becomes available. Laboratory director must review, evaluate and report to the WSLCB any result that is outside the stated acceptable margin of error.~~	-	-	-	-	-
i. The calibration curve shall be verified by preparing an independently prepared calibration standard (from neat materials) or with a standard from an independent source. Acceptance criteria for the standard calibration curve and the independent calibration verification standard shall be documented.	-	-	-	-	-

QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
ii. Instrument calibration/standardization shall be verified each 24-hour period of use, or at each instrument start-up if the instrument is restarted during the 24-hour period, by analysis of a continuing calibration verification standard. Acceptance criteria shall be documented.	-	-	-	-	-
iii. Calibration or working quantification ranges shall encompass the concentrations reported by the laboratory. Continuing calibration verification standards and continuing calibration blanks shall be analyzed in accordance with the specified test methods. Acceptance criteria shall be documented.	-	-	-	-	-
d. Assuring the Quality of Test Results.	-	-	-	-	-
i. The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.	-	-	-	-	-
ii. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.	-	-	-	-	-
iii. This monitoring shall be planned and reviewed and may include, but not be limited to, the following: a) regular use of certified reference materials and/or internal quality control using secondary reference materials; b) participation in interlaboratory comparison or proficiency-testing programs; c) replicate tests or calibrations using the same or different methods; d) retesting or recalibration of retained items; e) correlation of results for different characteristics of an item.	-	-	-	-	-
iv. Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from occurring.	-	-	-	-	-
v. The laboratory shall determine, where feasible, the accuracy and precision of all analyses performed.	-	-	-	-	-
vi. Acceptance limits for each method shall be established based on statistical evaluation of the data generated by the analysis of quality control check samples, unless specific acceptance limits are established by the method.	-	-	-	-	-
vii. Control charts or quality control databases shall be used to record quality control data and compare them with acceptance limits.	-	-	-	-	-
viii. Procedures shall be used to monitor trends and the validity of test results.	-	-	-	-	-
28. Proficiency.	-	-	-	-	-
i. Participation in approved PT programs for each field of testing.	-	-	-	-	-
ii. Passing PT results for two consecutive PTs	-	-	-	-	-
iii. Documentation of investigation for all failed PTs	-	-	-	-	-
29. Method validation: Scientifically valid testing methodology: ~~Either~~ AHP monograph compliant, other third-party validation; **or** the current version of a standard method. The following requirements are applied to other third-party validation:	-	-	-	-	-
~~30. Level II validation of methodology used for quantification of THC, THCA and CBD for total cannabinoid content (if reporting other cannabinoids, the method must also be validated for those compounds):~~	-	-	-	-	-
~~a. Single lab validation parameters are demonstrated for GC, HPLC data review:~~	-	-	-	-	-
~~i. Linearity of reference standards;~~	-	-	-	-	-
~~ii. Use of daily standard curve;~~	-	-	-	-	-
~~iii. Accuracy;~~	-	-	-	-	-
~~iv. Precision;~~	-	-	-	-	-

QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
~~v. Recovery (5 determinations not less than 90%);~~	-	-	-	-	-
~~vi. Reproducibility over time within a relative standard deviation of 5%.~~	-	-	-	-	-
~~b. Dynamic range of the instrumentation: Limits of quantification (LOQ) and limits of detection (LOD).~~	-	-	-	-	-
a. The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use.	-	-	-	-	-
b. The validation shall be as extensive as is necessary to meet the needs of a given application or field of application	-	-	-	-	-
c. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.	-	-	-	-	-
d. The customer shall be informed as to the method chosen.	-	-	-	-	-
e. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.	-	-	-	-	-
f. Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	-	-	-	-	-
g. Validation shall be documented and include the following elements as applicable: i. minimum acceptance criteria i. analyte specificity ii. linearity iii. range iv. accuracy v. precision vi. detection limit vii. quantification limit viii. stability of samples and reagents interlaboratory precision ix. analysis robustness x. presence of QC samples xi. use of appropriate internal reference standard xii. daily monitoring of the response of the instrument	-	-	-	-	-
~~c.~~h. Validation shall be performed for ~~M~~matrix extensions for each type of product tested, including data review of recovery for:	-	-	-	-	-
i. Solvent-based extract;	-	-	-	-	-
ii. CO_2 extraction or other "hash oil";	-	-	-	-	-
iii. Extract made with food grade ethanol;	-	-	-	-	-
iv. Extract made with food grade glycerin or propylene glycol;	-	-	-	-	-
v. Infused liquids;	-	-	-	-	-
vi. Infused solids;	-	-	-	-	-
vii. Infused topical preparations;	-	-	-	-	-
viii. Other oils, butter or fats.	-	-	-	-	-
~~d. Presence of QC samples and recording of daily testing.~~	-	-	-	-	-
~~e. Appropriate use of an internal reference standard.~~	-	-	-	-	-
~~f. Daily monitoring of the response of the instrument detection system.~~	-	-	-	-	-
30. Estimation of Uncertainty of Measurement.	-	-	-	-	-

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QA PROGRAM AND TESTING		Document Reference	Y	N	NA	Comments
a.	Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. The laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.	-	-	-	-	-
b.	In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions	-	-	-	-	-
c.	When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.	-	-	-	-	-
d.	Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.	-	-	-	-	-
e.	Test methods are classified as either qualitative or quantitative. Qualitative tests are defined as having non-numerical results. Although estimation of measurement uncertainty is not needed for these tests, laboratories are expected to have an understanding of the contributors to variability of the results. For quantitative tests, laboratories shall determine measurement uncertainty using appropriate statistical techniques.	-	-	-	-	-
f.	Laboratories shall make independent estimations of uncertainty for tests performed on samples with significantly different matrices.	-	-	-	-	-
g.	Laboratories are required to re-estimate measurement uncertainty when changes to their operations are made that may affect sources of uncertainty.	-	-	-	-	-
h.	When reporting measurement uncertainty, the test report shall include the coverage factor and confidence level used in the estimations (typically k = approximately 2 at the 95% confidence level).	-	-	-	-	-
31.	Other methods.	-	-	-	-	-
a.	Validated ~~M~~microbiological methods fit for purpose.	-	-	-	-	-
b.	Microbial contaminants within limits ~~of those listed in the most recent AHP monograph and otherwise~~ as directed by WSLCB.	-	-	-	-	-
c.	Moisture content testing fit for purpose. Scientifically valid testing methodology: ~~Either~~ AHP monograph compliant, or other third-party validation.	-	-	-	-	-
d.	Solvent residuals testing fit for purpose; solvent extracted products made with class 3 or other solvents used are not to exceed 500 parts per million (PPM) per one gram of solvent based product and are to be tested.	-	-	-	-	-
e.	Any other QA/QC methods is proven to be fit for purpose.	-	-	-	-	-
32.	Laboratory ~~notebooks~~records.	-	-	-	-	-
a.	Legible and in ink (or computerized system).	-	-	-	-	-
b.	Signed and dated.	-	-	-	-	-
c.	Changes initialed and dated.	-	-	-	-	-
d.	~~Periodically reviewed~~Evidence of periodic review and signed by a management representative.	-	-	-	-	-
33.	Preventive/corrective action.	-	-	-	-	-

	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
	The laboratory shall ~~have a process in place to document quality affecting preventive/corrective actions through resolution~~ establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations are identified.	-	-	-	-	-
a.	The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.	-	-	-	-	-
b.	Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.	-	-	-	-	-
c.	The laboratory shall document and implement any required changes resulting from corrective action investigations.	-	-	-	-	-
d.	Any PT round that leads to the non-proficient status of a laboratory shall be addressed by the corrective action process.	-	-	-	-	-
e.	The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.	-	-	-	-	-
f.	When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.	-	-	-	-	-
34.	Complaints.	-	-	-	-	-
a.	The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties.	-	-	-	-	-
b.	Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.	-	-	-	-	-
c.	Test Reports	-	-	-	-	-
d.	Each test report or calibration certificate shall include at least the following information, unless otherwise justified:	-	-	-	-	-
i.	A title (e.g., "Test Report" or "Calibration Certificate");	-	-	-	-	-
ii.	The name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;	-	-	-	-	-
iii.	Unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;	-	-	-	-	-
iv.	The name and address of the customer;	-	-	-	-	-
v.	Identification of the method used;	-	-	-	-	-
vi.	A description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;	-	-	-	-	-
vii.	The date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;	-	-	-	-	-
viii.	Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;	-	-	-	-	-
ix.	The test or calibration results with, where appropriate, the units of measurement;	-	-	-	-	-
x.	The name(s), function(s) and signature(s) or equivalent identification of Person(s) authorizing the test report or calibration certificate; and	-	-	-	-	-
xi.	Where relevant, a statement to the effect that the results relate only to the items tested or calibrated.	-	-	-	-	-

QA PROGRAM AND TESTING		Document Reference	Y	N	NA	Comments
34.	Periodic management review and internal audit.	-	-	-	-	-
a.	Laboratory management shall ~~periodically~~ annually review its quality system and associated procedures to evaluate continued adequacy. This review shall be documented.	-	-	-	-	-
b.	Periodically and in accordance with a predetermined schedule perform an internal audit of laboratory operations to verify compliance to the GLP checklist	-	-	-	-	-

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[Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 16-11-110, § 314-55-103, filed 5/18/16, effective 6/18/16; WSR 15-11-107, § 314-55-103, filed 5/20/15, effective 6/20/15.]

Washington State
Liquor and Cannabis Board

Date: November 30, 2016

To: Jane Rushford, Board Chair
Ollie Garrett, Board Member

From: Joanna Eide, Policy and Rules Coordinator

Copy: Rick Garza, Agency Director
Peter Antolin, Deputy Director
Justin Nordhorn, Chief of Enforcement
Becky Smith, Licensing Director
Karen McCall, Agency Rules Coordinator
Peter Corier, Marijuana Examiners Unit

Subject: **Approval to file Emergency Rules to create laboratory proficiency testing requirements and suspension/revocation of laboratory certification.**

Emergency rules are needed to protect consumer safety through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. Creating proficiency testing requirements to achieve and maintain certification and parameters for laboratories will promote accuracy and accountability in marijuana testing by certified laboratories. Additionally, current permanent rules provide how a laboratory may be certified by the WSLCB, but do not contain provisions on what a laboratory must do to remain certified or how the WSLCB may suspend or revoke the certification of a laboratory. WSLCB needs the authority to suspend or revoke the certification of a laboratory that does not follow rule requirements for testing or for those laboratories that do not consistently achieve accurate testing results.

The emergency rules are necessary for the preservation of the public health, safety, and general welfare. Staff is requesting the refiling of emergency rules on this subject previously adopted by the board while permanent rulemaking is underway.
The rule becomes effective upon filing with the Code Reviser's Office and will expire 120 days after filing or until such time as permanent rules become effective, whichever comes first. Existing emergency rules on this subject expire December 7, 2016. If the Board approves the refiling of emergency rules today, the emergency rules will be filed on December 7, 2016, to maintain the requirements previously adopted and as adjusted in this version of rules.

Process

The Rules Coordinator requests approval to file the Emergency Rules described above. An issue paper on these rule was presented at the Board meeting on November 30, 2016, and is attached to this order.

If approved for filing, the tentative timeline for the rule making process is outlined below:

November 30, 2016	Board is asked to approve filing the Emergency Rules
December 7, 2016	The Emergency Rules become effective
April 6, 2016	The Emergency Rules expire*

*The emergency rules will expire once permanent rules on this subject become effective.

_____ Approve _____ Disapprove _____ _____
Jane Rushford, Chair Date

_____ Approve _____ Disapprove _____ _____
Ollie Garrett, Board Member Date

Attachment: Issue Paper

Washington State Liquor and Cannabis Board

Issue Paper

Emergency Rules for Laboratory Proficiency Testing and Certification Suspension and Revocation.

Date: November 30, 2016

Presented by: Joanna Eide, Policy and Rules Coordinator

Description of the Issue

The purpose of this Issue Paper is to request approval from the Board to refile emergency rules related to laboratory proficiency testing requirements and laboratory certification suspension and revocation.

Why is rule making necessary?

Emergency rules are needed to protect consumer safety through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. Creating proficiency testing requirements to achieve and maintain certification and parameters for laboratories will promote accuracy and accountability in marijuana testing by certified laboratories. Additionally, current permanent rules provide how a laboratory may be certified by the WSLCB, but do not contain provisions on what a laboratory must do to remain certified or how the WSLCB may suspend or revoke the certification of a laboratory. WSLCB needs the authority to suspend or revoke the certification of a laboratory that does not follow rule requirements for testing or for those laboratories that do not consistently achieve accurate testing results.

Process

The emergency rules are necessary for the preservation of the public health, safety, and general welfare. The rule becomes effective upon filing with the Code Reviser's Office and will expire 120 days after filing. This emergency rule filing is a refiling of previously adopted emergency rules on this subject (August 10, 2016). Minor adjustments were made since the last filing of these rules based on feedback from certified labs, WSLCB's certifying vendor, and partner agencies. Permanent rulemaking for these rules is currently underway and these emergency rules are to maintain requirements until permanent rules take effect.

What are the changes?

New Section. WAC 314-55-1025 Proficiency testing.

The emergency rule creates requirements for proficiency testing for laboratories seeking certification, and for certified laboratories to maintain certification. The rule requires that laboratories may only use proficiency testing programs that are approved by the WSLCB or WSLCB's vendor. Laboratories seeking certification must complete one successful round of proficiency testing and provide proof of the successful completion prior to receiving certification, and certified laboratories must complete a minimum of two successful rounds of proficiency

testing for each field of testing per year to maintain certification. This rule draft was adjusted since the last filing to define what a passing result for PT testing is. The rule also provides requirements for laboratories that fail proficiency testing, as well as the ability of WSLCB to suspend a certification should the laboratory fail to successfully complete proficiency testing. Lastly, the rules detail an avenue for laboratories to remediate if the laboratory fails proficiency testing so that the laboratory's suspended certification may be reinstated.

New Section. WAC 314-55-1035 Laboratory certification – Suspension and revocation.

The emergency rule provides the ways in which the WSLCB may suspend or revoke the certification of laboratories that do not follow rule requirements for laboratories or testing of marijuana. The rule provides two separate levels of suspensions:

1. A summary suspension or revocation applying to more egregious and substantial violations, and
2. A graduated suspension and revocation approach for less serious violations.

The language also references suspensions for failing proficiency testing requirements under proposed WAC 314-55-1025. Lastly, the rule recognizes the right of a laboratory that receives a suspension or revocation to receive an administrative hearing if they choose under the provisions of the Administrative Procedure Act (Chapter 34.05 RCW).

NEW SECTION

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

(2) The WSLCB or its vendor determines the sufficiency of PTs and maintains a list of approved PT programs. Laboratories may request authorization to conduct PT through other PT programs but must obtain approval for the PT program from WSLCB or WSLCB's vendor prior to conducting PT. The WSLCB may add the newly approved PT program to the list of approved PT programs as appropriate.

(3) As a condition of certification, laboratories must participate in PT and achieve a passing score for each field of testing for which the lab will be or is certified.

(4) A laboratory must successfully complete a minimum of one round of PT for each field of testing the lab seeks to be certified for and provide proof of the successful PT results prior to initial certification.

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

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

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

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

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

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

(8) Laboratories are responsible for obtaining PT samples from vendors approved by WSLCB or WSLCB's vendor. Laboratories are responsible for all costs associated with obtaining PT samples and rounds of PT.

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

(10) The laboratory must authorize the PT provider to release all results used for certification and/or remediation of failed studies to WSLCB or WSLCB's vendor.

(11) The WSLCB may require the laboratory to submit raw data and all photographs of plated materials along with the report of analysis of PT samples. The laboratory must keep and maintain all raw data and all photographs of plated materials from PT for a period of three years.

(12) The WSLCB may waive proficiency tests for certain fields of testing if PT samples or PT programs are not readily available or for other valid reasons as determined by WSLCB.

(13)(a) The WSLCB will suspend a laboratory's certification if the laboratory fails to maintain a passing score on an ongoing basis in two out of three successive PT studies. The WSLCB may reinstate a laboratory's suspended certification if the laboratory successfully analyzes PT samples from a WSLCB or WSLCB's vendor approved PT provider, so long as the supplemental PT studies are performed at least fifteen days apart from the analysis date of one PT study to the analysis date of another PT study.

(b) The WSLCB will suspend a laboratory's certification if the laboratory fails two consecutive rounds of PT. WSLCB may reinstate a laboratory's suspended certification once the laboratory conducts an investigation, provides the WSLCB a deficiency report identifying the root cause of the failed PT, and successfully analyzes PT samples from a WSLCB or WSLCB'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.

NEW SECTION

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:

(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 or the marijuana 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 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.

(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.

(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.