SUBCHAPTER 185-10
COMMONWEALTH HEALTH CARE PROFESSIONS
LICENSING BOARD REGULATIONS

Part 3000 Medical Laboratory Technologist/Technician

Part 3000 Medical Laboratory Regulations Subpart A - General

§ 185-10-3001 Basis for the Regulations

The regulations in this part are promulgated pursuant to the authority of 3 CMC chapter 2.

§ 185-10-3005 Definitions

As used in this part, the words and terms defined herein have the following meanings:

(a) **"Hospital base laboratory"** is synonymous with "medical laboratory," and means any facility which uses microbiological, serological, immunohematological, cytological, histological, chemical, hematological, biophysical, toxicological, or other methods for "in-vitro" examination of tissues, blood, urine, secretions or other human body fluids to aid in diagnosis, prevention or treatment of disease, or for the assessment of a disease or infirmity.

(b) **"Service laboratory"** means a clinical laboratory making service available directly or indirectly to the general medical profession.

(c) **"Private laboratory"** means a clinical laboratory set up for the sole purpose of performing tests on his or her patients in the private practice of a doctor owner.

(d) **"Quality Control"** means a continuous program of internal quality control, using substances of known content daily.

(e) **"Proficiency testing"** means a program of external quality control testing of unknown samples provided by a vendor approved by the US Health and Human Services (USHHS) in procedures for which the laboratory is licensed.

(f) **"Laboratory director"** means a person responsible for the administration of the technical and scientific operation of a clinical laboratory, e.g., a licensed director or private physician.

(g) **"Medical laboratory technician/technologist"** is synonymous with "clinical laboratory technician/technologist" and means one who performs test procedures and has special training in medical laboratory techniques, including physical, chemical, and microscopic analysis of body fluids and tissues.

(h) **"Active status"** means laboratory personnel engaged in clinical laboratory work full time or at least 15 hours per week continuously.

(i) **"Inactive status"** means laboratory personnel are no longer actively engaged in clinical laboratory work.

(j) **"Office laboratory assistant"** means a certification title of a technical employee working in a private laboratory, if such employee does not meet the qualification set forth for licensed laboratory personnel.

§ 185-10-3010 General Requirements

(a) No person, corporation, partnership, or other form of business entity may operate, conduct, issue a report from, or maintain a clinical laboratory without first meeting the requirements and applying for a license from the Board.

(b) "A service laboratory" shall be licensed by the Board and shall have a licensed laboratory director.

(c) "A private laboratory" shall be required, in lieu of a license, to possess a certificate of registration.

(d) "The Board" will make periodic visits to the clinical laboratories to offer consultation on methods, reagents, and equipment; to inspect the operation of the service for the patient.

Subpart B Licensure and Registration

§ 185-10-3015 Application of Laboratory

(a) **Application for and issuance of license.** An application for a license must be submitted on forms provided by the Board, providing complete information regarding the physical plant, management, personnel, extent of testing services to be provided, and other pertinent matters requested by the Board.

(b) **Fees.** Any required fee shall accompany such application.

(c) **Site survey.** Upon receipt of the application, the laboratory shall undergo a site survey of its physical plant to determine whether its facilities are adequate and in compliance with Board regulations.

(d) **Review of application.** The application and accompanying credentials shall be subject to Board review.

§ 185-10-3020 Renewal

(a) Term and renewal of license. A license shall be valid for twenty-four calendar months from the date of issue and shall expire on the last day of the twenty-fourth calendar month after issue or renewal. It must be renewed on or before the last day of the twenty-fourth calendar month after issue, except that if the last day of the period of validity falls on a Saturday, Sunday, or legal holiday, it must be renewed by the close of business of the next following business day.

(b) A renewal application must be made in writing, accompanied by the renewal fee. Also, each laboratory should provide a current list of its technical staff.

(c) Failure to reapply for renewal within one month of the expiration date shall result in termination of the license.

(d) Lapse of license for more than three months will require a site survey before the laboratory can be reinstated and resume its services.

(e) Upon acceptance of the renewal application, the laboratory shall be provided with a renewal license or seal to be affixed to the license.

§ 185-10-3025 Display of License

Validity display of the license. The license issued pursuant to the regulations in this subchapter shall be valid only for the laboratory and premises for which it is issued, and it shall be prominently displayed in such laboratory. Any such license shall become void 30 days after a change in laboratory location, ownership, and/or directorship, except that uninterrupted continuation of such license shall be permitted on re-application and approval of the Board.

Subpart C Minimum Standards of Medical Laboratories

§ 185-10-3030 Performance Standards

(a) Proficiency. Each laboratory shall participate in proficiency test programs as provided or approved by the Board to monitor the level of accuracy in test performance, such as the College of American Pathologists' quality evaluation program.

(b) Quality Control. There should be an adequate quality control program in effect, including the use of reference or control reagents and other biological samples, concurrent calibration standards, and control charts that record standard readings.

(c) Procedure Manuals. Manuals of appropriate, current laboratory methods shall be available at the workstations to which they apply.

Subpart D Specimens; Collection, Examination, Referrals

§ 185-10-3035 Specimen Collection

(a) No person other than a licensed physician or dentist may manipulate a patient for the collection of specimens, except that qualified technical personnel of a laboratory may collect blood, remove stomach contents, perform specific diagnostic skin tests, collect urine, or collect material for slides and cultures, under the sanction of the laboratory operator.

(b) Needles and syringes at blood drawing stations and in trays shall always be kept under security, guarded against unauthorized removal.

(c) A specimen may be accepted by a laboratory and referred to another laboratory for testing. In all cases, the name of the laboratory doing the work shall be shown in an accession record as well as on the report rendered.

(d) If the laboratory receives reference specimens from another laboratory, it shall report back to the laboratory submitting the specimens.

(e) Specimen Records. The laboratory shall maintain a daily accession record of specimens, each of which is numbered or otherwise appropriately identified. Records shall be retained for at least the minimum time required by CMS/CLIA. The current retention requirements are 2 years for clinical laboratory tests and 10 years for Blood Bank, Cytology, and Histology records.

§ 185-10-3040 Specimen Examination

(a) Examination Requests. A laboratory shall examine specimens only at the request of a licensed physician or other person authorized by law to use the findings of laboratory tests and examinations in their practice. It shall report the results of tests only to such people or their authorized representatives.

(b) If the patient presents himself at the laboratory for testing, the required lab procedures shall be done only to report to people authorized by law to use findings of lab tests.

(c) If only a specimen is received, it shall be accompanied by an authorized written request. The request form shall contain the following information:

(1) Name and other identification of the person from whom the specimen was taken.

(2) Name of licensed physician, another authorized person, or laboratory that submitted specimen.

(3) Date and time the specimen was collected for testing.

(4) Type of, or specific test(s) required.

(d) Verbal requests may be accepted in case of emergency, but only from authorized people.

§ 185-10-3045 Laboratory Reports to the Requesting Source

(a) Content

(1) Name and address of reporting laboratory.

(2) Date and time specimen received in laboratory.

(3) Condition of specimen, if considered unsatisfactory on receipt, e.g., broken, leaked, hemolyzed, or turbid.

(4) Specific type of test performed.

(5) Result of laboratory test along with normal ranges, where applicable.

(6) Date of reporting and initials of the technologist or supervisor.

(7) No interpretation of test results, diagnosis, prognosis, or suggested treatment may appear on the laboratory report unless the report is made or evaluated by a licensed physician.

(b) Distribution

(1) The laboratory report shall be sent promptly to the respective authorized person who requested the test.

(2) No results of lab tests and procedures, or transcripts thereof, shall be divulged to the respective patient or any other party without the consent of the respective physician or authorized agency that requested the tests.

(3) Duplicate copies or a suitable record of all laboratory reports shall be filed in the laboratory in a manner that permits ready identification and accessibility.

§ 185-10-3050 Facilities and Safety

(a) Equipment should be maintained in proper working order, routinely checked, precisely calibrated, and records of such surveillance maintained.

(b) Workbench space shall be ample, well-lit, and conveniently located near sinks, water, gas, suction, and electrical outlets as necessary.

(c) The laboratory shall be adequately ventilated, with temperatures controlled within the requirements of the tests performed.

(d) Adequate fire extinguishing equipment shall be present and available.

(e) Free from physical, chemical, and biological hazards both to the personnel and to the environment.

(f) Equipment and materials shall be kept sterilized.

(1) **Before use.** Sterile, disposable bloodletting devices, such as syringes, needles, and lancets, should not be reused. Reusable bloodletting devices shall be sterilized before each use and protected to ensure they remain sterile between uses.

(2) **After use.** All microbial materials and cultures shall be treated to ensure proper decontamination before being disposed of through a public disposal service. All disposable needles and syringes shall be destroyed and rendered useless before discarding.

§ 185-10-3055 Medical Laboratory Technologist/Technician

(a) **License to practice.** Every person desiring to practice as a medical laboratory technologist or medical laboratory technician shall, before beginning to practice, obtain from the Board a license or permit authorizing such practice.

(b) **Medical Laboratory Technologist** - A license or permit may be issued to any person who meets one of the following requirements:

(1) Be a Doctor of Medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; OR

(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical, or medical laboratory science, or medical technology, or nursing from an accredited institution; OR

(3) **Meet bachelor's degree equivalency; And**

(a) has at least 16 semester hours of additional graduate-level coursework in biology, chemistry, medical technology, clinical, or medical science; **OR**

(b) has at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or medical laboratory science and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health of human beings; **OR**

(4) At least 120 semester hours, or equivalent from an accredited institution that at a minimum includes either:

(a) Forty-eight (48) semester hours of medical laboratory science or medical laboratory technology courses; or

(b) Forty-eight (48) semester hours of science courses that include:

(1) Twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(2) Twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology, or genetics; and

(3) Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination

(c) **Medical Laboratory Technician -** a license or permit may be issued to any person who meets one of the following requirements:

(1) Have earned an associate degree in chemical, biological, clinical, or medical laboratory science, or medical laboratory technology, or nursing from an accredited institution; **OR**

(2) Be a high school graduate or equivalent and have completed an official military medical laboratory procedures course of at least 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); **OR**

(3) Have earned a high school diploma or equivalent; **AND**

(d) Have documentation of laboratory training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has:

(1) The skills required for proper specimen collection, including patient preparation, if applicable, labelling, handling, preservation, or fixation, processing or preparation, transportation, and storage of specimens;

(2) The skills required for implementing all standard laboratory procedures

(3) The skills required for performing each test method and for the proper instrument use;

(4) The skills required for performing preventative maintenance,

(5) troubleshooting, calibration procedures related to each test performed;

(6) a working knowledge of reagent stability and storage;

(7) The skills required to implement the quality control policies and

(8) procedures of the laboratory;

(9) vii. An awareness of the factors that influence test results;

(10) viii. The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values before reporting patient test results.

§ 185-10-3060 Medical Laboratory Director

(a) Be a physician certified in anatomical and/or clinical pathology by an accrediting body acceptable to the Board, or possess qualifications equivalent to those required for such certification; or

(b) Be a physician who is certified by an accrediting body such as the American Board of Clinical Chemistry, if acceptable to the Board, and, has had, after graduation, no less than four years of general clinical laboratory training and experience, at least two years of which were spent acquiring proficiency in one of the medical laboratory specialties with a director at the doctorate level in a medical laboratory of a health department, university or medical research institution; or

(c) Hold an earned doctorate from an accredited institution, with chemical, physical, or biological science as his primary subject, and shall be certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other certifying body acceptable to the Board; or

(d) Be a physician, licensed to practice in the CNMI, whose experience is acceptable to the Board,

(e) and/or by examination, is considered qualified to direct those medical laboratory procedures requested in his application.

§ 185-10-3065 Private Laboratory Operator Qualifications

(a) All people applying for a license to practice as a private laboratory operator must be a physician owner, licensed to practice in the CNMI as an M.D., D.O., or D.C.

(b) A private laboratory must be registered under the physician-owner's name.