Washington State Department of HEALTH

MEDICAL TEST SITES – EXPEDITED RULEMAKING

Medical Test Sites (MTS) Program

- 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.

- The Washington DOH MTS program is responsible for ensuring that the public receives accurate and reliable clinical laboratory test results by monitoring and evaluating medical test sites for compliance with the minimal standards under Chapter 70.42 RCW and Chapter 246-338 WAC.

CLIA Exempt State Status

- Washington is CLIA-exempt and receives approval from CMS CLIA to enforce rules.
- Washington State requirements must be equal to or more stringent that CLIA's statutory and regulatory requirements.
- To ensure compliance with these requirements, the Washington Medical Test Site Program has identified amendments that must be made to chapter 246-338 WAC, Medical Test Site Rules.

Expedited Rulemaking

- CLIA made changes to federal requirements, which are effective in 2024. One rule related to proficiency testing went into effect in July 2024. Another rule related to personnel requirements goes into effect in December 2024.

- A CR-105 was filed with the Code Reviser as WSR 24-20-089 on September 29, 2024.

- Expedited rulemaking can only take place when certain requirements are met. The amendments to chapter 246-338 WAC qualify for expedited rulemaking because they incorporate by reference federal statutes and regulations.

- A minimum 45-day public comment period is provided.

Types of Amendments

- The amendments to chapter 246-338 WAC are divided into three categories:

1. Incorporating new CLIA rules that are effective in 2024.
2. Incorporating existing federal rules that are not explicitly written in chapter 246-338 WAC.
3. Correcting technical information.

New CLIA Rules

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.861 -- Standard; Unexpected antibody detection. (a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.	WAC 246-338-050: Proficiency testing. (3) The department will evaluate proficiency testing results by using the following criteria: (b) Maintenance of a minimum acceptable score of 80 percent for all tests, subspecialties, and specialties except 100 percent for: (iv) Unexpected antibody detection;

- The passing proficiency test score for Unexpected Antibody Detection changed from 80% to 100%.
- This CLIA rule went into effect on July 11, 2024.
- Enforcement begins on January 1, 2025.

New CLIA Rules

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.1407 -- Standard; Laboratory director responsibilities. (Moderate complexity) eCFR :: 42 CFR 493.1445 -- Standard; Laboratory director responsibilities. (High complexity) (c) The laboratory director must: (1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be onsite more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.	WAC 246-338-060 Personnel. (3) Medical test site directors must: (d) Conduct on-site visits at the licensed medical test site at least once every six months, with a minimum four-month interval between 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.

- WAC 246-338-060(3)(c) already required that MTS directors be present, on call, or delegate the duties of the director to an on-site technical person during testing.

Incorporating Existing CLIA Rules

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.35 -- Application for a certificate of waiver. eCFR :: 42 CFR 493.43 -- Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance. eCFR :: 42 CFR 493.55 -- Application for registration certificate and certificate of accreditation. (b) ***Exceptions.*** (3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.	WAC 246-338-022 Initial application for medical test site license. (1) **Application procedure.** Applicants requesting a medical test site license must: (b) File a separate application for each test site **except** under the following conditions: (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;

- While the MTS Program has allowed hospitals to file a single application or multiple applications for sites within the same physical location or street address, it was not explicitly stated in chapter 246-338 WAC.

Incorporating Existing CLIA Rules

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.1101 -- Standard: Facilities. (a) The laboratory must be constructed, arranged, and maintained to ensure the following: (2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. and (b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.	WAC 246-338-080 Quality assurance. (6) The owner must: (b) Ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized; (d) Ensure the laboratory has appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs;

- The omission of these federal requirements from WAC made it appear as if they were not required, so they must be added so as not to appear optional.
- Due to the additions of (b) and (d) to WAC, the paragraph was renumbered.

Incorporating Existing CLIA Rules

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.1271 -- Standard: Immunohematology. (d) ***Retention of samples of transfused blood.*** According to the laboratory's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.	WAC 246-338-090 Quality control. (ii) Blood and blood products: (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.

- The omission of these federal requirements from WAC made it appear as if they were not required, so they must be added so as not to appear optional.

Technical Correction

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.559 -- Publication of approval of deeming authority or CLIA exemption. **(a) *Notice of deeming authority or exemption.*** CMS publishes a notice in the Federal Register when it grants deeming authority to an accreditation organization or exemption to a State licensure program. The following Federal Register publications were used to update the list of accreditation organizations: CMS-3436-N ACHC CMS-3422-N A2LA CMS-3449-N AABB CMS-3450-N Joint Commission	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) Accreditation Commission for Health Care (ACHC); (b) American Association for Laboratory Accreditation (A2LA); (c) American Society of Histocompatibility and Immunogenetics (ASHI); (d) Association for the Advancement of Blood and Biotherapies (AABB); (e) COLA; (f) College of American Pathologists (CAP); and (g) Joint Commission.

- The Washington MTS Program allows labs to seek accreditation status by a CMS approved AO.
- Technical corrections were made to add organizations that were not previously listed, correct the names if they have been updated, and to alphabetize the list.

Technical Correction

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.1274 -- Standard: Cytology. (e) ***Slide examination and reporting.*** The laboratory must establish and follow written policies and procedures that ensure the following: (5) The report contains narrative descriptive nomenclature for all results.	WAC 246-338-070 Records. Medical test sites must maintain records as described in this section. (4) CYTOLOGY REPORTS must: (b) Provide narrative descriptive nomenclature for all results, using a recognized system of disease nomenclature such as the Bethesda System;

- Previously, the Washington rule stated that the narrative descriptions on cytology reports were required for abnormal results.
- The rule has been updated to reflect that the narrative descriptive nomenclature is required for all results.

Technical Correction

CLIA Rule	Washington Rule
eCFR :: 42 CFR 493.1274 -- Standard: Cytology. (b) ***Staining.*** The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.	WAC 246-338-090 Quality control. (h) Cytology. (i) Processing specimens: (A) All gynecological slide preparations must be stained using a Papnicolaou or a modified Papnicolaou staining method;

- Previously, the Washington rule stated that the specimens were gynecological smears. The terminology has been corrected to gynecological slide preparations.

Summary

- A CR-105 was filed to amend chapter 246-338 WAC: Medical Test Site Rules.
- A 45-day comment period is open at https://fortress.wa.gov/doh/policyreview/ and comments must be received by December 2, 2024.
- Once the comment period is closed, Washington Department of Health responds to comments in a Concise Explanatory Statement.
- The amended rules go into effect on December 28, 2024, and a notice will be sent to interested parties.

Questions?

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