

WAC 246-338-080 Quality assurance. Each medical test site performing moderate complexity (including PPMP) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program. The quality assurance program must be designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The medical test site's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable, and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the medical test site must revise policies and procedures based upon the results of those evaluations. The medical test site must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

(1) The medical test site must establish and implement a written quality assurance plan, including policies and procedures, designed to:

(a) Monitor, evaluate, and review quality control data, proficiency testing results, and test results, including biannual verification of:

(i) Accuracy of test results for:

(A) Tests that are not covered by proficiency testing;

(B) Tests that are covered by proficiency testing but have unsatisfactory scores, are not scored by the proficiency testing program, or where scoring does not reflect actual test performance (e.g., the proficiency testing program does not obtain the agreement required for scoring); and

(ii) Relationship between test results when the medical test site performs the same test on different instruments or at different locations within the medical test site;

(b) Identify and correct problems;

(c) Establish and maintain accurate, reliable, and prompt reporting of test results;

(d) Verify all tests performed and reported by the medical test site conform to specified performance criteria in quality control under WAC 246-338-090;

(e) Establish and maintain the adequacy and competency of the technical personnel; and

(f) Establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

(2) The quality assurance plan must include mechanisms or systems to:

(a) Establish and apply criteria for specimen acceptance and rejection;

(b) Notify the appropriate individuals as soon as possible when test results indicate potential life-threatening conditions;

(c) Assess problems identified during quality assurance reviews and discuss them with the appropriate staff;

(d) Evaluate all test reporting systems to verify accurate and reliable reporting, transmittal, storage, and retrieval of data;

(e) Document all action taken to identify and correct problems or potential problems;

(f) Issue corrected reports when indicated;

- (g) Provide appropriate instructions for specimen collection, handling, preservation, and transportation;
 - (h) Ensure that specimens are properly labeled, including patient name or unique patient identifier and, when appropriate, specimen source;
 - (i) Ensure confidentiality of patient information throughout all phases of the testing process; and
 - (j) Provide clients updates of testing changes that would affect test results or the interpretation of test results.
- (3) The medical test site must establish criteria for and maintain appropriate documentation of any remedial action taken in response to quality control, quality assurance, personnel, proficiency testing, and transfusion reaction investigations.
- (4) When results of control or calibration materials fail to meet the established criteria for acceptability, the medical test site must have a system in place to determine if patient test results have been adversely affected. The system must include:
- (a) A review of all patient test results obtained in the unacceptable test run; and
 - (b) A review of all patient test results since the last acceptable test run.
- (5) The medical test site must have a system in place to assure:
- (a) All complaints and problems reported to the medical test site are documented and investigated when appropriate; and
 - (b) Corrective actions are instituted as necessary.
- (6) The owner must:
- (a) Maintain adequate space, facilities, and essential utilities for the performance and reporting of tests;
 - (b) Ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized;
 - (c) Ensure that molecular amplification procedures that are not contained in closed systems have a unidirectional workflow. This must include separate areas for specimen preparation, amplification and production detection, and as applicable, reagent preparation;
 - (d) Ensure the laboratory has appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs;
 - (e) Establish, make accessible, and observe safety precautions to ensure protection from physical, chemical, biochemical, and electrical hazards and biohazards; and
 - (f) Establish and implement policies and procedures for infectious and hazardous medical wastes consistent with local, state, and federal authorities.
- (7) Information that must be available to authorized persons ordering or utilizing the test results includes:
- (a) A list of test methods, including performance specifications;
 - (b) Reference ranges; and
 - (c) Test method limitations.
- (8) If the medical test site refers specimens to another site for testing, the site to which specimens are referred must have a valid medical test site license or meet equivalent requirements as determined by CMS.

[Statutory Authority: RCW 70.42.220. WSR 25-02-002, s 246-338-080, 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, § 246-338-080, 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, § 246-338-080, filed 3/1/00, effective 4/1/00. Statutory Authority: Chapter 70.42 RCW. WSR 93-18-091 (Order 390), § 246-338-080, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-080, filed 10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-080, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-080, filed 9/21/90, effective 10/22/90.]