

TITLE 140: COMMONWEALTH HEALTHCARE CORPORATION

SUBCHAPTER 140-50.1 HEALTH CARE PROFESSIONALS LICENSING RULES AND REGULATIONS

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Part 500 - Medical Laboratory Regulations Subpart A -General

§ 140-50.1-501 Basis for the Regulations

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

§ 140-50.1-505 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, secretions or other human body fluids for the purpose of aiding 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 own patients in the private practice of a doctor owner.
- (d) **“Proficiency testing”** means a continuous program of internal quality control, daily using substances of known content as well as testing unknown samples provided or approved by the Board in procedures for which the laboratory is licensed.
- (e) **“Laboratory director”** means a person responsible for administration of the technical and scientific operation of a clinical laboratory, e.g., a licensed director or private physician.
- (f) **“Medical laboratory technologist”** is synonymous with “clinical laboratory 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.
- (g) **“Active status”** means laboratory personnel engaged in clinical laboratory work full time or at least 15 hours per week on a continuing basis.
- (h) **“Inactive status”** means laboratory personnel no longer actively engaged in clinical laboratory work.
- (i) **“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.

§ 140-50.1-510 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 license from the Board.

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- (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 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 service for the patient.

Subpart B - Licensure and Registration

§ 140-50.1-515 Application of Laboratory

- (a) Application for and issuance of license. Application for license shall be made on forms provided by the Board, giving the complete information requested regarding physical plant, management, personnel, extent of testing service to be provided, and other pertinent matters requested by the Board.
- (b) Fees. Such application shall be accompanied by any required fee.
- (c) Site survey. Upon receipt of the application, the laboratory shall be subject to a site survey of the 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.

§ 140-50.1-520 Renewal

- (a) Term and renewal of license. A license shall be valid for a period of twenty-four calendar months from 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) Application for renewal shall made in writing, accompanied by a renewal fee. Also, each laboratory shall provide a current list of its technical staff.
- (c) Failure to reapply for renewal within one month the expiration date, shall result in termination of license.*

*So in original.

- (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.

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§ 140-50.1-525 Display of License

Validity; display of 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

§ 140-50.1-530 Performance Standards

- (a) Proficiency. Each laboratory shall participate in such appropriate proficiency test programs as are provided or approved by the Board for the purpose of monitoring level or accuracy of test performance, such as the College of American Pathologists' quality evaluation program.
- (b) Quality Control. There shall be an adequate quality control program in effect, including the use, reference or control reagents and other biological samples, concurrent calibrating standards, and control charts recording standard readings.
- (c) Procedure Manuals. Manuals of appropriate, current laboratory methods shall be available at the work stations to which they apply.

Subpart D - Specimens; Collection, Examination, Referrals

§ 140-50.1-535 Specimen Collection

- (a) No person other than a licensed physician or dentist may manipulate a patient for collection of specimens, except that qualified technical personnel of a laboratory may collect blood, remove stomach contents, perform certain diagnostic skin tests, or collect material for slides and cultures, under sanction of the laboratory operator.
- (b) Needles and syringes at blood drawing stations and in trays shall be kept under security at all times, 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.

§ 140-50.1-540 Specimen Examination

- (a) Examination Requests. A laboratory shall examine specimens only at the request of a licensed

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physician or other person authorized by law to use the findings of laboratory tests and examinations in his practice; and shall report the results of tests only to such persons or their authorized representatives.

- (b) If the patient presents himself at the laboratory for testing, the required lab procedures shall be done only for the purpose or* reporting to persons 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. Request form shall contain the following information:
 - (1) Name and other identification of person from whom specimen was taken.
 - (2) Name of licensed physician, other authorized person or laboratory that submitted specimen.
 - (3) Date and time 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 persons.

* So in original.

§ 140-50.1-545 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, 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

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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 which permits ready identification and accessibility.

§ 140-50.1-550 Facilities and Safety

- (a) Equipment shall be maintained in proper working order, routinely checked, precisely calibrated, and records of such surveillance maintained.
- (b) Work bench space shall be ample, well-lighted, and located convenient to sink, water, gas, suction, and electrical outlets as necessary.
- (c) 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 type blood letting devices, e.g., syringes, needles, lancets, shall not be reused. Reusable type blood letting devices shall be sterilized prior to each use, and they shall be protected to ensure they remain sterile between uses.
 - (2) After use. All microbial materials and cultures shall be treated so as to assure proper decontamination before discard to a public disposal service. All disposable needles and syringes shall be destroyed and rendered useless before discard.

Subpart E - Position Qualifications

§ 140-50.1-555 Medical Laboratory Technologist

- (a) License to practice. Every person desiring to practice as a medical laboratory technologist or medical laboratory technician shall, before beginning to practice, procure from the Board a license or permit authorizing such practice.
- (b) Qualifications. A license or permit may be issued to any person who:
 - (1) Has successfully completed a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university; plus at least 12 months, of training at a school of medical technology approved by the Board; or
 - (2) Has successfully completed three years' academic study (a minimum of 90 semester hours or equivalent) at an accredited college in a pre-medical technology curriculum; plus at least 12 months of training at a school of medical technology approved by the Board; or
 - (3) Has successfully completed a course of study for a bachelor's degree in one of the chemical,

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physical, or biological sciences at an accredited college, along with additional experience and/or training in medical technology, e.g., three years documented experience (rotating through all the disciplines) under a qualified person at the doctorate level; or

- (4) Lacking in the required academic background, has at least one year formal training in a school of medical technology acceptable to the Board plus at least six years experience in a clinical laboratory, two or more years of which were under the supervision of a person at the doctorate level. Also, he shall have successfully passed all portions of a written oral or performance examination provided or approved by the Board.

§ 140-50.1-560 Medical Laboratory Director

Qualifications

Every person applying for a license to practice as medical laboratory director shall meet at least one of the following requirements:

- (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, subsequent to 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 degree from an accredited institution, with chemical, physical or biological science as his major 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, and/or by examination, is considered as qualified to direct those medical laboratory procedures requested in his application.

§ 140-50.1-565 Private Laboratory Operator Qualifications

- (a) All persons applying for a license to practice as a private laboratory operator must be physician(s)-owner(s), licensed to practice in the CNMI as a M.D., D.O., or D.C.
- (b) A private laboratory must be registered under the physician(s)-owner(s) name(s).