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 Physicians; 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).

(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.

[Statutory Authority: RCW 70.42.220, 43.70.041, and 42 C.F.R. 493.1291(l), 1832, 1241(b), 1299, 1256 (2)(iv, v), 1273(a). WSR 16-18-073, § 246-338-010, filed 9/2/16, effective 10/3/16. Statutory Authority: RCW 70.42.005 and 42 C.F.R. Part 493. WSR 05-04-040, § 246-338-010, 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, § 246-338-010, filed 3/1/00, effective 4/1/00. Statutory Authority: Chapter 70.42 RCW. WSR 94-17-099, § 246-338-010, filed 8/17/94, effective 9/17/94; WSR 93-18-091 (Order 390), § 246-338-010, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-010, filed 10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-010, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-010, filed 9/21/90, effective 10/22/90.]