

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 received 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;

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

(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.

[Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 17-12-032, § 314-55-0995, filed 5/31/17, effective 8/31/17.]