

WAC 314-55-1025 Proficiency testing. (1) For the purposes of this chapter, the following definitions apply:

(a) "Field of testing" means the categories of subject matter the laboratory tests, such as pesticide, microbial, potency, residual solvent, heavy metal, mycotoxin, foreign matter, and moisture content detection.

(b) "Proficiency testing (PT)" means the analysis of samples by a laboratory obtained from providers where the composition of the sample is unknown to the laboratory performing the analysis and the results of the analysis are used in part to evaluate the laboratory's ability to produce precise and accurate results.

(c) "Proficiency testing (PT) program" means an operation offered by a provider to detect a laboratory's ability to produce valid results for a given field of testing.

(d) "Provider" means a third-party company, organization, or entity not associated with certified laboratories or a laboratory seeking certification that operates an approved PT program and provides samples for use in PT testing.

(e) "Vendor" means an organization(s) approved by the board to certify laboratories for cannabis testing, approve PT programs, and perform on-site assessments of laboratories.

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

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

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

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

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

(6) If the laboratory fails to achieve a passing score on at least 80 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 80 percent of the analytes. If the PT provider does not provide individual acceptance criteria for each analyte, the following criteria will be applied to determine whether the lab achieves a passing score for the round of PT:

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

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

(7) If a laboratory fails a round of PT or reports a false negative on a micro PT, the laboratory must investigate the root cause of

the laboratory's performance and establish a corrective action report for each unsatisfactory analytical result. The corrective action report must be kept and maintained by the laboratory for a period of three years, available for review during an on-site assessment or inspection, and provided to the board or the board's vendor upon request.

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

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

(10) The laboratory must authorize the PT provider to release all results at the same time, whether pass or fail, to the laboratory and the board, or the board's vendor.

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

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

(13)(a) The board will suspend a laboratory's certification if the laboratory fails to maintain a passing score on an ongoing basis in two out of three successive PT studies. The board may reinstate a laboratory's suspended certification if the laboratory successfully analyzes PT samples from the board or the board's vendor approved PT provider, so long as the supplemental PT studies are performed at least 15 days apart from the analysis date of one PT study to the analysis date of another PT study.

(b) The board will suspend a laboratory's certification if the laboratory fails two consecutive rounds of PT. The board may reinstate a laboratory's suspended certification once the laboratory conducts an investigation, provides the board a deficiency report identifying the root cause of the failed PT, and successfully analyzes PT samples from a board or board's vendor approved PT provider. The supplemental PT studies must be performed at least 15 days apart from the analysis date of one PT study to the analysis date of another PT study.

(14) If a laboratory fails to remediate and have its certification reinstated under subsection (13)(a) or (b) of this section within six months of the suspension, the laboratory must reapply for certification as if the laboratory was never certified previously.

(15) A laboratory that has its certification suspended or revoked under this section may request an administrative hearing to contest the suspension as provided in chapter 34.05 RCW.

[Statutory Authority: RCW 69.50.342 and 2022 c 16 § 168. WSR 22-14-111, § 314-55-1025, filed 7/6/22, effective 8/6/22. Statutory Authority: RCW 69.50.345 and 69.50.348. WSR 22-06-097, § 314-55-1025, filed 3/2/22, effective 4/2/22. Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 17-12-032, § 314-55-1025, filed 5/31/17, effective 8/31/17.]