

WAC 246-338-050 Proficiency testing. (1) All licensed medical test sites, excluding those granted a certificate of waiver, must:

(a) Comply with federal proficiency testing requirements listed in 42 C.F.R. Part 493 - Laboratory Requirements, Subparts H and I;

(b) Submit to the department a copy of proficiency testing enrollment confirmation form(s) for the tests the medical test site will perform during the following calendar year, by December 31st of each year; and

(c) Authorize the proficiency testing program to release to the department all data required to determine the medical test site's compliance with this section.

(2) The department will:

(a) Recognize only those proficiency testing programs approved by HHS; and

(b) Furnish, upon request:

(i) A copy of 42 C.F.R. Part 493 Subparts H and I;

(ii) A list of the proficiency testing programs approved by HHS; and

(iii) A list of tests that must be covered by proficiency testing.

(3) The department will evaluate proficiency testing results by using the following criteria:

(a) An evaluation of scores for the last three testing events of proficiency testing samples including:

(i) Tests;

(ii) Subspecialties; and

(iii) Specialties;

(b) Maintenance of a minimum acceptable score of 80 percent for all tests, subspecialties, and specialties except 100 percent for:

(i) ABO grouping and Rh typing;

(ii) Compatibility testing;

(iii) Antihuman immunodeficiency virus; and

(iv) Unexpected antibody detection;

(c) Unsatisfactory performance occurs when:

(i) Unsatisfactory scores are obtained in any specialty or subspecialty in a testing event; or

(ii) An unsatisfactory score is obtained on a single test in a testing event.

(4) Unsatisfactory performance on two of any three successive testing events is considered unsuccessful participation, and will result in the following actions:

(a) The department will mail a letter to the director stating that the medical test site may choose to:

(i) Discontinue patient testing for the identified test, specialty or subspecialty; or

(ii) Follow a directed plan of correction; and

(b) The medical test site must notify the department, within 15 days of receipt of the notice of the decision to:

(i) Discontinue testing patient specimens for the identified test, subspecialty or specialty; or

(ii) Agree to a directed plan of correction.

(5) Continued unsatisfactory performance for a test, specialty or subspecialty in either of the next two consecutive sets of proficiency testing samples, after completing a directed plan of correction, will result in the following action:

(a) The department will send, by certified mail, a notice to the owner and director of the medical test site to cease performing the identified test, subspecialty, or specialty; and

(b) The owner must notify the department in writing within 15 days of the receipt of the notice of the decision to voluntarily stop performing tests on patient specimens for the identified test, subspecialty, or specialty.

(6) The owner may petition the department for reinstatement of approval to perform tests on patient specimens after demonstrating satisfactory performance on two successive testing events of proficiency testing samples for the identified test, subspecialty, or specialty.

(7) The department will notify the owner in writing, within 15 days of receipt of petition, of the decision related to the request for reinstatement.

[Statutory Authority: RCW 70.42.220. WSR 25-02-002, s 246-338-050, filed 12/18/24, effective 12/28/24. Statutory Authority: RCW 70.42.005 and 42 C.F.R. Part 493. WSR 05-04-040, § 246-338-050, filed 1/27/05, effective 3/19/05. Statutory Authority: RCW 70.42.005, 70.42.060 and chapter 70.42 RCW. WSR 00-06-079, § 246-338-050, filed 3/1/00, effective 4/1/00. Statutory Authority: Chapter 70.42 RCW. WSR 94-17-099, § 246-338-050, filed 8/17/94, effective 9/17/94; WSR 93-18-091 (Order 390), § 246-338-050, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-050, filed 10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-050, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-050, filed 9/21/90, effective 10/22/90.]