

**Rules Governing Maine Medical Laboratories
And
Health Screening Permits
10-144 C.M.R. Ch. 256**

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PART ONE
CLIA CERTIFICATION and STATE-ISSUED LICENSE

PURPOSE

The purpose of these rules is (1) to develop, establish and enforce minimum standards for the licensing of nonexempt medical laboratories pursuant to the Maine Medical Laboratory Act; (2) to incorporate by reference the federal regulations governing the Clinical Laboratory Improvement Amendments of 1988, as amended (CLIA); (3) to align state and federal requirements; and (4) to establish procedures for the issuance of permits for health screening laboratories (HSLs). Medical laboratories provide essential health services by aiding medical practitioners in the diagnosis and treatment of disease. See 22 M.R.S.A. §2012.

SECTION 1. DEFINITIONS. As used in these rules the following terms have the following meanings, unless the context indicates otherwise.

- 1.1 Approved accreditation organization for laboratories.** “Approved accreditation organization for laboratories” means a private, nonprofit accreditation organization that has formally applied for and received approval from the federal Centers for Medicare and Medicaid Services (CMS) based on the organization’s compliance with federal CLIA regulations. See 42 Code of Federal Regulations (CFR) Part 493.
- 1.2 Category of testing by complexity.** “Category of testing by complexity” means laboratory tests are categorized by complexity as one of the following: (1) waived tests; (2) tests of moderate complexity, including provider-performed microscopy (PPM) procedures; or (3) tests of high complexity. See 42 C.F.R. Part 493.
- 1.3 CMS.** “CMS” means the Centers for Medicare and Medicaid Services, U. S. Department of Health and Human Services.
- 1.4 CLIA.** “CLIA” means the federal Clinical Laboratory Improvement Amendments of 1988, as amended. Federal CLIA regulations apply to all laboratories that perform testing on human specimens. See 42 C.F.R. Part 493.
- 1.5 CLIA Certificate.** “CLIA Certificate” means any of the following types of certificates issued by CMS or its agent:
 - 1.5.1 Certificate of Compliance.** A “Certificate of Compliance” means a certificate issued to a laboratory after a CLIA inspection that finds the laboratory to be in compliance with all applicable condition level requirements.
 - 1.5.2 Certificate for Provider-Performed Microscopy (PPM) Procedures.** A “Certificate for Provider-Performed Microscopy (PPM) Procedures” means a certificate issued to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests.

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- 1.5.3 Certificate of Accreditation.** A “Certificate of Accreditation” means a certificate issued based on the laboratory’s accreditation by an accreditation organization approved by CMS, indicating that the laboratory is held to have met applicable CLIA requirements.
- 1.5.4 Certificate of Registration.** A “Certificate of Registration” or “registration certificate” means an issued certificate that enables the entity to conduct moderate or high complexity laboratory testing or both prior to a survey by CMS or its agent, or accreditation by an approved accreditation organization.
- 1.5.5 Certificate of Waiver.** A “Certificate of Waiver” means a certificate issued by CMS to a laboratory to perform only the list of waived tests approved by federal law. See 42 CFR Part 493.
- 1.6 Department.** Unless otherwise indicated, “department” means the Maine Department of Health and Human Services or DHHS.
- 1.7 Directed plan of correction.** “Directed plan of correction” is an enforcement measure that directs a medical laboratory or a Health Screening Laboratory (HSL) to take specific corrective action within specific periods in order to achieve regulatory compliance.
- 1.8 Director of medical laboratory.** “Director of medical laboratory” means an individual who is responsible for the professional, technical and scientific operation of a medical laboratory, including the reporting of the findings of medical laboratory tests. The director of a medical laboratory may not be merely nominal, but must be responsible for its operation to such extent as may be necessary to assure compliance with these rules. See 22 M.R.S.A. §2014(3).
- 1.9 Exempt laboratory.** “Exempt laboratory” means a medical laboratory that does not have to secure a state license to operate a medical laboratory. Exempt medical laboratories must be CLIA certified. See 22 M.R.S.A. §2013-A(1).
- 1.10 Final agency action.** “Final agency action” means a decision by DHHS that affects the legal rights, duties or privileges of specific persons, which is dispositive of all issues, legal and factual, and for which no further recourse, appeal or review is provided within DHHS. See 5 M.R.S.A. §8002 (4).
- 1.11 Health screening laboratory (HSL).** “Health screening laboratory” (HSL) means a testing site that is not at a fixed location that performs only approved health screening tests for the public. A permit is required to operate a HSL. HSL testing is for screening purposes only and not for diagnostic purposes. HSLs include but are not limited to screening laboratories that move from testing site to testing site such as mobile units providing laboratory screening tests at health fairs, or other temporary screening test locations. See 22 M.R.S.A. §2013-A(1)(G).
- 1.11.1** A HSL does not include a workplace health screening event for employees only.
- 1.12 Laboratory personnel.** “Laboratory personnel” means personnel that meet state personnel requirements and federal CLIA personnel requirements for medical laboratories. CLIA

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personnel requirements include qualifications for laboratory directors, technical supervisors, general supervisors, technical consultants, clinical consultants and testing personnel. See 42 CFR Part 493, Subpart B (waived testing) and Subpart M (non-waived testing).

- 1.13 Licensee.** “Licensee” means an individual, corporation, partnership, association or similar entity that has been issued a Maine medical laboratory license.
- 1.14 Medical Laboratory.** “Medical Laboratory” or “laboratory” means any institution, building or place that provides through its ownership or operation an entity for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. See 42 CFR Part 493, Subpart A and 22 M.R.S.A. §2014(4).
- 1.15 Midlevel practitioner.** “Midlevel practitioner” means a licensed nurse midwife, nurse practitioner or physician assistant. See 42 C.F.R. Part 493, Subpart A.
- 1.16 Nonexempt laboratory.** “Nonexempt laboratory” means a medical laboratory that must secure a state license to operate a medical laboratory. Nonexempt medical laboratories must be CLIA certified. See 22 M.R.S.A. §2013-A.
- 1.17 Owner.** “Owner” means a person, corporation, partnership, association or similar entity that owns any interest in the laboratory.
- 1.17.1 Exception.** A person with an interest in a laboratory whose stock or securities are publicly traded is not an “owner” for the purposes of these rules. See 42 C.F.R. Part 493, Subpart A.
- 1.18 Permit.** For the purposes of these rules, “permit” means a department-issued document authorizing a laboratory to perform health screening tests as set out in PART TWO of these rules.
- 1.19 Person.** “Person” means any individual, corporation, partnership, association or similar entity.
- 1.20 Reference laboratory.** “Reference laboratory” means a medical laboratory that accepts referrals from other entities to perform laboratory testing on the other entity’s patients.
- 1.21 Resident of Maine.** “Resident of Maine” means an individual living in the state with the intention of making a home in Maine. Proof of residency includes but is not limited to a Maine driver’s license or a non-driver photo identification card issued by Maine.
- 1.22 Waived Test.** “Waived test” means a test system, assay or examination that meets the federal CLIA statutory waiver criteria and is listed as a waived test approved by federal law.

SECTION 2. CLIA CERTIFICATION

- 2.1 CLIA certification required.** All medical laboratories that perform testing on human specimens must be certified pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), as amended. Laboratories subject to PART ONE or PART TWO of these rules must comply with CLIA.
- 2.2 Federal CLIA standards and certification requirements.** All applicants and certificate-holders must comply with the federal CLIA standards and certification requirements set forth in 42 Code of Federal Regulations Part 493, as revised October 1, 2010, which is incorporated herein by reference pursuant to 5 M.R.S.A. §8056 of the Maine Administrative Procedures Act.
- 2.2.1** Copies of the federal CLIA standards and certification requirements (42 CFR Part 493), including the Certificate of Waiver and the Provider Performed Microscopy Certificate requirements, may be obtained from the Department of Health and Human Services, Division of Licensing and Regulatory Services, 11 State House Station, 41 Anthony Ave, Augusta, Maine 04333; the Maine Office of the Secretary of State, 101 State House Station, Augusta, Maine 04333, or online at <http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/xml/CFR-2010-title42-vol5-part493.xml> .
- 2.3 Violation of these rules.** A violation of any of the federal CLIA standards, certification requirements or conditions of participation constitutes a violation of these rules.

SECTION 3. MAINE REQUIREMENTS AND LABORATORY LICENSE EXEMPTIONS

STATE STANDARDS

- 3.1 Laboratories operating in Maine.** The Maine Medical Laboratory Act applies to medical laboratories operating in the State, except as otherwise stated in these rules. See 22 M.R.S.A. §2013-A.
- 3.2 Requirements.** All medical laboratories whether licensed or exempt from state licensure, must comply with state standard set out in Sections 3.3 and 3.4 of these rules.
- 3.3 Public health reporting requirements.** Medical laboratories whether licensed or exempt from state licensure, regardless of location, must comply with the public health reporting requirements in Title 22, chapter 250 of the Maine Revised Statutes (notifiable diseases, communicable diseases). This applies to laboratories that receive, forward or analyze specimens of material from the human body or referred cultures of specimens from the human body and report the results to health care providers who use the data for purposes of patient care. See 22 M.R.S.A. §2013-A(3).
- 3.4 Employee drug testing.** Medical laboratories testing employees and applicants for substances of abuse for employment related purposes must be licensed in accordance with the laws and rules governing Maine Drug Testing Laboratories. See 26 M.R.S.A. §§ 681-690 and 10-144 C.M.R. Chapter 265.
- 3.5 Maternal serum alpha-fetoprotein (AFP) testing.** Medical laboratories are subject to Section 6.8 of these rules that governs the performance of maternal serum alpha-fetoprotein (AFP) testing. See 22 M.R.S.A. §2013-A(2).

EXEMPT LABORATORIES

- 3.6 No state license required.** Medical laboratories exempt from state licensure must have the required CLIA certification. The following medical laboratories are exempt from state licensure.
- 3.6.1 Government operated laboratories.** Medical laboratories operated by the United State Government, the State or municipalities of the State.
- 3.6.2 Hospital laboratories.** Laboratory facilities and laboratory services operated in a hospital licensed by the State.
- 3.6.3 Laboratories for exclusive testing of their own patients.** Medical laboratories operated by the following entities are exempt from state licensure if they perform only tests that are within the scope of their CLIA certificate exclusively for the examination of their own patients.
- 3.6.3.1** Physicians;
- 3.6.3.2** Physician assistants;

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- 3.7.4 Each location licensed.** A separate license must be obtained for each nonexempt laboratory location. The license is not valid for any premises other than the location for which the license was issued.
- 3.7.5 License displayed.** The license must be displayed in a prominent place in the nonexempt medical laboratory where it may be seen by the public.
- 3.7.5.1** A medical laboratory must not in any advertisement, announcement, letter, circular, poster, sign, or any other manner include any statement expressly or by implication to the effect that it is approved or endorsed by the department. See 22 M.R.S.A. §2019.
- 3.7.6 License not transferable.** No license issued pursuant to these rules may be sold, assigned or transferred.
- 3.7.7 Valid license.** A license is valid only for the person(s) to whom it is issued. See 22 M.R.S.A. §2018.
- 3.7.8 Unlicensed nonexempt laboratories.** No person, firm, partnership, association, corporation or other entity shall establish, operate, maintain, or direct or engage in the business of operating a nonexempt medical laboratory, without a state-issued license. See 22 M.R.S.A. §2037(1).
- 3.7.9 License required: incorporated laboratories for mutual use of owners.** Medical laboratories incorporated for the mutual use of physician or group practice owners must secure a state-issued license and are subject to the provisions of these rules. An incorporated mutual use laboratory is a reference laboratory. See 22 M.R.S.A. §2013-A(C).

SECTION 4. LICENSE APPLICATION AND RENEWAL PROCESS

APPLICATION

- 4.1 Application for license.** Nonexempt medical laboratories must submit a written application for a license on a department-approved form. The application is considered incomplete if the application fee and required documentation are not included. An initial license application is considered incomplete if the Office of the State Fire Marshal's report is not included.
- 4.1.1** A separate application and application fee must be submitted for each laboratory location.
- 4.1.2** An applicant for an initial license must secure a report of a satisfactory inspection by the Office of the State Fire Marshal, Maine Department of Public Safety. The cost of an inspection shall be borne by the applicant. The applicant must submit the fire marshal's report to the department with the initial license application.
- 4.1.3** A copy of the laboratory's CLIA certification must accompany the application for a state license.
- 4.1.4** If the laboratory has been inspected by CLIA or an accreditation agency a copy of the most recent inspection report and other pertinent documentation prepared by CLIA or an accreditation agency must accompany the application for a state license.
- 4.2 Information on application.** The application must contain at least the following information:
- 4.2.1** The name and location of the medical laboratory;
- 4.2.2** The name of the owner or owners of the laboratory;
- 4.2.3** The name of the director of the laboratory;
- 4.2.4** A description of the services provided by the laboratory; and
- 4.2.5** Other information required by the department. See 22 M.R.S.A. §2016.

ISSUED LICENSE

- 4.3 Issuance of license.** After a review of the application and required documents, the department issues a license to an applicant if the information submitted by the applicant demonstrates satisfactory evidence of compliance with applicable federal CLIA requirements and these rules.
- 4.3.1 Location licensed.** The department issues a separate license for each location.
- 4.3.2 License issued to owner and director jointly.** When the owner is not the director, the department issues the license jointly to the owner and the director for the premises stated in the application. They are severally and jointly responsible to the department

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for the maintenance and conduct of the licensed medical laboratory and for any violations of these rules. See 22 M.R.S.A. §2018.

4.3.3 Limited license issued to a laboratory that performs only CLIA waived tests. Medical laboratories that perform only tests categorized as waived by CLIA are issued a limited license to perform only those waived tests for which the supervisor is qualified.

4.3.4 Information on a license. The issued license must include at least the following information:

4.3.4.1 The name of the laboratory director;

4.3.4.2 The official name and address of the laboratory;

4.3.4.3 The testing specialties and categories certified by CLIA;

4.3.4.4 The effective date and the expiration date of the issued license; and

4.3.4.5 Other information required by the department.

4.4 Inspections. Maintenance of state licensure is contingent on successful compliance with initial and subsequent on-site inspections required by the medical laboratory's CLIA certification type and conducted by CLIA or its agent. See 42 C.F.R. Part 493, Subpart Q. Loss of CLIA certification results in loss of state license.

4.5 Term of license. The term of the license is three (3) years from the date of issuance. See 22 M.R.S.A. §2017.

4.6 New location, director or owner: new license. A new license, for the unexpired length of time of the original license, may be secured when there is a new location, director or owner. The new license must be obtained prior to the actual change and the change must comply with these rules. See 22 M.R.S.A. §2018. The licensee may obtain the new license upon payment of the fee set out in Section 5.4 of these rules.

4.7 Duplicate license. A licensee may obtain a copy of a current license upon payment of the fee set out in Section 5.5 of these rules. See 22 M.R.S.A. §2022.

4.8 Failure to renew license. If a license is not renewed, it expires on the expiration date and operation of the medical laboratory must cease.

RENEWAL OF LICENSE

4.9 Department notice to renew license. Sixty (60) calendar days prior to the expiration of a license, the department shall send licensees a notice that their license must be renewed with a department-approved renewal form. The department notice may be sent electronically.

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4.10 Renewal of license: 30 days prior to expiration. Completed department-approved renewal forms must be received by the department with the renewal fee and required documentation at least thirty (30) calendar days prior to the expiration date of the license. The renewal request is considered incomplete if the renewal fee and required documentation are not submitted with the renewal form.

4.10.1 Renewal process. Licenses are renewed in the same manner and subject to the same conditions as the issuance of the original license and upon payment of a renewal fee. See 22 M.R.S.A. §2017.

4.10.2 Renewal documentation. With the completed department-approved renewal form, the licensee must submit at least the following information:

4.10.2.1 A copy of the most recent inspection report and other pertinent documentation prepared by CLIA or its agent, or an accreditation agency; and

4.10.2.2 Other information required by the department.

REFUSAL TO ISSUE OR RENEW A LICENSE

4.11 Refusal to issue or renew a license. The department may refuse to issue or renew a state-issued medical laboratory license, based on any of the following criteria:

4.11.1 Misrepresentation, materially incorrect or insufficient information on the license application or renewal form;

4.11.2 The premises do not meet the requirements for issuing or renewing a license;

4.11.3 The designated laboratory director does not meet CLIA requirements;

4.11.4 Failure to comply with any of these rules;

4.11.5 Knowingly accepting an assignment for medical laboratory tests or specimens from, and rendering a report to, persons not authorized by law to submit specimens;

4.11.6 Conviction of a Class A, B or C crime or a similar crime in other jurisdictions;

4.11.7 Conviction of any crime under the laws of any state or the United States arising out of or in connection with the operation of a medical laboratory; or

4.11.8 Knowingly lending the use of the name of a licensed medical laboratory or its director to an unlicensed medical laboratory. See 22 M.R.S.A. §2035.

SUSPENSION or REVOCATION

4.12 Suspension or revocation of license. The department may suspend or revoke a medical laboratory's license in accordance with Section 11.5 of these rules.

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SECTION 5. FEES

LICENSE FEES

- 5.1 Nonrefundable fees.** Fees required by these rules may not be refunded to the applicant or licensee under any circumstances. See 22 M.R.S.A. §2020.
- 5.2 Application fees.** The license application fees are:
- 5.2.1** \$500 for the first category of testing; and
- 5.2.2** \$60 for each additional category.
- 5.3 Renewal fees.** The license renewal fees are:
- 5.3.1** \$200 for the first category of testing; and
- 5.3.2** \$60 for each additional category. See 22 M.R.S.A. §2017.
- 5.4 Duplicate license fee.** A licensee may obtain a duplicate copy of a current license upon payment of a \$2.00 fee per copy to the department. See 22 M.R.S.A. §2022.
- 5.5 Rebates or fee splitting prohibited.** The owner or director of a licensed medical laboratory, either personally or through an agent, shall not offer or imply to offer rebates or other fee-splitting inducements to persons submitting specimens to the laboratory for testing.
- 5.5.1** The owner or director of a licensed medical laboratory shall not participate in any fee-splitting arrangement. This applies to contents of fee schedules, billing methods or personal solicitation.
- 5.5.2** The contractual provision of laboratory services for a fixed fee independent of the number of specimens submitted for testing is a violation of these rules. See 22 M.R.S.A. §2033.

HSL PERMIT FEES

- 5.6 Fee for permit.** The HSL permit fee is \$100. HSL permit fees are nonrefundable. HSL permits expire 24 months after date issued. HSL permits are not renewable.
- 5.7 Duplicate permit fee.** A HSL permit-holder may obtain a copy of the current permit upon payment of a \$2.00 fee per copy to the department.
- 5.8 Fee-splitting and other prohibitions.** HSLs must comply with Section 5.5 of these rules.

SECTION 6. LABORATORY OPERATION

- 6.1. Medical laboratory operation.** The operation of medical laboratories must comply with applicable provisions set out in these rules.
- 6.2. Performance standards.** Medical laboratories are subject to performance standards in accordance with these rules. Performance standards are essential for the achievement of accurate, reliable results and the protection of public health. See 22 M.R.S.A. §2023(5).
- 6.3. Records.** Medical laboratories must maintain laboratory records, including but not limited to reports of laboratory tests. Upon request, laboratory records must be available at all times for inspection by the department. Laboratory records must be retained for 6 years, except when the CLIA record retention requirements establish a lesser or greater time period. See 22 M.R.S.A. §2034.
- 6.4. Physician requested tests.** A medical laboratory shall perform patient testing only at the request of a licensed physician or person authorized by Maine law to request and use the findings of laboratory testing. See 22 M.R.S.A. §2030(1).
- 6.4.1. Exception.** Without a physician's or authorized person's request, a medical laboratory may examine specimens for a limited number of tests including but not limited to the following:
- 6.4.1.1** Urine pregnancy testing;
 - 6.4.1.2** Cholesterol testing;
 - 6.4.1.3** Colon cancer testing;
 - 6.4.1.4** Fecal occult blood testing; and
 - 6.4.1.4** Glucose testing for persons previously diagnosed with diabetes. See 22 M.R.S.A. §2030(2).
- 6.4.2. Option.** These rules do not require medical laboratories to perform any test without a physician's or authorized person's request, including urine pregnancy testing, cholesterol testing, colon cancer testing, fecal occult blood testing, or glucose testing of persons with diabetes. See 22 M.R.S.A. §2030(3).
- 6.5. Reference laboratory testing.** A medical laboratory that does not perform a specific test may make a referral to have the test performed by a reference laboratory that is CLIA certified to perform the test. The test report shall identify the reference laboratory and shall bear or be accompanied by a clear statement that the findings were obtained by the reference laboratory. See 22 M.R.S.A. §2015.
- 6.6. Test results.** Test results are reported directly to the licensed physician or authorized person who requested the test, or to their designee. A report of test results issued by a medical

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laboratory must clearly identify that medical laboratory and the director. See 22 M.R.S.A. §2031.

- 6.7 Specimens.** The following persons may collect or process specimens: licensed health care professionals; designees of licensed health care professionals acting within their scope of practice; and qualified medical laboratory personnel who are authorized by the director of the medical laboratory. See 22 M.R.S.A. §2032.
- 6.8 Maternal AFP testing standards.** Medical laboratories performing maternal AFP testing, including AFP4 testing (AFP), unconjugated Estriol (UE3), Human Chorionic Gonadotrophin (HCG) and dimeric Inhibin A (DIA) must at a minimum adhere to the following standards of performance:
- 6.8.1 Test volume.** The laboratory must perform a minimum test volume of twenty-five (25) patient tests per week.
- 6.8.2 Reference data.** The laboratory must establish its own population-based reference data for each maternal screening test that is performed by the laboratory (maternal AFP, UE3, HCG and DIA) using the method chosen for testing and samples obtained from the population to be screened.
- 6.8.2.1** Individual test results must be expressed as multiples of the unaffected population median (Multiples of the Median or MoM) which is obtained by dividing the test value by the median value for the relevant gestational week.
- 6.8.2.2** Since the MoM is a ratio of two concentrations, the MoM value can be readily adjusted to take into account the other variables like maternal weight and ethnicity that affect the interpretation of biochemical markers.
- 6.8.2.3** Medical laboratories must update their established medians at least annually.
- 6.8.3 Laboratory report.** The laboratory report must be simple and clear, presenting the test results in units of assay measurement and in MoM values and a categorization into screen-positive or screen-negative according to pre-assigned criteria.
- 6.8.3.1** Risk assessment must be given for Down Syndrome (DS) screen-positives and optionally for screen-negatives.
- 6.8.4 Review and follow-up guidelines.** The laboratory must establish written guidelines specifying when results need to be reviewed and follow-up recommendations made.
- 6.8.4.1** The laboratory shall recommend that women who screen positive for a Neural Tube Defect (NTD) or DS whose gestational age was determined by Last Menstrual Period (LMP) should have an ultrasound scan to estimate gestational age.

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- 6.8.4.1.1** The laboratory must revise the gestational age and recalculate the risk only if the difference between the ultrasound estimate of gestational age and the LMP estimate is greater than the laboratory's preset number of days.
- 6.8.4.2** The laboratory shall recommend that women with an ultrasound dated gestational age who are screen-positive for NTD should consider having a detailed ultrasound to identify the cranial markers of spina bifida and to determine whether spina bifida is present or absent.
- 6.8.4.3** The laboratory shall recommend that women with an ultrasound dated gestational age who are screen-positive for DS should consider having an amniocentesis performed for a rapid diagnosis of DS using PCR (Polymerase Chain Reaction) or FISH (Fluorescence IN SITU Hybridization) followed by a karyotype.
- 6.8.4.4** The laboratory shall request outcome information on all pregnancies in order to determine the false-positive and false-negative rates.
- 6.8.4.5** Information on test results and pregnancy outcomes shall be provided to the department upon request. See 22 M.R.S.A. §2023(5).
- 6.9** **Restriction: pathologic anatomy examinations.** A medical laboratory may not perform examinations in the field of pathologic anatomy, including exfoliative cytology, unless the director or an employee of the laboratory is a diplomat of the American Board of Pathology certified in pathologic anatomy or the American Osteopathic Board of Pathology certified in pathologic anatomy, or unless the director is a physician licensed to practice medicine in the State of Maine who possesses special qualifications acceptable to the department, or unless the director is a dentist licensed in Maine and is certified by the American Board of Oral Pathology. See 22 M.R.S.A. §2029(3).
- 6.10** **Itemized billing statements.** A medical laboratory that performs services under these rules shall send an itemized billing statement to the patient.

SECTION 7. PERSONNEL

- 7.1 Personnel.** Laboratory personnel must meet state personnel requirements and federal CLIA personnel requirements for medical laboratories including qualifications for laboratory directors, general supervisors, technical supervisors, technical consultants, clinical consultants, and testing personnel.
- 7.2 Laboratory Director.** Each medical laboratory must have a director who is a legal resident of the State of Maine. See 22 M.R.S.A. §2029.
- 7.2.1 Compliance.** The laboratory director is responsible for the medical laboratory's compliance with these rules. See 22 M.R.S.A. §2014(3).
- 7.2.2 Accessible.** The director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.
- 7.2.3 On-site.** The director, if not a full time employee, must make and document a minimum of monthly visits to the laboratory. Up to one-half of the monthly visits in a six month period may be made by a qualified supervisor on the director's staff.
- 7.2.4 Limitation.** No individual shall be director of more than 5 laboratories that perform CLIA non-waived tests. This limitation applies whether the medical laboratory is licensed or exempt from state licensure.
- 7.2.5 Absence.** If the director is to be absent for a period exceeding one month, then the director must arrange for another person, qualified to be a laboratory director, to be accessible to laboratory personnel.
- 7.2.6 Director qualifications.** The laboratory director must comply with state personnel requirements in these rules and with federal CLIA personnel qualifications and requirements. The laboratory director must possess one of the following qualifications:
- 7.2.6.1 Certification.** The individual is a physician licensed to practice medicine in the State of Maine who is certified by the American Board of Pathology or the American Osteopathic Board of Pathology, or an individual who is a physician who possesses qualifications acceptable to the department that are equivalent to such certification; or
- 7.2.6.2 Special qualifications.** The individual is a physician licensed to practice medicine with special qualifications acceptable to the department; or
- 7.2.6.3 Qualified persons other than physicians.** The individual has an earned doctorate degree in a chemical, physical or biological science from an accredited institution and either is certified in at least one laboratory specialty by the American Board of Clinical Chemistry, American Board of Medical Microbiology or other national accrediting board acceptable to the department.

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7.2.6.3.1 Medical laboratories directed by persons qualified under 7.2.6.3 must only perform those examinations within the scientific area in which members of the staff are trained and certified. See 22 M.R.S.A. §2029(3).

7.2.7 Continued employment. Individuals qualified and employed as a laboratory director of state licensed medical laboratories prior to the effective date of these rules shall be permitted to continue to function in that capacity as long as they maintain employment at that specific laboratory where they are currently employed.

7.3 Laboratory personnel. Laboratory personnel must meet state personnel requirements and federal CLIA personnel requirements for medical laboratories. See Section 1.12 of these rules.

SECTION 8. PROFICIENCY TESTING

- 8.1 Proficiency testing.** Medical laboratories must comply with applicable federal CLIA proficiency testing requirements and state proficiency testing requirements set out in these rules.
- 8.2 CLIA-approved proficiency testing program.** Proficiency in the performance of the tests offered by the medical laboratory is demonstrated through successful participation in a CLIA-approved proficiency testing program. The medical laboratory must have documentation of enrollment in a CLIA-approved proficiency testing program. Upon request, the laboratory's performance records must be provided to the department. See 22 M.R.S.A. §2025.
- 8.3 Proficiency testing: employee drug testing.** Medical laboratories testing employees and applicants for substances of abuse for employment related purposes must demonstrate satisfactory performance in proficiency testing in compliance with the laws and rules governing Maine Drug Testing Laboratories. See 26 M.R.S.A. §§ 681-690 and 10-144 C.M.R. Chapter 265.

SECTION 9. BUILDING AND SAFETY STANDARDS

- 9.1 Building codes.** The laboratory building must comply with applicable state and local plumbing, heating, lighting, ventilation, and electrical codes, and other similar requirements. 22 M.R.S.A. §2023(2).
- 9.2 Specimen collection areas.** Specimen collection areas must comply with the following standards:
- 9.2.1** Collection areas must have adequate workspace to separate clean and contaminated tasks;
 - 9.2.2** Collection areas must have adequate space for patient seating;
 - 9.2.3** Collection areas must have adequate space for washing stations;
 - 9.2.4** Collection areas must be designed to protect patient privacy and confidentiality; and
 - 9.2.5** The urine and feces specimen collection room must be equipped with a lavatory. 22 M.R.S.A. §2023(3).
- 9.3 Safety policies and procedures.** Medical laboratories must have written policies and procedures regarding safety that are available to the department, upon request.
- 9.4 Infection control program.** Medical laboratories must develop and implement a written infection control program that includes at least the following provisions:
- 9.4.1 Hand washing.** Policies and training on proper hand washing techniques and universal precautions;
 - 9.4.2 Disposal of laboratory waste.** Policies and training for the safe disposal of laboratory waste.
 - 9.4.2.1** Potentially infectious materials and waste must be handled, stored and disposed in accordance with good laboratory practices and the Biomedical Waste Management Rules of the Maine Department of Environmental Protection. See 06-096 Code of Maine Rules (C.M.R.) Chapter 900.
 - 9.4.2.2** Chemical waste must be disposed of in accordance with good laboratory practices and applicable rules of the Maine Department of Environmental Protection and applicable provisions of the federal Occupational Safety and Health Administration (OSHA). See 06-096 C.M.R. Chapters 850-857, and 29 Code of Federal Regulations (C.F.R.) Subtitle B, Chapter XVII.

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- 9.5 Contamination precaution policies.** Medical laboratories must develop and implement written contamination precaution policies and practices that include at least the following provisions:
- 9.5.1** The use of tobacco products, including smoking, is prohibited in the specimen collection, processing and testing areas of the laboratory;
 - 9.5.2** Eating and drinking is prohibited in the specimen collection, processing and testing areas of the laboratory;
 - 9.5.3** Applying cosmetics is prohibited in the specimen collection, processing and testing areas of the laboratory; and
 - 9.5.4** Any other precautions needed to avoid contamination.
- 9.6 Demonstrated knowledge of safety precautions.** Precautions must be known and demonstrated by laboratory employees to ensure safety and freedom from unnecessary physical, chemical, biological and electrical hazards.
- 9.7 Chemicals and solvents.** Volatile chemicals and flammable solvents must be stored according to manufacturer's instructions in areas where ignition is unlikely and where restricted from open flame or heat. Medical laboratories must comply with applicable state and federal regulations.
- 9.8 Hazardous material.** Appropriate enclosures, such as fume hoods and biological safety cabinets, must be utilized when handling and storing hazardous materials.
- 9.9 Posting precautions and laws.** Medical laboratories must post precautions and occupational safety and health laws in areas frequented by and visible to employees.
- 9.10 Fire prevention and control program.** The laboratory must develop and implement a written fire prevention and control program that includes at least the following provisions:
- 9.10.1** All entrances and exits to the laboratory must be accessible at all times;
 - 9.10.2** All means of egress shall be maintained free from obstruction;
 - 9.10.3** All freestanding tanks of compressed gases must be firmly secured to the adjacent wall; and
 - 9.10.4** A written plan for fire safety and emergency evacuation shall be adopted and posted in key areas throughout the laboratory.
- 9.11 Report fires to department.** The medical laboratory must report to the department, by the next business day, any fire that:
- 9.11.1** Requires movement or evacuation of patients;

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- 9.11.2** Results in an injury to a patient;
- 9.11.3** Results in an injury to an employee;
- 9.11.4** Results in loss of patient specimens;
- 9.11.5** Results in damage to laboratory equipment.

SECTION 10. INSPECTIONS

- 10.1 Inspection of premises and operation.** The department is authorized to inspect the premises and operation of all medical laboratories, subject to state licensure or any provisions of the Maine Medical Laboratory Act. See 22 M.R.S.A. §2024.
- 10.1.1 Exempt from state inspection.** Medical laboratories are exempt from state inspection if they possess a valid:
- 10.1.1.1** CLIA Certificate of Compliance; or
- 10.1.1.2** CLIA Certificate of Accreditation.
- 10.1.2 State inspection required.** Medical laboratories are subject to state inspection every three (3) years if they possess a valid:
- 10.1.2.1** CLIA Certificate of Waiver; or
- 10.1.2.2** CLIA Provider-Performed Microscopy Procedures Certificate (PPM).
- 10.1.3 CLIA standards used for state inspections.** CLIA standards for a Certificate of Waiver and a Certificate of Provider-Performed Microscopy Procedures (PPM) are used during state inspections to determine compliance with these rules, in accordance with Section 2.2 of these rules.
- 10.2 Notice of inspection.** The department must notify medical laboratories in writing at least ten (10) business days prior to a state inspection, except as set out in Sections 10.2.1 and 10.2.2 of these rules.
- 10.2.1 Complaints and suspected violations of rules.** Without notice, medical laboratories may be inspected by the department in response to a complaint or suspected violation of these rules.
- 10.2.2 Code violations.** Medical laboratories may be inspected without notice by the department, or another state agency, or a municipality for violations of building codes, fire codes, life safety codes or for other purposes unrelated to laboratory licensing or accreditation.
- 10.3 Statement of deficiency.** The department, after inspection, shall issue a written statement of deficiency when the department determines that a violation of these rules has occurred and the laboratory shall be required to submit a plan of correction.
- 10.4 Plan of correction.** Except as provided in Section 10.4.1 of these rules, the laboratory must submit a written plan of correction to the department within 10 business days of receipt of the statement of deficiency.

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- 10.4.1 Federal plan of correction: accepted by department.** When a plan of correction is required, the department shall accept a CLIA-accepted federally required plan of correction when the federal plan of correction addresses the violations in the state-issued statement of deficiency.
- 10.5 Failure to implement plan of correction: directed plan of correction.** When a medical laboratory fails to implement the plan of correction, the department is authorized to issue a directed plan of correction that must be implemented by the laboratory. The department may take additional enforcement actions in accordance with these rules.

SECTION 11. ENFORCEMENT AND APPEALS

- 11.1 Compliance.** Applicants and licensees must comply with these rules.
- 11.2 Operating an unlicensed nonexempt laboratory.** It is unlawful for a person to operate, maintain, direct or engage in the business of operating a medical laboratory unless the person has obtained a medical laboratory license from the department. The performance of any act set out in this section constitutes a crime punishable, upon conviction, by a fine not less than \$50 and not more than \$500, or by imprisonment for not more than one year, or both. See 22 M.R.S.A. §§ 2037(1) and 2038.
- 11.3 Unsupervised laboratory.** It is unlawful for a person to conduct, maintain or operate a medical laboratory unless the medical laboratory is under the direct and responsible supervision and direction of a person possessing the required qualifications as set out in these rules. The performance of any act set out in this section constitutes a crime punishable, upon conviction, by a fine not less than \$50 and not more than \$500, or by imprisonment for not more than one year, or both. See 22 M.R.S.A. §§ 2037(2) and 2038.
- 11.4 Injunction.** In addition to other available remedies, the department through the Office of the Attorney General may bring an action for an injunction to restrain violations of these rules or to enjoin the continued operation of a medical laboratory. See 22 M.R.S.A. §2039.
- 11.5 Suspension or revocation of license.** The department may petition the District Court to suspend or revoke a state-issued medical laboratory license. Before the Court renders a decision, the license-holder may be heard to show cause why a license should not be suspended or revoked. See 22 M.R.S.A. §2036.
- 11.6 Grounds for suspension or revocation of license.** Grounds for the suspension or revocation of a state issued license include but are not limited to the following:
- 11.6.1** Violation of these rules and applicable laws;
 - 11.6.2** Permitting, aiding or abetting the commission of any illegal act at the laboratory;
 - 11.6.3** Conduct or practices detrimental to the welfare of a client;
 - 11.6.4** The conviction of the laboratory owner or director of a Class A, B or C crime or a similar crime in any jurisdiction;
 - 11.6.5** The conviction of the laboratory owner or director of any crime arising out of, or in connection with, the operation of a medical laboratory; See 22 M.R.S.A. §2035;
 - 11.6.6** Knowingly lending the use of the name of a licensed medical laboratory or its director to an unlicensed medical laboratory;

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- 11.6.7** Knowingly accepting from an unauthorized person an assignment for medical laboratory tests or specimens from and the rendering of a report of those test results to the unauthorized person; See 22 M.R.S.A. 2035 (2);
- 11.6.8** Incompetent or unprofessional conduct, including but not limited to:
- 11.6.8.1** Fabricating results;
 - 11.6.8.2** Unauthorized disclosure of confidential information;
 - 11.6.8.3** Willful misrepresentation of results;
 - 11.6.8.4** False or deceptive advertising; or
- 11.6.9** Making a false or deceptive representation on an initial application or renewal form for a state issued medical laboratory license.
- 11.7** **Emergency suspension or revocation of license.** When the department finds conditions exist that, in the opinion of the department, immediately endanger the health or safety of patients or otherwise create an emergency, the department may petition the District Court to immediately suspend or revoke the license. See 4 M.R.S.A. §184(6).
- 11.8** **Appeal.** Any person aggrieved by a final agency action of the department may file an appeal with the District Court pursuant to Title 5, chapter 375 of the Maine Revised Statutes. See 22 M.R.S.A. §2040.

PART TWO
PERMITS FOR HEALTH SCREENING LABORATORIES

SECTION 12. HEALTH SCREENING LABORATORY (HSL)

12.1 Health screening laboratory (HSL). PART TWO of these rules govern health screening laboratories (HSLs) as defined in Section 1.11 of these rules.

12.1.1 Applicable rules. The purpose, applicable definitions and other provisions in Sections 1 through 11 of these rules apply to HSLs.

12.1.2 CLIA certification. HSLs must be CLIA certified and must comply with the federal CLIA standards, certification requirements and conditions of participation in accordance with Sections 2.1 and 2.2 of these rules.

12.1.2.1 A violation of any of the federal CLIA standards, certification requirements or conditions of participation constitutes a violation of HSL rules.

12.2 Responsibility for compliance. The HSL applicant and permit-holder must comply with the provisions of these rules.

12.3 Permit required. Except as set out in Section 1.11.1 of these rules, no medical laboratory is authorized to operate as a HSL without a department-issued permit. Prior to securing a department-issued permit, no specimens may be obtained and no testing may be performed.

12.3.1 Term of permit. The issued permit expires 24 months after the date issued. Permits are not renewable. Upon approval of a new HSL application, a new permit is issued.

12.3.2 Valid permit. A permit is valid only for the HSL identified on the issued permit.

12.3.3 Nontransferable. An issued HSL permit is not transferable or assignable.

12.3.4 Permit posted at test site. During the HSL event, the issued permit must be posted at the HSL location where it is visible to the public.

12.4 Exempt from state licensure. HSLs are exempt from state licensure. See 22 M.R.S.A. §2013-A(1)(G).

SECTION 13. HSL PERMIT APPLICATION

- 13.1 Permit application.** Application for a permit must be made on a department-approved form. A permit application is not considered complete until the department receives the application form, required documents, and the application fee, set out in Section 5.6 of these rules.
- 13.2 Required information.** An application for a permit must include at least the following information:
- 13.2.1** The HSL owner's name, address and contact information;
 - 13.2.2** Location (street and city address) of the HSL event(s);
 - 13.2.3** The HSL's CLIA certification information;
 - 13.2.4** Health screening tests that will be performed;
 - 13.2.5** Name and credentials of personnel who will perform health screening tests and client education;
 - 13.2.6** Identification of each piece of equipment that will be used at the health screening location, including equipment serial number or similar identification;
 - 13.2.7** Written policies and practices to ensure safety during the HSL event including but not limited policies regarding contamination, fire prevention and infection control precautions;
 - 13.2.8** The HSLs health education protocols;
 - 13.2.9** Copies of health education information to be distributed to clients during the HSL event; and
 - 13.2.10** Other information required by the department.
- 13.3 Department decision.** After a review of the application and required documentation, the department shall issue the HSL permit, or send the applicant a written decision that the permit application is denied, the basis for the decision, and the right to appeal.
- 13.3.1 Appeal.** The permit applicant may appeal the department's decision in accordance with Section 19.8 of these rules.
- 13.4 Information on a permit.** The issued permit must contain at least the following information:
- 13.4.1** The name, address and contact information of the legal owner(s) of the HSL;
 - 13.4.2** The health screening tests the HSL is authorized to perform;

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13.4.3 The effective date and the expiration date of the issued permit; and

13.4.4 Other information required by the department.

SECTION 14. HSL OPERATION

- 14.1 Itinerary sent to department.** Fourteen (14) business days prior to the earliest scheduled screening event, the department must receive an itinerary of planned HSL events from the permit-holder.
- 14.1.1 Changes in itinerary.** Notice of any change that is made to an itinerary must be received by the department at least one business day prior to the changed screening event.
- 14.1.2 Valid use of permit.** The HSL permit is valid only for those HSL events identified on the itinerary and submitted changes received by the department.
- 14.2 Individuals request testing.** Individuals request the screening test and the test results are given to the individual at the time the on-site testing occurs. A physician's referral is not needed for an individual to be tested by a HSL.
- 14.3 Authorized HSL tests.** HSLs may be authorized to perform any of the following health screening tests. All other testing by HSLs is prohibited.
- 14.3.1** Fecal occult blood testing;
- 14.3.2** Colon cancer testing;
- 14.3.3** Testing for total cholesterol, triglycerides, high density lipoprotein cholesterol (HDL); low density lipoprotein cholesterol (LDL); and
- 14.3.4** Glucose testing.
- 14.4 Client present during tests.** HSL tests must be performed while the client is present.
- 14.5 Screening purposes only.** The results of the testing must not be used for diagnostic purposes. The results of the HSL testing are used for health screening purposes only.
- 14.6 Specimen referrals prohibited.** Referral of specimens to other laboratories is prohibited. Specimens must only be taken for on-site testing of fecal occult blood, colon cancer, total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol or glucose.
- 14.7 Reporting test results to client.** The results of the screening tests must be in writing and provided only to the client and, with the client's consent, the client's physician. The department-approved report form must contain at least the following information:
- 14.7.1** The name of the HSL and contact information;
- 14.7.2** The date and location of the HSL testing;

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- 14.7.3** Whether the client was fasting at the time of testing, as this affects triglyceride and glucose results;
 - 14.7.4** The HSL test results; and
 - 14.7.5** The name(s), initials or other identification of the person(s) performing the HSL testing and health education for the client.
- 14.8 Client health education.** A qualified HSL educator provides health education information to clients in accordance with HSL policies and procedures. Health education information is provided to help clients maintain or improve their health status.
- 14.9 Follow-up referral information.** Information regarding follow-up options is available to clients, including referral to physicians or other authorized persons if the client does not have a primary care physician.
- 14.9.1** Referrals must not be made to any physician or authorized person who has a direct financial interest in the HSL.

SECTION 15. HSL PERFORMANCE STANDARDS AND PERSONNEL

- 15.1 Performance standards.** HSLs must comply with applicable performance standards in Section 6 of these rules and those set out in this section. Performance standards are essential for the achievement of accurate, reliable results and the protection of public health.
- 15.2 Federal CLIA standards.** HSLs must comply with the federal CLIA standards, certification requirements and conditions of participation in accordance with Sections 2.1 and 2.2 of these rules.
- 15.2.1** A violation of any of the federal CLIA standards, certification requirements or conditions of participation constitutes a violation of HSL rules.
- 15.3 On-site HSL area.** The on-site HSL testing area must be in an enclosed area separate from other activities.
- 15.3.1** If a separate room is not available, suitable partitions must be used to limit the risk of potential blood borne pathogen exposure and to provide patient confidentiality.
- 15.4 Laboratory equipment.** HSL test equipment must be calibrated for accuracy and linearity according to the manufacturer's instructions. The HSL testing equipment must produce linear results throughout the range at which results will be reported and have a digital readout and a printed result.
- 15.4.1** Only instruments or methods capable of direct measurement are authorized for HDL cholesterol testing.
- 15.4.2** LDL cholesterol levels may be calculated.

PERSONNEL

- 15.5 Qualified personnel.** Only qualified personnel may perform testing and health education at on-site HSL events.
- 15.5.1 Multiple roles.** HSL personnel may fulfill multiple roles provided they meet the qualifications for each role. This rule regarding multiple roles applies only to HSLs.
- 15.6 HSL medical director.** A HSL medical director is responsible for providing oversight for the HSL, including establishing and implementing written policies and procedures that cover all phases of the health screening process.
- 15.6.1** The HSL medical director determines which tests shall be performed and provides guidance as to the focus and content of the health education provided based on the test results.
- 15.6.2** The HSL medical director establishes written protocols for referrals and suggested follow-up information given to clients.

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- 15.6.3** The HSL medical director does not have to be on-site during a HSL event.
- 15.6.4** The HSL medical director may delegate technical oversight of the HSL testing to the CLIA Laboratory Director or a designee. See Section 1.8.
- 15.6.5** An individual who meets one of the following minimum qualifications may be a HSL medical director:
 - 15.6.5.1** A physician licensed to practice medicine in the State of Maine.
 - 15.6.5.2** A midlevel practitioner authorized to practice in the State of Maine.
 - 15.6.5.3** Other person with credentials acceptable to the department.
- 15.7** **New HSL Medical Director.** Prior notification and approval of the department must be obtained prior to hiring a new HSL medical director for the health screening laboratory.
- 15.8** **HSL supervisor.** A HSL supervisor is responsible for the day-to-day operation of the HSL and must be present on-site whenever testing is performed.
 - 15.8.1** The HSL supervisor is responsible for supervising the personnel that perform testing and health education.
 - 15.8.2** The HSL supervisor must coordinate and monitor the screening and personnel to ensure that all protocols are followed and personnel are properly trained.
 - 15.8.3** The HSL supervisor must possess the following minimum qualifications:
 - 15.8.3.1** Qualify as a HSL technician as described in Section 15.9 of these rules.
 - 15.8.3.2** Possess at least an associate level degree in one of the health or science disciplines or other credentials acceptable to the department, and documentation of at least three months experience in a health care setting or HSL laboratory.
 - 15.8.3.3** Possess knowledge of basic first aid.
 - 15.8.3.4** Possess knowledge of applicable federal Occupational Safety and Health Administration laws (OSHA).
 - 15.8.3.5** Have documentation of six months of laboratory or supervisory experience in a health care setting or HSL laboratory.
- 15.9** **HSL technician.** A HSL technician is responsible for following all laboratory procedures and protocols including procedures and protocols for obtaining specimens, performing the tests and recording results.

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15.9.1 The HSL technician must possess the following minimum qualifications:

15.9.1.1 A high school diploma or a general educational development (GED) certificate.

15.9.1.2 Training, including instruction and direct hands-on experience, conducted by qualified trainers on the same type of instrument used by the laboratory. Training must include but is not limited to equipment calibration, maintenance, and operation, quality control testing, detecting errors and troubleshooting problems.

15.9.1.3 Training on pertinent OSHA laws.

15.9.1.4 Documentation of orientation under direct supervision covering such aspects of the laboratory's operation as specimen collection, safety, client relations, testing, reporting and confidentiality.

15.10 HSL educator. A HSL educator is responsible for reviewing the test results with the client and providing health education to the client.

15.10.1 Clients receive pertinent information from the HSL educator based on the HSLs established protocols and the pertinent recommendations of established authorities such as the Maine Cardiovascular Health Council's guidelines for blood pressure screening, the Adult Treatment Panel of the National Cholesterol Education Program, and the American Diabetes Association's Clinical Practice Recommendations.

15.10.2 The HSL educator must possess the following minimum qualifications:

15.10.2.1 An associate level degree in one of the health or science disciplines or other credentials acceptable to the department.

15.10.2.2 Documentation of training on the clinical guidelines and health education curriculum of the Maine Cardiovascular Health Council guidelines for blood pressure screening or its equivalent, the Adult Treatment Panel of the National Cholesterol Education Program or its equivalent, and the American Diabetes Association's Clinical Practice Recommendations or its equivalent.

15.10.2.3 Documentation of orientation under direct supervision covering such aspects of health education as the testing process, the interpretation of test results, the provision of health education material to clients, appropriate actions when a client's results warrant immediate intervention, and confidentiality requirements.

SECTION 16. HSL RECORDS AND POLICIES

- 16.1 HSL records.** HSL records including but not limited to records of laboratory services and copies of reports of laboratory tests must be kept in accordance with these rules.
- 16.2 HSL record maintenance and retention.** HSLs must maintain and retain at least the following records and, upon request, make them available for inspection by the department:
- 16.2.1** Copies of laboratory test reports must be maintained in a confidential manner for a minimum of two (2) years.
 - 16.2.2** Laboratory records including quality assurance, equipment maintenance, and personnel records must be retained for a minimum of two (2) years.
 - 16.2.3** Confidentiality must be maintained when disposing of records.
- 16.3 HSL policies and procedures.** The HSL must have written policies and procedures that are available to the HSL staff and, upon request, to the department. There must be written policies and procedures at least for the following:
- 16.3.1** Specimen collection;
 - 16.3.2** Performing tests;
 - 16.3.3** Equipment maintenance;
 - 16.3.4** Quality control;
 - 16.3.5** Safety;
 - 16.3.6** Reporting test results to clients and providing health education;
 - 16.3.7** Confidentiality of all client information;
 - 16.3.8** Client referral guidelines based on an individual's test results, clinical protocols, and the HSLs policy;
 - 16.3.9** HSL personnel training guidelines and required documentation; and
 - 16.3.10** Other policies and procedures to safely operate the on-site HSL.

SECTION 17. HSL QUALITY CONTROL AND PROFICIENCY TESTING

- 17.1 Quality Control.** Quality control must be practiced and documented as a routine part of the HSLs operation.
- 17.2 Laboratory instruments.** Each HSL instrument must be calibrated for accuracy and linearity according to the manufacturer's instructions.
- 17.2.1** Each day (24 hour shift) of operation, each instrument must be checked for proper function according to the manufacturer's instructions.
- 17.2.2** Each day (24-hour shift), each instrument must be checked with two different levels of quality control material.
- 17.2.3** If available, standards and controls must be of the same matrix as client specimen, such as whole blood, serum, and similar specimen.
- 17.2.4** Acceptable ranges must be established for all aspects of the quality control program. Client test results must not be reported until causes for out of range quality control results have been resolved.
- 17.3 Repeat test.** Client test results that meet the following criteria must be repeated at the same sitting:
- 17.3.1** Total cholesterol test results on clients that are above 300 mg/dL or below 100 mg/dL.
- 17.3.2** HDL cholesterol results above 100 mg/dl or below 15 mg/dl.
- 17.3.3** Triglyceride results above 400 mg/dl.
- 17.3.4** Glucose results above 350 mg/dl or below 50 mg/dl.

PROFICIENCY TESTING

- 17.4 Proficiency testing program.** HSLs must be enrolled and successfully participate in a CLIA proficiency testing program for each test performed.
- 17.5 Documentation of enrollment.** Documentation of enrollment in a CLIA proficiency testing program and records of the laboratory's performance must be provided upon request to the department.
- 17.6 Instrument performance records.** HSL records must be maintained on the performance of each instrument.

SECTION 18. HSL SAFETY STANDARDS AND INSPECTIONS

- 18.1 Safety.** HSLs must comply with the rules in this section and applicable standards in Section 9 of these rules.
- 18.2 Laboratory safety.** Applicable OSHA laws must be known and demonstrated by HSL personnel to ensure freedom from unnecessary physical, chemical, biological and electrical hazards.
- 18.3 Prohibited activity.** Smoking, drinking and eating are prohibited in the HSL work area.
- 18.4 Infectious material and waste.** Potentially infectious materials and waste must be handled, stored and disposed in accordance with the Maine Department of Environmental Protection, Biomedical Waste Management Rules, 06-096 C.M.R. Chapter 900.
- 18.5 Inspection.** HSLs are subject to inspection at any time testing is offered at a HSL screening location.
- 18.5.1 Complaints and suspected violations of rules.** HSLs are subject to inspection by the department in response to a complaint or suspected violation of these rules.
- 18.5.2 Code violations.** HSLs are subject to inspection by the department, or another state agency, or a municipality for suspected violations of building codes, fire codes, life safety codes or for other similar purposes.

SECTION 19. HSL ENFORCEMENT PROCEDURES AND APPEALS

- 19.1 Compliance.** HSL permit-applicants and permit-holders must comply with these rules. HSLs that fail to comply with these rules are subject to the enforcement provisions in this section and applicable provisions in Section 11 of these rules.
- 19.2 Operating a HSL without a permit: fines or imprisonment.** A person who operates, maintains, directs or engages in the business of operating a HSL without a department-issued permit is in violation of these rules. The performance of any of the acts set out in this section constitutes a crime punishable, upon conviction, by a fine not less than \$50 and not more than \$500, or by imprisonment for not more than one year, or both.
- 19.3 Unsupervised HSL: fines or imprisonment.** A person who conducts, maintains or operates a HSL without the direct and responsible supervision and direction of a person possessing the required qualifications is in violation of these rules. The performance of any of the acts set out in this section constitutes a crime punishable, upon conviction, by a fine not less than \$50 and not more than \$500, or by imprisonment for not more than one year, or both.
- 19.4 Injunction.** The department, through the Office of the Attorney General may, in addition to other available remedies, bring a court action for an injunction to restrain the operation of a HSL that is in violation of these rules or to enjoin the continued operation of a HSL until compliance with these rules is achieved.
- 19.5 Suspension or revocation of HSL permit.** The department may petition the District Court to suspend or revoke a HSL permit.
- 19.6 Grounds for suspension or revocation of HSL permit.** Grounds for the suspension or revocation of a HSL permit include but are not limited to the following:
- 19.6.1** A violation of these rules and applicable laws;
 - 19.6.2** Permitting, aiding or abetting the commission of any illegal act at the HSL;
 - 19.6.3** Conduct or practices detrimental to the welfare of a HSL client;
 - 19.6.4** A criminal conviction in any jurisdiction of the HSL medical director or the HSL supervisor arising out of or in connection with the operation of a HSL;
 - 19.6.5** Knowingly lending the use of the name of the HSL or the name of its director to a non-permitted HSL;
 - 19.6.6** Incompetent or unprofessional conduct, including but not limited to:
 - 19.6.6.1** Fabricating results;
 - 19.6.6.2** Unauthorized disclosure of confidential information;

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19.6.6.3 Willful misrepresentation of results;

19.6.6.4 False or deceptive advertising; or

19.6.7 Making a false or deceptive representation on an application for a department-issued HSL permit.

19.7 **Emergency suspension or revocation of HSL permit.** When the department finds conditions exist that, in the opinion of the department, immediately endanger the health or safety of clients or otherwise create an emergency, the department may petition the District Court to immediately suspend or revoke the HSL permit.

19.8 **Appeal.** Any person aggrieved by the final agency action of the department may file an appeal with the District Court pursuant to Title 5, chapter 375 of the Maine Revised Statutes. See 22 M.R.S.A. §2040.

STATUTORY AUTHORITY

22 M.R.S.A. Chapter 411;
22 M.R.S.A. §42;
22-A M.R.S.A. §205; and PL 2011, Ch 531.

REGULATORY HISTORY

EFFECTIVE DATE:

May 7, 1979

AMENDED:

December 27, 1988

May 1, 1990

EFFECTIVE DATE (ELECTRONIC CONVERSION):

May 5, 1996

NON-SUBSTANTIVE CORRECTION:

September 29, 1997 - replaced missing period in (4)(C).

AMENDED:

October 1, 1997

May 25, 1999

REPEALED and REPLACED:

May 9, 2012 – filing 2012-141