EXPEDITED RULE MAKING

CR-105 (June 2024)
(Implements RCW 34.05.353)

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STATE OF WASHINGTON
FILED

DATE: September 29, 2024
TIME: 6:00 PM

WSR 24-20-089

Agency: Department of Health

Title of rule and other identifying information: (describe subject) Medical Test Site (MTS) Federal rule compliance updates. The Department of Health (department) is proposing amendments to sections WAC 246-338-022, 246-338-040, 246-338-050, 246-338-060, 246-338-070, 246-338-080, and 246-338-090 to incorporate existing minimum standards that are missing, make technical corrections to rules, and adopt new federal requirements.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The MTS program must have minimum standards in place that are at least as stringent as federal requirements, therefore, amendments are proposed based on the following three justifications: existing federal standards are missing in chapter 246-338 WAC and must be included, technical corrections to the chapter are needed for clarity, and new federal rules have been introduced that go into effect in 2024.

The department is proposing amendments to add missing existing federal standards to WAC 246-338-022 to specify when a hospital may file a single MTS application, WAC 246-338-080 to add additional quality assurance requirements for medical test sites, and WAC 246-338-090 to add quality control requirements for retention of transfused blood.

The department is proposing technical corrections to WAC 246-338-040 to update and alphabetize the list of approved laboratory accrediting organizations, WAC 246-338-070 to clarify that narrative description nomenclature on cytology reports is required for all results, and WAC 246-338-090 to correct the term gynecological smears to gynecological slide preparations.

New federal rule requirements going into effect in 2024 require an amendment to WAC 246-338-050 to raise the minimum passing score for proficiency testing for unexpected antibody detection from 80 percent to 100 percent, and WAC 246-338-060 to describe new requirements for MTS directors to perform on-site visits of the licensed medical test site at a specified frequency and interval.

Reasons supporting proposal: Clinical Laboratory Improvement Amendments (CLIA) provides federal standards that are applicable to all U.S. facilities or sites that test human specimens for health assessment to diagnose, prevent, or treat disease. Washington is CLIA-exempt, meaning that all laboratories in the state, called medical test sites, must obtain an MTS license instead of a federal CLIA license to perform medical tests. Washington receives approval from CLIA to enforce federal rules for medical test sites. The MTS program must comply with federal requirements described in 42 CFR Part 493 to maintain the exemption from CLIA. Adding the missing minimum standards requirements, making technical corrections, and adding new federal standards will align chapter 246-338 WAC with the federal requirements.

Statutory authority for adoption: RCW 70.42.220

Statute being implemented: Chapter 70.42 RCW

Is rule necessary because of a:

Federal Law?	☒ Yes	☐ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION: 42 CFR Parts 493.35(b), 493.43(b), 493.55(b), 493.861(a), 493.1407(c) effective 12/28/2024, 493.1445(c) effective 12/28/2024, 493.1274(e)(5), 493.1101(a)(2), 493.1101(b), 493.1274(b)(1), 493.1271(d), and Federal Register publication numbers CMS-3422-N, CMS-3436-N, CMS-3449-N, and CMS-3450-N.

Name of proponent: (person or organization) Department of Health

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
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Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☒ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☒ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

☐ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☐ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): New federal requirements for laboratory directors and proficiency testing begin in 2024. The additions and technical corrections to chapter 246-338 WAC are currently existing federal requirements that must be adopted to allow immediate enforcement.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

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BEGINNING (date/time) The date and time of this filing **AND RECEIVED BY** (date/time) December 2, 2024 at 11:59 pm

Date: September 24, 2024 **Name:** Kristin Peterson, JD for Umair A. Shah, MD, MPH **Title:** Chief of Policy for Secretary of Health	**Signature:** 

AMENDATORY SECTION (Amending WSR 06-15-132, filed 7/19/06, effective 8/19/06)

WAC 246-338-022 Initial application for medical test site license. (1) **Application procedure.**

Applicants requesting a medical test site license must:

(a) Submit a completed application on forms furnished by the department, signed by the owner or authorized representative;

(b) File a separate application for each test site **except** under the following conditions:

(i) If the test site is not at a fixed location and moves from testing site to testing site, or uses a temporary testing location such as a health fair, the medical test site may apply for a single license for the home base location;

(ii) If the medical test site is a not-for-profit or state or local government and performs a combination of ((~~fifteen~~)) 15 or less of either waived or moderate complexity test procedures at different locations, the owner may file an application for a single license;

(iii) If the medical test sites within a hospital are located at contiguous buildings on the same campus and are under common direction, the owner may file a single application or multiple applications for the sites within the same physical location or street address;

(c) Furnish full and complete information to the department in writing:

(i) Name, address, phone number, and federal tax ID number of the medical test site;

(ii) Name of owner;

(iii) Number and types of tests performed, planned, or projected;

(iv) Name and qualifications including educational background, training, and experience of the director;

(v) Names and qualifications including educational background, training, and experience of technical personnel, if requested by the department;

(vi) Name of proficiency testing program or programs used by the medical test site and a copy of the enrollment confirmation form, if applicable;

(vii) Methodologies for tests performed, if requested by the department; and

(viii) Other information as requested by the department;

(d) Submit the designated fee in the time period indicated, upon receipt of a fee statement from the department;

(e) If applying for an accredited license, submit proof of accreditation by an approved accreditation organization. If application has been made to an accreditation organization, submit a copy of the application, followed by proof of accreditation within ((~~eleven~~)) 11 months of issuance of the medical test site license.

(2) **Issuing an initial license.**

(a) An initial license will be issued for a medical test site when the applicant:

(i) Submits a completed application and any information requested by the department;

(ii) Pays the designated license fee; and

(iii) Meets the requirements of chapter 70.42 RCW and this chapter.

(b) License expiration dates will be based on a two-year licensure cycle, expiring on June 30th of odd-numbered years. The license

period for an initial license begins the day of the month that payment is received and expires on June 30th of odd-numbered years.

(c) For licenses issued for a period of less than two years, the license fee will be prorated for the remainder of the two-year cycle under WAC 246-338-990.

(d) The department may issue a provisional license valid for a period of up to two years when a medical test site applies for licensure for the first time.

(e) The department will terminate a provisional license at the time a two-year license for the medical test site is issued.

(f) License fees are listed under WAC 246-338-990.

AMENDATORY SECTION (Amending WSR 05-04-040, filed 1/27/05, effective 3/19/05)

WAC 246-338-040 Approval of accreditation organizations. (1) The department will recognize the accreditation organizations granted deemed status by CMS.

(2) The CMS-approved accreditation organizations are:

(a) ((~~American Association of Blood Banks (AABB)~~)) Accreditation Commission for Health Care (ACHC);

(b) ((~~American Osteopathic Association (AOA)~~)) American Association for Laboratory Accreditation (A2LA);

(c) American Society of Histocompatibility and Immunogenetics (ASHI);

(d) ((~~College of American Pathologists (CAP)~~)) Association for the Advancement of Blood and Biotherapies (AABB);

(e) COLA; ((~~and~~))

(f) ((~~Joint Commission on Accreditation of Healthcare Organizations (JCAHO)~~)) College of American Pathologists (CAP); and

(g) Joint Commission.

(3) The accreditation organizations must:

(a) Allow the department to have jurisdiction to investigate complaints, do random on-site validation inspections, and take disciplinary action against a medical test site if indicated;

(b) Notify the department within ((~~fifteen~~)) 15 days of any medical test site that:

(i) Has had its accreditation withdrawn, revoked, or limited;

(ii) Is sanctioned as a result of a routine inspection or complaint investigation; or

(iii) When adverse action has been taken for unsuccessful proficiency testing performance;

(c) Notify the department within five days of any deficiency that jeopardizes the public health, safety, or welfare; and

(d) Provide the department with a list of inspection schedules, as requested, for the purpose of conducting on-site validation inspections.

(4) The department will:

(a) Revoke deemed status from any organization which has deeming authority removed by CMS; and

(b) Notify the medical test site if approval of an accreditation organization is withdrawn by the department.

AMENDATORY SECTION (Amending WSR 05-04-040, filed 1/27/05, effective 3/19/05)

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 ((~~eighty~~)) 80 percent for all tests, subspecialties, and specialties except ((~~one hundred~~)) 100 percent for:

(i) ABO grouping and Rh typing;

(ii) Compatibility testing; ((~~and~~))

(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 ((~~fifteen~~)) 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 ((~~fifteen~~)) 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 ((~~fifteen~~)) 15 days of receipt of petition, of the decision related to the request for reinstatement.

AMENDATORY SECTION (Amending WSR 05-04-040, filed 1/27/05, effective 3/19/05)

WAC 246-338-060 Personnel. (1) Medical test site owners must:

(a) Have a director responsible for the overall technical supervision and management of the test site personnel including oversight of the performance of test procedures and reporting of test results;

(b) Have technical personnel, competent to perform tests and report test results; and

(c) Meet the standards for personnel qualifications and responsibilities in compliance with federal regulation, as listed in 42 C.F.R. Part 493 Subpart M - Personnel for Non-waived Testing.

(2) The department will furnish a copy of 42 C.F.R. Part 493 Subpart M upon request.

(3) Medical test site directors must:

(a) Establish and approve policies for:

(i) Performing, recording, and reporting of tests;

(ii) Maintaining an ongoing quality assurance program;

(iii) Supervision of testing; and

(iv) Compliance with chapter 70.42 RCW and this chapter;

(b) Evaluate, verify, and document the following related to technical personnel:

(i) Education, experience, and training in test performance and reporting test results;

(ii) Sufficient numbers to cover the scope and complexity of the services provided;

(iii) Access to training appropriate for the type and complexity of the test site services offered; and

(iv) Maintenance of competency to perform test procedures and report test results;

(c) Be present, on call, or delegate the duties of the director to an on-site technical person during testing;

(d) Conduct on-site visits at the licensed medical test site at least once every six months, with a minimum four-month interval be-

tween the mandatory on-site visits. On-site visits must be documented and include evidence of performing activities that are part of the lab director responsibilities.

AMENDATORY SECTION (Amending WSR 16-18-073, filed 9/2/16, effective 10/3/16)

WAC 246-338-070 Records. Medical test sites must maintain records as described in this section.

(1) REQUISITIONS must include the following information, in written or electronic form:

(a) Patient name, identification number, or other method of patient identification;

(b) Name and address or other suitable identifiers of the authorized person ordering the test. The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within ((~~thirty~~)) 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization;

(c) Date of specimen collection, and time, if appropriate;

(d) Source of specimen, if appropriate;

(e) Type of test ordered;

(f) Sex, and age or date of birth, of the patient; and

(g) For cytology and histopathology specimens:

(i) Pertinent clinical information; and

(ii) For Pap smears:

(A) Date of last menstrual period; and

(B) Indication whether the patient had a previous abnormal report, treatment, or biopsy.

(2) TEST RECORD SYSTEMS MUST:

(a) Consist of instrument printouts, worksheets, accession logs, corrective action logs, and other records that ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported; and

(b) Include:

(i) The patient's name or other method of specimen identification;

(ii) The date and time the specimen was received;

(iii) The reason for specimen rejection or limitation;

(iv) The date of specimen testing; and

(v) The identification of the personnel who performed the test.

(3) TEST REPORTS must:

(a) Be maintained in a manner permitting identification and reasonable accessibility;

(b) Except as provided in WAC 246-338-070 (3)(c) be released only to authorized persons or designees;

(c) Upon a request by a patient or patient's personal representative, the laboratory may provide patients, their personal representatives, and those persons specified under 45 C.F.R. 164.524 (c)(3)(ii), with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient;

(d) Include:

(i) Name and address of the medical test site, or where applicable, the name and address of each medical test site performing each test;

(ii) Patient's name and identification number, or a unique patient identifier and identification number;

(iii) Date reported;

(iv) Time reported, if appropriate;

(v) Specimen source, when appropriate, and any information regarding specimen rejection or limitation; and

(vi) Name of the test performed, test result, and units of measurement, if applicable.

(4) CYTOLOGY REPORTS must:

(a) Distinguish between unsatisfactory specimens and negative results;

(b) Provide narrative ((~~descriptions for any abnormal~~)) descriptive nomenclature for all results, using a recognized system of disease nomenclature such as the ((~~2001~~)) Bethesda System ((~~of terminology as published in the *Journal of the American Medical Association*, 2002, Volume 287, pages 2114-2119~~)); and

(c) Include the signature or initials of the technical supervisor, or an electronic signature authorized by the technical supervisor, for nongynecological preparations and gynecological preparations interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial neoplasia lesions including human papillomavirus-associated changes) or malignant category.

(5) HISTOPATHOLOGY REPORTS must include the signature or initials of the technical supervisor or an electronic signature authorized by the technical supervisor on all reports. Reports must be signed by the same qualified individual who performs the diagnostic interpretation and evaluation, and must utilize appropriate terminology such as the SnoMed system.

(6) CYTOGENETICS REPORTS must:

(a) Use the International System for Human Cytogenetic Nomenclature on final reports;

(b) Include the number of cells counted and analyzed; and

(c) Include a summary and interpretation of the observations.

(7) If a specimen is referred to another laboratory for testing, the medical test site must:

(a) Report the essential elements of the referred test results without alterations that could affect the clinical interpretation of the results; and

(b) Retain or be able to produce an exact duplicate of each testing report from the referral laboratory.

(8) The medical test site must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

(9) If the medical test site ceases operation, it must make provisions to ensure that all records and, as applicable, slides, blocks and tissue are retained and available for the time frames specified in Table 070-1.

Table 070-1 Record/Slide/Tissue Retention Schedule

		Two Years	Five Years	Ten Years
(a)	General Requirements for all Laboratory Specialties	• Test requisitions or equivalent; • Test records, including instrument printouts if applicable; • Test reports; • Quality control records; • Quality assurance records; • Proficiency testing records; • Hard copy of report, or ability to reproduce a copy, for all specimens referred for testing; and • Discontinued procedures for all specialty areas		
(b)	Transfusion Services		• Test requisitions or equivalent; • Test records; • Test reports; • Quality control records; and • Quality assurance records	• Individual product records*
(c)	Cytology		• All cytology slides, from date of examination of the slide	• All cytology reports
(d)	Histopathology/Oral Pathology	• Specimen blocks, from date of examination		• All histopathology and oral pathology • reports; and Stained slides, from date of examination of the slide
(e)	Histopathology/Oral Pathology-Tissues	Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic examination have been examined and diagnosed		
(f)	Instrument/method Validation Studies	For life of instrument/method plus two years		

* Must be retained for no less than ((~~ten~~)) 10 years in accordance with 21 C.F.R. 606.160 (7)(d).

AMENDATORY SECTION (Amending WSR 05-04-040, filed 1/27/05, effective 3/19/05)

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;

((~~(c)~~)) (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

((~~(d)~~)) (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.

AMENDATORY SECTION (Amending WSR 16-18-073, filed 9/2/16, effective 10/3/16)

WAC 246-338-090 Quality control. The medical test site must use quality control procedures, providing and assuring accurate and reliable test results and reports, meeting the requirements of this chapter.

(1) The medical test site must have and follow written procedures and policies available in the work area for:

(a) Analytical methods used by the technical personnel including:

(i) Principle;

(ii) Specimen collection and processing procedures;

(iii) Equipment/reagent/supplies required;

(iv) Preparation of solutions, reagents, and stains;

(v) Test methodology;

(vi) Quality control procedures;

(vii) Procedures for reporting results (normal, abnormal, and critical values);

(viii) Reference range;

(ix) Troubleshooting guidelines - limitations of methodology;

(x) Calibration procedures; and

(xi) Pertinent literature references; and

(b) Alternative or backup methods for performing tests including the use of a reference facility if applicable.

(2) The medical test site must establish written criteria for and maintain appropriate documentation of:

(a) Temperature-controlled spaces and equipment;

(b) Preventive maintenance activities;

(c) Equipment function checks;

(d) Procedure calibrations; and

(e) Method/instrument validation procedures.

(3) The medical test site must maintain documentation of:

(a) Expiration date, lot numbers, and other pertinent information for:

(i) Reagents;

(ii) Solutions;

(iii) Culture media;

(iv) Controls;

(v) Calibrators;

(vi) Standards;

(vii) Reference materials; and

(viii) Other testing materials; and

(b) Testing of quality control samples.

(4) For **quantitative tests**, the medical test site must perform quality control as follows:

(a) Include two reference materials of different concentrations each day of testing unknown samples, if these reference materials are available; or

(b) Follow an equivalent quality testing procedure that meets federal CLIA regulations.

(5) For **qualitative tests**, the medical test site must perform quality control as follows:

(a) Use positive and negative reference material each day of testing unknown samples; or

(b) Follow an equivalent quality testing procedure that meets federal CLIA regulations.

(6) The medical test site must:

(a) Use materials within their documented expiration date;

(b) Not interchange components of kits with different lot numbers, unless specified by the manufacturer;

(c) Determine the statistical limits for each lot number of unassayed reference materials through repeated testing;

(d) Use the manufacturer's reference material limits for assayed material, provided they are:

(i) Verified by the medical test site; and

(ii) Appropriate for the methods and instrument used by the medical test site;

(e) Make reference material limits readily available;

(f) Report patient results only when reference materials are within acceptable limits;

(g) Rotate control material testing among all persons who perform the test;

(h) Use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system, if using calibration material as a control material;

(i) For each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process;

(j) For each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition is required; and

(k) Comply with general quality control requirements as described in Table 090-1, unless otherwise specified in subsection (9)(a) through (l) of this section.

(7) The medical test site must perform, when applicable:

(a) Calibration and calibration verification for **moderate and high complexity testing** as described in Table 090-2;

(b) Validation for **moderate complexity testing** by verifying the following performance characteristics when the medical test site introduces a new procedure classified as moderate complexity:

(i) Accuracy;

(ii) Precision;

(iii) Reportable range of patient test results; and

(iv) If using the reference range provided by the manufacturer, that it is appropriate for the patient population;

(c) Validation for **high complexity testing:**

(i) When the medical test site introduces a new procedure classified as high complexity;

(ii) For each method that is developed in-house, is a modification of the manufacturer's test procedure, or is an instrument, kit or test system that has not been cleared by FDA; and

(iii) By verifying the following performance characteristics:

(A) Accuracy;

(B) Precision;

(C) Analytical sensitivity;

(D) Analytical specificity to include interfering substances;

(E) Reference ranges (normal values);

(F) Reportable range of patient test results; and

(G) Any other performance characteristic required for test performance.

(8) When patient values are above the maximum or below the minimum calibration point or the reportable range, the medical test site must:

(a) Report the patient results as greater than the upper limit or less than the lower limit or an equivalent designation; or

(b) Use an appropriate procedure to rerun the sample allowing results to fall within the established linear range.

Table 090-1 General Quality Control Requirements

		Control Material	Frequency
(a)	Each batch or shipment of reagents, discs, antisera, and identification systems	• Appropriate control materials for positive and negative reactivity	• When prepared or opened, unless otherwise specified
(b)	Each batch or shipment of stains	• Appropriate control materials for positive and negative reactivity	• When prepared or opened; and • Each day of use, unless otherwise specified
(c)	Fluorescent and immunohistochemical stains	• Appropriate control materials for positive and negative reactivity	• Each time of use, unless otherwise specified
(d)	Quality control for each specialty and subspecialty	• Appropriate control materials; or • Equivalent mechanism to assure the quality, accuracy, and precision of the test if reference materials are not available	• At least as frequently as specified in this section; • More frequently if recommended by the manufacturer of the instrument or test procedure; or • More frequently if specified by the medical test site
(e)	Direct antigen detection systems without procedural controls	• Positive and negative controls that evaluate both the extraction and reaction phase	• Each batch, shipment, and new lot number; and • Each day of use

Table 090-2 Calibration and Calibration Verification—Moderate and High Complexity Testing

	Calibration Material	Frequency
CALIBRATION	• Calibration materials appropriate for methodology	• Initial on-site installation/implementation of instrument/method; • At the frequency recommended by the manufacturer; and • Whenever calibration verification fails to meet the medical test site's acceptable limits for calibration verification.
CALIBRATION VERIFICATION	• Use assayed material, if available, at the lower, mid-point, and upper limits of procedure's reportable range; or • Demonstrate alternate method of assuring accuracy at the lower, mid-point, and upper limits of procedure's reportable range	• At least every six months; • When there is a complete change of reagents (i.e., new lot number or different manufacturer) is introduced; • When major preventive maintenance is performed or there is a replacement of critical parts of equipment; or • When controls are outside of the medical test site's acceptable limits or exhibit trends.

(9) The medical test site must perform quality control procedures as described for each specialty and subspecialty in (a) through (l) of this subsection.

(a) **Chemistry.**

Perform quality control procedures for chemistry as described in Table 090-3 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-3 Quality Control Procedures—Chemistry

Subspecialty/Test	Qualitative		Quantitative	
	Control Material	Frequency	Control Material	Frequency
Routine Chemistry	• Positive and negative reference material	• Each day of use	• Two levels of reference material in different concentrations	• Each day of use

Subspecialty/Test	Qualitative		Quantitative	
	Control Material	Frequency	Control Material	Frequency
Toxicology				
• GC/MS for drug screening	• Analyte-specific control	• With each run of patient specimens	• Analyte-specific control	• With each analytical run
• Urine drug screen	• Positive control containing at least one drug representative of each drug class to be reported; must go through each phase of use including extraction	• With each run of patient specimens		
Urinalysis				
• Nonwaived instrument			• Two levels of control material	• Each day of use
• Refractometer for specific gravity			• Calibrate to zero with distilled water	• Each day of use
			• One level of control material	
Blood Gas Analysis			• Calibration	• Follow manufacturer's specifications and frequency
			• One level of control material	• Each eight hours of testing, using both low and high values on each day of testing
			• One-point calibration or one control material	• Each time patient specimen is tested, unless automated instrument internally verifies calibration every ((~~thirty~~)) 30 minutes
Electrophoresis	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell

(b) **Hematology.**

(i) Run patient and quality control samples in duplicate for manual cell counts;

(ii) If reference material is unavailable, document the mechanism used to assure the quality, accuracy, and precision of the test; and

(iii) Perform quality control procedures for hematology as described in Table 090-4 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-4 Quality Control Procedures—Hematology

	Control Material	Frequency
Automated	• Two levels of reference material in different concentrations	• Each day that patient samples are tested
Manual Blood Counts	• One level of reference material	• Every eight hours that patient samples are tested

	Control Material	Frequency
Qualitative Tests	• Positive and negative reference material	• Each day of testing

(c) **Coagulation.**

(i) Run patient and quality control samples in duplicate for manual coagulation test (tilt tube);

(ii) If reference material is unavailable, document the mechanism used to assure the quality, accuracy, and precision of the test; and

(iii) Perform quality control procedures for coagulation as described in Table 090-5 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-5 Quality Control Procedures—Coagulation

	Control Material	Frequency
Automated	• Two levels of reference material in different concentrations	• Every eight hours that patient samples are tested; and • Each time reagents are changed
Manual Tilt Tube Method	• Two levels of reference material in different concentrations	• Every eight hours that patient samples are tested; and • Each time reagents are changed

(d) **General immunology.**

(i) Employ reference materials for all test components to ensure reactivity;

(ii) Report test results only when the predetermined reactivity pattern of the reference material is observed; and

(iii) Perform quality control procedures for general immunology as described in Table 090-6 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-6 Quality Control Procedures—General Immunology

	Control Material	Frequency
Serologic tests on unknown specimens	• Positive and negative reference material	• Each day of testing
Kits with procedural (internal) controls	• Positive and negative reference material (external controls) • Procedural (internal) controls	• When kit is opened; and • Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations • Each time patient sample is tested

(e) **Syphilis serology.**

(i) Use equipment, glassware, reagents, controls, and techniques that conform to manufacturer's specifications;

(ii) Employ reference materials for all test components to ensure reactivity; and

(iii) Perform serologic tests on unknown specimens each day of testing with a positive serum reference material with known titer or graded reactivity and a negative reference material.

(f) **Microbiology.**

(i) Have available and use:

(A) Appropriate stock organisms for quality control purposes; and

(B) A collection of slides, photographs, gross specimens, or text books for reference sources to aid in identification of microorganisms;

(ii) Document all steps (reactions) used in the identification of microorganisms on patient specimens;

(iii) For antimicrobial susceptibility testing:

(A) Record zone sizes or minimum inhibitory concentration for reference organisms; and

(B) Zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results; and

(C) Perform quality control on antimicrobial susceptibility testing media as described in Table 090-8;

(iv) For noncommercial media, check each batch or shipment for sterility, ability to support growth and, if appropriate, selectivity, inhibition, or biochemical response;

(v) For commercial media:

(A) Verify that the product insert specifies that the quality control checks meet the requirements for media quality control as outlined by the Clinical Laboratory Standards Institute (CLSI). *M22-A3 Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard-Third Edition*. June 2004. (Volume 24, Number 19);

(B) Keep records of the manufacturer's quality control results;

(C) Document visual inspection of the media for proper filling of the plate, temperature or shipment damage, and contamination before use; and

(D) Follow the manufacturer's specifications for using the media; and

(vi) For microbiology subspecialties:

(A) **Bacteriology:** Perform quality control procedures for bacteriology as described in Tables 090-7 and 090-8.

Table 090-7 Quality Control Procedures—Bacteriology

	Control Material	Frequency
Reagents, disks, and identification systems Catalase, coagulase, oxidase, and Beta-lactamase Cefinase™ reagents Bacitracin, optochin, ONPG, X and V disks or strips	• Positive and negative reference organisms, unless otherwise specified	• Each batch, shipment, and new lot number unless otherwise specified
Stains, unless otherwise specified; DNA probes; and all beta-lactamase methods other than Cefinase™	• Positive and negative reference organisms	• Each batch, shipment, and new lot number; and • Each day of use
Fluorescent stains	• Positive and negative reference organisms	• Each batch, shipment, and new lot number; and • Each time of use
Gram stains	• Positive and negative reference organisms	• Each batch, shipment, and new lot number; and • Each week of use
Direct antigen detection systems without procedural controls	• Positive and negative controls that evaluate both the extraction and reaction phase	• Each batch, shipment, and new lot number; and • Each day of use
Test kits with procedural (internal) controls	• Positive and negative reference material (external) controls • Procedural (internal) controls	• Each batch, shipment, and new lot number; and • Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations • Each time patient sample is tested

	Control Material	Frequency
Antisera	• Positive and negative reference material	• Each batch, shipment, and new lot number; and • Every six months

Table 090-8 Quality Control Procedures—Bacteriology - Media for Antimicrobial Susceptibility Testing

	Control Material	Frequency
Check each new batch of media and each new lot of antimicrobial disks or other testing systems (MIC)	• Approved reference organisms (ATCC organisms)	• Before initial use and each day of testing; or • May be done weekly if the medical test site can meet the quality control requirements for antimicrobial disk susceptibility testing as outlined by CLSI *M100S Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Sixth Edition*.

(B) **Mycobacteriology:** Perform quality control procedures for mycobacteriology as described in Table 090-9.

Table 090-9 Quality Control Procedures—Mycobacteriology

	Control Material	Frequency
All reagents or test procedures used for mycobacteria identification unless otherwise specified	• Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction	• Each day of use
Acid-fast stains	• Acid-fast organism that produces a positive reaction and an organism that produces a negative reaction	• Each day of use
Fluorochrome acid-fast stains	• Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction	• Each time of use
Susceptibility tests performed on *Mycobacterium tuberculosis* isolates	• Appropriate control organism(s)	• Each batch of media, and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use • Each week of use

(C) **Mycology:** Perform quality control procedures for mycology as described in Table 090-10.

Table 090-10 Quality Control Procedures—Mycology

	Control Material	Frequency
Susceptibility tests: Each drug NOTE: Establish control limits and criteria for acceptable control results prior to reporting patient results	• One control strain that is susceptible to the drug	• Each day of use
Lactophenol cotton blue stain	• Appropriate control organism(s)	• Each batch or shipment and each lot number
Acid-fast stains	• Organisms that produce positive and negative reactions	• Each day of use
Reagents for biochemical and other identification test procedures	• Appropriate control organism(s)	• Each batch or shipment and each lot number
Commercial identification systems utilizing two or more substrates	• Organisms that verify positive and negative reactivity of each media type	• Each batch or shipment and each lot number

(D) **Parasitology:**

(I) Have available and use:

• Reference collection of slides or photographs and, if available, gross specimens for parasite identification; and

• Calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(II) Check permanent stains each month of use with reference materials.

(E) **Virology:**

(I) Have available:

• Host systems for isolation of viruses; and

• Test methods for identification of viruses that cover the entire range of viruses that are etiologically related to the clinical diseases for which services are offered; and

(II) Simultaneously culture uninoculated cells or cell substrate as a negative control when performing virus identification.

(g) **Histopathology:** Fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, include a control slide of known reactivity with each slide or group of slides and document reactions.

(h) **Cytology.**

(i) Processing specimens:

(A) ((~~Stain all gynecological smears~~)) All gynecological slide preparations must be stained using a Papanicolaou or a modified Papanicolaou staining method;

(B) Have methods to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process; and

(C) Stain nongynecological specimens that have a high potential for cross-contamination separately from other nongynecological specimens, and filter or change the stains following staining.

(ii) Performing specimen examinations:

(A) All cytology preparations must be evaluated on the premises of the medical test site;

(B) Technical personnel must examine, unless federal law and regulation specify otherwise, no more than ((~~one hundred~~)) 100 cytological slides (one patient specimen per slide; gynecologic, nongynecologic, or both) in a ((~~twenty-four~~)) 24-hour period and in no less than an eight-hour work period;

(C) Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecological cases and previously examined nongynecologic cytology preparations and tissue pathology slides examined by a technical supervisor are not included in the ((~~one hundred~~)) 100 slide limit;

(D) Each nongynecologic slide preparation made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

(E) Records of the total number of slides examined by each individual at all sites during each ((~~twenty-four~~)) 24-hour period must be maintained.

(iii) Establish and implement a quality assurance program that ensures:

(A) There is criteria for submission of material;

(B) All providers submitting specimens are informed of these criteria;

(C) All samples submitted are assessed for adequacy;

(D) Records of initial examinations and rescreening results are available and documented;

(E) Rescreening of benign gynecological slides is:

(I) Performed by an individual who meets the personnel requirements for technical or general supervisor in cytology as defined under 42 C.F.R. Part 493 Subpart M;

(II) Completed before reporting patient results on those selected cases;

(III) Performed and documented on:

• No less than ((~~ten~~)) 10 percent of the benign gynecological slides; and

• Includes cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;

(F) The technical supervisor:

(I) Confirms all gynecological smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial neoplasia lesions including human papillomavirus-associated changes) or malignant category;

(II) Reviews all nongynecological cytological preparations; and

(III) Establishes, documents, and reassesses, at least every six months, the workload limits for each cytotechnologist;

(G) All cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms are correlated with prior cytology reports and with histopathology reports if available, and the causes of any discrepancies are determined;

(H) Review of all normal or negative gynecological specimens received within the previous five years, if available in the laboratory system, or records of previous reviews, for each patient with a current high grade intraepithelial lesion or moderate dysplasia of CIN-2 or above;

(I) Notification of the patient's physician if significant discrepancies are found that would affect patient care and issuance of an amended report;

(J) An annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis, number of cases where cytology and histology are discrepant, number of cases where histology results were unavailable for comparison, and number of cases where rescreen of negative slides resulted in reclassification as abnormal; and

(K) Evaluation and documentation of the performance of each individual examining slides against the medical test site's overall statistical values, with documentation of any discrepancies, including reasons for the deviation and corrective action, if appropriate.

(i) **Immunohematology/transfusion services.**

(i) Perform ABO grouping, Rh (D) typing, antibody detection and identification, and compatibility testing as described by the Food and Drug Administration (FDA) under 21 C.F.R. Parts 606 and 640.

(A) Perform ABO grouping:

(I) By concurrently testing unknown red cells with FDA approved anti-A and anti-B grouping sera;

(II) Confirm ABO grouping of unknown serum with known A1 and B red cells;

(B) Perform Rh (D) typing by testing unknown red cells with anti-D (anti-Rh) blood grouping serum; and

(C) Perform quality control procedures for immunohematology as described in Table 090-11.

(ii) Blood and blood products:

(A) Collecting, processing, and distributing:

(I) Must comply with FDA requirements listed under 21 C.F.R. Parts 606, 610.40, 610.53, and 640; and

(II) Must establish, document, and follow policies to ensure positive identification of a blood or blood product recipient.

(B) Labeling and dating must comply with FDA requirements listed under 21 C.F.R. 606 Subpart G, and 610.53.

(C) Storing:

(I) There must be an adequate temperature alarm system that is regularly inspected.

(II) The system must have an audible alarm system that monitors proper blood and blood product storage temperature over a ((~~twenty-four~~)) 24-hour period.

(III) High and low temperature checks of the alarm system must be documented.

(D) Collection of heterologous or autologous blood products on-site:

(I) Must register with the FDA; and

(II) Have a current copy of the form FDA 2830 "Blood Establishment Registration and Product Listing."

(E) Retention of samples of transfused blood:

(I) Establish and follow procedures to retain samples of each unit of transfused blood for further testing in the event of transfusion reactions; and

(II) Promptly dispose of blood not retained for further testing that has passed its expiration date.

(iii) Must have an agreement approved by the director for procurement, transfer, and availability to receive products from outside entities.

(iv) Promptly investigate transfusion reactions according to established procedures, and take any necessary remedial action.

Table 090-11 Quality Control Procedures—Immunohematology

Reagent	Control Material	Frequency
ABO antisera	• Positive control	• Each day of use
Rh antisera	• Positive and negative controls	• Each day of use
	• Patient control to detect false positive Rh test results	• When required by the manufacturer
Other antisera	• Positive and negative controls	• Each day of use
ABO reagent red cells	• Positive control	• Each day of use
Antibody screening cells	• Positive control using at least one known antibody	• Each day of use

(j) **Histocompatibility.**

(i) Use applicable quality control standards for immunohematology, transfusion services, and diagnostic immunology as described in this chapter; and

(ii) Meet the standards for histocompatibility as listed in 42 C.F.R. Part 493.1278, Standard: Histocompatibility, available from the department upon request.

(k) **Cytogenetics.**

(i) Document:

(A) Number of metaphase chromosome spreads and cells counted and karyotyped;

(B) Number of chromosomes counted for each metaphase spread;
(C) Media used;
(D) Reactions observed;
(E) Quality of banding; and
(F) Sufficient resolution appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided;
(ii) Assure an adequate number of karyotypes are prepared for each patient according to the indication given for performing cytogenetics study;
(iii) Use an adequate patient identification system for:
(A) Patient specimens;
(B) Photographs, photographic negatives, or computer stored images of metaphase spreads and karyotypes;
(C) Slides; and
(D) Records; and
(iv) Perform full chromosome analysis for determination of sex.
(l) **Radiobioassay and radioimmunoassay.**
(i) Check the counting equipment for stability each day of use with radioactive standards or reference sources; and
(ii) Meet Washington state radiation standards described under chapter 70.98 RCW and chapters 246-220, 246-221, 246-222, 246-232, 246-233, 246-235, 246-239, 246-247, 246-249, and 246-254 WAC.