RULE-MAKING ORDER

CR-103E (May 2009)
(Implements RCW 34.05.360)

Agency: Washington State Liquor and Cannabis Board

Emergency Rule Only

Effective date of rule:
Emergency Rules
☒ Immediately upon filing.
☐ Later (specify) _____

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?
☐ Yes ☒ No If Yes, explain:

Purpose: New rules are needed to protect consumer safety through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. WSLCB also needs rules 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. This is a refiling of these emergency rules to maintain requirements until permanent rules take effect.

Citation of existing rules affected by this order:
Repealed:
Amended:
Suspended:

Statutory authority for adoption: RCW 69.50.342 and 69.50.345

Other authority :

EMERGENCY RULE
Under RCW 34.05.350 the agency for good cause finds:
☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.
☐ That in order to implement the requirements or reductions in appropriations enacted in any budget for fiscal years 2009, 2010, or 2011, which necessitates the need for the immediate adoption, amendment, or repeal of a rule, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the fiscal needs or requirements of the agency.

Reasons for this finding: Marijuana and marijuana products sold in WSLCB licensed retail stores are a consumable product and it is important that they are safe for human consumption. These emergency rules relating to accurate testing procedures and results and laboratory accountability are needed to ensure the public health, and safety of the citizens of Washington. Permanent rulemaking is currently underway for these rules.

Date adopted: December 7, 2016

NAME (TYPE OR PRINT)
Jane Rushford

SIGNATURE

TITLE
Chair

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: December 07, 2016
TIME: 10:50 AM

WSR 16-24-093

(COMPLETE REVERSE SIDE)

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New _____ Amended _____ Repealed _____

The number of sections adopted in the agency's own initiative:

New 2 Amended _____ Repealed _____

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New _____ Amended _____ Repealed _____

The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	_____	Repealed	_____

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.