RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 13, 2024
TIME: 1:34 PM

WSR 24-11-059

Agency: Department of Health

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: Medical test site (MTS) licensure for naturopath and licensed midwife professions.To align with federal rules, the Department of Health (department) is removing the professions of naturopath licensed under chapter 18.36A RCW and midwife licensed under chapter 18.50 RCW from the list of licensed professionals that may perform a provider performed microscopic procedure (PPMP) in WAC 246-338-020. The department is clarifying that both the laboratory director and testing personnel of PPMP must be a licensed professional. There is also a technical citation adjustment to a definition in WAC 246-338-010.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-338-010 and 246-338-020
Suspended: None

Statutory authority for adoption: RCW 70.42.220

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 24-05-019 on February 9, 2024 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting: N/A

Name:
Address:
Phone:
Fax:
TTY:
Email:
Web site:
Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	2	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	2	Repealed	0

Date Adopted: 5/13/2024

Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH

Title: Chief of Policy for Secretary of Health

Signature:

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

WAC 246-338-010 Definitions. For the purposes of this chapter, the following words and phrases have these meanings unless the context clearly indicates otherwise.

(1) "Accreditation organization" means a public or private organization or agency approved by CMS as having standards which are consistent with federal law and regulation, and judged by the department to be equivalent to this chapter.

(2) "Authorized person" means any individual allowed by Washington state law or rule to order tests or receive test results.

(3) "Biannual verification" means a system for verifying the accuracy of test results, at least twice a calendar year, for those tests for which proficiency testing is not required by the department.

(4) "Calibration" means a process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.

(5) "Calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results.

(6) "Calibrator" means a material, solution, or lyophilized preparation designed to be used in calibration. The values or concentrations of the analytes of interest in the calibration material are known within limits ascertained during its preparation or before use.

(7) "Case" means any slide or group of slides, from one patient specimen source, submitted to a medical test site, at one time, for the purpose of cytological or histological examination.

(8) "CDC" means the federal Centers for Disease Control and Prevention.

(9) "CMS" means the federal Centers for Medicare and Medicaid Services.

(10) "CLIA" means Section 353 of the Public Health Service Act, Clinical Laboratory Improvement Amendments of 1988, and regulations implementing the federal amendments, 42 C.F.R. Part 493-Laboratory Requirements in effect on September 22, 2003.

(11) "Control" means a material, solution, lyophilized preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the analytes of interest in the control material are known within limits ascertained during its preparation or before routine use.

(12) "Control slide" means a preparation of a material known to produce a specific reaction which is fixed on a glass slide and is used in the process of quality control.

(13) "Days" means calendar days.

(14) "Deemed status" means recognition that the requirements of an accreditation organization have been judged to be equal to, or more stringent than, the requirements of this chapter and the CLIA requirements, and the accreditation organization has agreed to comply with all requirements of this chapter and CLIA.

(15) "Deficiency" means a finding from an inspection or complaint investigation that is not in compliance with this chapter and requires corrective action.

(16) "Department" means the department of health.

(17) "Direct staff time" means all state employees' work time; travel time; telephone contacts and staff or management conferences; and expenses involved with a complaint investigation or an on-site follow-up visit.

(18) "Director," defined as the designated test site supervisor in RCW 70.42.010, means the individual responsible for the technical functions of the medical test site. This person must meet the qualifications for Laboratory Director, listed in 42 C.F.R. Part 493 Subpart M - Personnel for Nonwaived Testing.

(19) "Disciplinary action" means license or certificate of waiver denial, suspension, condition, revocation, civil fine, or any combination of the preceding actions, taken by the department against a medical test site.

(20) "Facility" means one or more locations within one campus or complex where tests are performed under one owner.

(21) "Forensic" means investigative testing in which the results are never used for clinical diagnosis, or referral to a health care provider for treatment of an individual.

(22) "HHS" means the federal Department of Health and Human Services.

(23) "High complexity" means a test system, assay, or examination that is categorized under CLIA as a high complexity test.

(24) "May" means permissive or discretionary.

(25) "Medical test site" or "test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A medical test site does not mean:

(a) A facility or site, including a residence, where a test approved for home use by the Federal Food and Drug Administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction; or

(b) A facility or site performing tests solely for forensic purposes.

(26) "Moderate complexity" means a test system, assay, or examination that is categorized under CLIA as a moderate complexity test.

(27) "Must" means compliance is mandatory.

(28) "Nonwaived" means all tests categorized under CLIA as:

(a) Moderate complexity tests, including provider-performed microscopic procedures; or

(b) High complexity tests.

(29) "Owner" means the person, corporation, or entity legally responsible for the business requiring licensure or a certificate of waiver as a medical test site under chapter 70.42 RCW.

(30) "Patient's personal representative" means a person legally authorized to make health care decisions on an individual's behalf.

(31) "Performance specification" means a value or range of values for a test that describe its accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference range.

(32) "Person" means any individual, public organization, private organization, agent, agency, corporation, firm, association, partnership, or business.

(33) "Physician" means an individual with a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine, or equivalent degree who is a licensed professional under chapter 18.71 RCW Physi-

cians; chapter 18.57 RCW Osteopathy—Osteopathic medicine and surgery; or chapter 18.22 RCW Podiatric medicine and surgery.

(34) "Provider-performed microscopic procedures" means only those moderate complexity tests listed under WAC 246-338-020 (2)(b)(i) through (x), when the tests are performed in conjunction with a patient's visit by a licensed professional meeting qualifications specified in WAC 246-338-020 (2)(a)(i) through ((~~(vi)~~)) (iv).

(35) "Provisional license" means an interim approval issued by the department to the owner of a medical test site.

(36) "Records" means books, files, reports, or other documentation necessary to show compliance with the quality control and quality assurance requirements under this chapter.

(37) "Reference material" means a material or substance, calibrator, control, or standard where one or more properties are sufficiently well established for use in calibrating a process or for use in quality control.

(38) "Specialty" means a group of similar subspecialties or tests. The specialties for a medical test site are as follows:

(a) Chemistry;

(b) Cytogenetics;

(c) Diagnostic immunology;

(d) Immunohematology;

(e) Hematology;

(f) Histocompatibility;

(g) Microbiology;

(h) Pathology; and

(i) Radiobioassay.

(39) "Standard" means a reference material of fixed and known chemical composition capable of being prepared in essentially pure form, or any certified reference material generally accepted or officially recognized as the unique standard for the assay regardless of level or purity of the analyte content.

(40) "Subspecialty" means a group of similar tests. The subspecialties of a specialty for a medical test site are as follows, for:

(a) Chemistry, the subspecialties are routine chemistry, urinalysis, endocrinology, and toxicology;

(b) Diagnostic immunology, the subspecialties are syphilis serology and general immunology;

(c) Immunohematology, the subspecialties are ABO grouping and Rh typing, antibody detection, antibody identification, and compatibility testing;

(d) Hematology, the subspecialties are routine hematology and coagulation;

(e) Microbiology, the subspecialties are bacteriology, mycology, parasitology, virology, and mycobacteriology; and

(f) Pathology, the subspecialties are histopathology (including dermatopathology), diagnostic cytology, and oral pathology.

(41) "Supervision" means authoritative procedural guidance by an individual qualified under 42 C.F.R. Part 493 Subpart M - Personnel for Non-waived Testing, assuming the responsibility for the accomplishment of a function or activity by technical personnel.

(42) "Technical personnel" means individuals employed to perform any test or part of a test.

(43) "Test" means any examination or procedure conducted on a sample taken from the human body.

(44) "Validation inspection" means an on-site inspection by the department of an accredited medical test site to determine that the accreditation organization's regulations are equivalent to this chapter and are enforced.

(45) "Waived test" means a test system that is:

(a) Cleared by the Food and Drug Administration for home use; or

(b) A simple laboratory examination or procedure that has an insignificant risk of an erroneous result.

In order for a test system to be waived, it must be approved for waiver under CLIA.

(46) "Will" means compliance is mandatory.

AMENDATORY SECTION (Amending WSR 02-12-105, filed 6/5/02, effective 7/6/02)

WAC 246-338-020 Licensure—Types of medical test site licenses. After July 1, 1990, any person advertising, operating, managing, owning, conducting, opening, or maintaining a medical test site must first obtain a license from the department. License types are described in Table 020-1.

(1) Certificate of waiver.

Applicable if the medical test site performs only the tests classified as waived.

(2) Provider performed microscopic procedures (PPMP).

Applicable if the medical test site restricts its testing performance to one or more of the following moderate complexity tests performed by one of the licensed professionals listed, in conjunction with a patient's visit. In addition, the medical test site can perform tests classified as waived with this type of license.

(a) ((~~PPMP may be performed only by one of~~)) The following licensed professionals may serve as the laboratory director and testing personnel for microscopic procedures under a PPMP medical test site license:

(i) Physician licensed under chapter 18.71 RCW, Physicians; chapter 18.57 RCW, Osteopathy—Osteopathic medicine and surgery; or chapter 18.22 RCW, Podiatric medicine and surgery;

(ii) Advanced registered nurse practitioner, licensed under chapter 18.79 RCW, Nursing care;

(iii) ((~~Midwife licensed under chapter 18.50 RCW, Midwifery;~~

~~(iv)~~)) Physician assistant licensed under chapter 18.71A RCW, Physician assistants; or

((~~(v) Naturopath licensed under chapter 18.36A RCW, Naturopathy; or~~

~~(vi)~~)) (iv) Dentist licensed under chapter 18.32 RCW, Dentistry.

(b) Microscopic procedures authorized under a PPMP license are:

(i) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements;

(ii) All potassium hydroxide (KOH) preparations;

(iii) Pinworm examinations;

(iv) Fern tests;

(v) Postcoital direct, qualitative examinations of vaginal or cervical mucous;

(vi) Urine sediment examinations;

(vii) Nasal smears for granulocytes;

(viii) Fecal leukocyte examinations;

(ix) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility); and

(x) Any other tests subsequently categorized under CLIA as provider-performed microscopy procedures.

(3) Moderate/high complexity.

(a) Low volume, Category A-J, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived or qualified as PPMP under subsection (2) of this section. Under this type of license, the medical test site may also perform tests classified as waived.

(b) Accredited: Low volume, Category A-J, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived, and is accredited and inspected by an accreditation organization approved by the department under WAC 246-338-040. Under this type of license, the medical test site may also perform tests classified as waived.

020-1 Table of Requirements for Each License Type

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
(1) **Certificate of Waiver**	• Restrict testing to tests classified as waived. • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections. • Follow manufacturers' instructions for performing the test.	• Complaint • Technical assistance	• When indicated
(2) **PPMP**	• Restrict testing to tests classified as PPMP or waived. • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing the test.	• Complaint • Technical assistance	• When indicated
(3) **Moderate/High Complexity**			
(a) **Low Volume, Category A-J**	• Perform tests classified as moderate or high complexity.	• Initial	• First 6 months of license

LICENSE TYPE		REQUIREMENTS	INSPECTIONS	
			TYPE	FREQUENCY
		• Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing test.	• Routine • Complaint • On-site follow-up • Technical assistance	• Every 2 years • When indicated • When indicated • When indicated
(b)	**Accredited: Low Volume, Category A-J**	• Perform tests classified as moderate or high complexity. • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing the test. • Submit to the department upon request, or authorize the accreditation organization to submit: • Proof of accreditation; • On-site inspection results; • Statement of deficiencies; • Plan of correction for the deficiencies cited; • Any disciplinary action and results of any disciplinary action taken by the accreditation organization against the medical test site.	• Validation • Complaint • On-site follow-up • Technical assistance	• 2.5% of accredited sites annually • When indicated • When indicated • When indicated