

## **TITLE 216 - DEPARTMENT OF HEALTH**

### **CHAPTER 60 – LABORATORIES AND MEDICAL EXAMINER**

#### **SUBCHAPTER 05 – STATE LABORATORY**

##### **PART 4 – Clinical Laboratories and Stations**

#### **4.1 Authority**

These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-16.2-5, and are established for the purpose of adopting minimum standards for licensure of clinical laboratories and for the protection of the health, safety and welfare of the public.

#### **4.2 Definitions**

A. Wherever used in this Part the following terms shall be construed to mean:

1. "Act" means R.I. Gen. Laws Chapter 23-16.2, entitled, "Laboratories."
2. "Authorized medical personnel" means licensed health professionals working under the auspices of a physician or other licensed health care professional acting within his/her scope of practice.
3. "Clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, radiobioassay, cytological, pathological, or other 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, pursuant to R.I. Gen. Laws § 23-16.2-2(2) of the Act.
4. "Director" means the Director of the Rhode Island Department of Health.
5. "Licensing agency" means the Rhode Island Department of Health.
6. "Limited function test" means those tests listed in the Federal Register under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as waived tests.
7. "Persons" means any individual, firm, partnership, corporation, company, association, or joint stock association.

8. "Reference laboratory" means a Rhode Island-licensed laboratory to which another Rhode Island laboratory has referred patient samples for testing.
9. "Specialty" means a group of laboratory tests recognized by the U.S. Department of Health and Human Services.
10. "Station" means a facility for the collection, processing, and transmission of such materials for such purposes pursuant to R.I. Gen. Laws § 23-16.2-2(5) of the Act.

### **4.3 General Requirements**

- A. It shall be unlawful for any person, corporation or other form of business entity to perform clinical laboratory services on specimens collected in this state or to own, conduct or maintain a clinical laboratory or station in this state without a license pursuant to the requirements of the Act, and this Part, unless exempt in accordance with R.I. Gen. Laws § 23-16.2-3 as follows:
  1. A laboratory maintained by a hospital licensed under R.I. Gen. Laws Chapter 23-17, or by food preparation or processing establishments performing analysis to determine the quality of their own products, or by a licensed physician or group of licensed physicians who make the tests referred to in R.I. Gen. Laws § 23-16.2-2 personally and solely in connection with the treatment of their own patients; however, an independent laboratory which makes the tests on its own responsibility for a single physician or group of physicians is subject to the Act; and
  2. Any temporary or ad hoc health promotion screening program conducted for the general public which offers generally accepted mass screening procedures; provided the health promotion or screening program is conducted pursuant to a permit issued in accordance with rules and regulations pertaining to Permits for Screening Programs (Part 20-10-1 of this Title).
- B. A clinical laboratory or station shall represent itself in its advertisements, publications, or other forms of communication, as providing only those services for which it is licensed and shall not advertise in a manner which tends to mislead the public.

### **4.4 Application for License**

- A. Application for a license to establish, conduct, maintain, or operate a clinical laboratory or a station shall be made to the licensing agency on forms provided by the licensing agency for initial licensure and for license renewal.

1. Each application for license and renewal thereof shall contain such information as the licensing agency reasonably requires that includes affirmative evidence of ability to comply with the provisions of the Act and this Part.
2. Each application for licensure or renewal thereof as a station, shall be accompanied by the fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
3. Each application for license or renewal thereof as a clinical laboratory shall be accompanied by the fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title) for each specialty in which the laboratory seeks licensure. The check shall be made payable to the General Treasurer, State of Rhode Island and submitted to the Department of Health.
4. Application for license renewal shall be submitted to the licensing agency one month prior to the expiration date of the license.

#### **4.5 Issuance and Renewal of License**

- A. No less than thirty (30) days after receipt of an application for an initial license, the licensing agency shall issue a license, if the applicant meets the requirements of the Act and this Part. Said license, unless sooner suspended or revoked, shall expire on the 30th day of December of every other the year following the date of license.
- B. A license shall be issued only for the premises and persons named in the application and shall not be transferable.
- C. The license issued to a clinical laboratory shall clearly identify the specialty(ies) the laboratory is licensed to provide. Such specialties shall include, but not be limited to, the following:
  1. Microbiology, including bacteriology, virology, mycology and parasitology;
  2. Immunohematology, including blood group and Rh typing and crossmatching;
  3. Diagnostic immunology, including syphilis serology and general immunology;
  4. Pathology, including tissue, oral and cytology;
  5. Hematology, including coagulation;

6. Clinical chemistry, including urinalysis, endocrinology, and toxicology;
  7. Radiobioassay techniques; and
  8. Other specialties and subspecialties as recognized by the U.S. Department of Health and Human Services.
- D. Prior to issuing a license, the licensing agency shall review the following documents required to be provided by a laboratory prior to licensure:
1. Laboratory Director: provide documentation of the qualifications of the individual designated as laboratory director and a copy of that individual's resume;
  2. Laboratory staff: provide a list of technical personnel that includes qualification designations (MT, MLT, etc); also designate the individuals' primary special area(s), if the application is for more than one specialty area;
  3. Hours of operation: provide a statement about the laboratory hours of operation;
  4. Laboratory facility: provide floor plans or a description of the facility that supports a statement that the facility is adequate for the scope of services for which licensure is requested;
  5. Equipment: provide a current equipment list representing all of the testing equipment for the specialty area(s) for which licensure is requested;
  6. Summary of tests performed: provide a list of all the tests for which licensure is requested;
  7. Proficiency testing program: identify the proficiency testing program(s) for each specialty, subspecialty, or analyte for which licensure is requested;
  8. Quality control program: provide information regarding how the daily quality control program is achieved and used to ensure accurate testing;
  9. Quality assurance: provide a description of the laboratory's quality assurance program or a copy of the quality assurance plan;
  10. Fees: see §§ 4.4(A)(1) and (2) of this Part and the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).
- E. A license issued under this Part shall be the property of the state and loaned to the licensee and shall be kept posted in a conspicuous place on the licensed premises.

#### F. Out-of-State Laboratories

1. In addition to meeting the requirements stated in §§ 4.5(A) through (E) of this Part, an out-of-state laboratory shall be required to meet the additional requirements stated in § 4.5(F)(3) of this Part.
2. Notwithstanding the foregoing, upon payment of any applicable license fees, the Director may grant immediate licensure to any clinical laboratory licensed as such in another state and certified under the Clinical Laboratory Improvements Act of 1988, when such clinical laboratory has been asked to perform a clinical laboratory service which is not offered by any other clinical laboratory then licensed in this state.
3. Any out-of-state laboratory performing clinical laboratory tests on specimens collected in Rhode Island shall be licensed in accordance with the requirements stated in this Part.
  - a. Prior to issuing a license, the licensing agency shall review documentation of certification/licensure status supplied by the out-of-state laboratory to determine if the laboratory is:
    - (1) Certified by a federal agency in the specialties for which it is seeking licensure; and/or
    - (2) Licensed in good standing by the state agency in which the laboratory is located, and provided the laws, rules and regulations for licensure of said state are deemed equivalent to or exceed the laws, rules and regulations in this Part as determined by the Director of Health.
4. If an out-of-state laboratory meets the all of the requirements stated in this Part, the licensing agency shall issue a license.

#### 4.6 Inspections

- A. The licensing agency shall make, or cause to be made, such inspections and investigations as it deems necessary in accordance with R.I. Gen. Laws § 23-16.2-9.
- B. Each clinical laboratory and station shall be given prompt notice by the licensing agency of all deficiencies recorded as a result of an inspection or investigation.

#### 4.7 Denial, Suspension or Revocation of License

- A. In addition to those grounds stated in R.I. Gen. Laws § 23-16.2-7(a), the licensing agency may deny, revoke, or suspend the license of any clinical laboratory or station for engaging in conduct that includes, but is not limited to, the following:

1. Failure to comply with the rules and regulations in this Part and any state or federal regulations or statutes;
  2. Making false or deceptive representation of any testing results and reports thereof;
  3. Not abiding by the statutory provisions of the Confidentiality of Health Care Communications and Information Act, R.I. Gen. Laws Chapter 5-37.3;
  4. Engaging in false or deceptive advertising;
  5. Making false or deceptive representation on any application for licensure or renewal thereof; and/or
  6. Failure to maintain prevailing standards of laboratory practice that may be considered grounds for licensure suspension, revocation, or curtailment of activities or other disciplinary action at the discretion of the Director.
- B. Lists of deficiencies noted in inspections and investigations conducted by the licensing agency, shall be maintained on file in the licensing agency, and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license of a clinical laboratory or station.
- C. Whenever action shall be proposed to deny, suspend or revoke a license or take other disciplinary action, the licensing agency shall notify the facility by certified mail setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with R.I. Gen. Laws § 42-35-9, and the rules and regulations regarding Practices and Procedures Before the Department of Health (Part 10-05-4 of this Title) and Access to Public Records (Part 10-05-1 of this Title) pursuant to § 4.11.3 of this Part.
1. However, if the licensing agency finds that public health, safety and welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the licensing agency may order summary suspension of license pending proceedings for revocation or other action in accordance with R.I. Gen. Laws §§ 23-1-21 and 42-35-14(c).
- D. The appropriate state and federal reimbursement agencies shall be notified of any action taken by the licensing agency pertaining to either denial, suspension, or revocation of license or other disciplinary action.

## **4.8 Organization and Management**

### **4.8.1 Governing Body and Management**

- A. Each clinical laboratory and/or station shall have a governing body or equivalent legal authority ultimately responsible for:
1. The management and control of the operation;
  2. The assurance of the quality of services;
  3. The compliance with all federal, state and local laws and regulations; and
  4. Compliance with other relevant health and safety requirements, including the rules and regulations of this Part.

#### **4.8.2 Director of Laboratory**

- A. Each clinical laboratory shall have a laboratory director who shall be responsible for the day to day management and operation of the laboratory and to ensure the achievement and maintenance of quality standards of practice. The director shall meet the following minimum qualifications:
1. Be a person of good moral character;
  2. Has earned from an accredited college or university a doctorate of philosophy, science, public health or medicine after successful completion of a curriculum that has been accredited by a national or regional certifying authority and has a minimum of one (1) year experience in supervising laboratory procedures, or has earned a master's degree in chemistry, bacteriology, biology or allied sciences and has at least two (2) years experience in laboratory procedures that includes one year of supervision; or has earned a bachelor's degree in bacteriology, biology, chemistry or allied sciences and has a minimum of at least four (4) years experience in laboratory procedures, including two (2) years of supervision.
- B. The director of each clinical laboratory or his/her designee who meets the qualifications of § 4.8.2(A)(2) of this Part shall furthermore be responsible for no less than the following:
1. Be present on the premises of the laboratory during the hours of operation for a sufficient period of time to ensure adequate and appropriate supervision of laboratory activities;
  2. The accurate performance of all tests in the laboratory including the submission of appropriate reports on all tests pursuant to § 4.8.4 of this Part;
  3. The work of all personnel in the laboratory and for hiring adequately trained personnel commensurate with the workload;

4. Be available at all times during the hours of operation for personal or telephone consultation with personnel;
  5. Notify the licensing agency within ten (10) days of any change in laboratory services or supervisory personnel;
  6. Establish and maintain an effective quality assurance program; and
  7. Other such activity(ies) as may be deemed appropriate.
- C. In the event the director of the laboratory is absent for a continuous period of time longer than one (1) month duration, the laboratory shall not operate unless a person who meets the qualifications of § 4.8.2(A)(2) of this Part is in attendance.

#### **4.8.3 Personnel**

- A. Each clinical laboratory and station shall employ a sufficient number of qualified personnel who are licensed and/or certified pursuant to provisions of R.I. Gen. Laws § 23-16.2-6 commensurate with the workload to ensure that services are provided effectively and safely and in accordance with current laboratory standards of practice.
1. A job description for each position shall be established, clearly delineating qualifications, duties, and responsibilities for each position.
  2. Personnel records shall be maintained for each employee that shall contain no less than:
    - a. Current background information pertaining to qualifications, to justify initial and continued employment;
    - b. Evidence of periodic evaluation of technical work performance;
    - c. Such other data as may be deemed appropriate.
- B. Stations
1. Personnel in blood collection stations shall be proficient in venipuncture, specimen processing and shall have training in patient management and emergency situations.

#### **4.8.4 Records and Reports**

- A. Each clinical laboratory shall maintain appropriate records and reports, that shall be available for inspection by authorized representatives of the licensing agency. Such records and reports shall include:
1. Records of the operation and maintenance of all laboratory equipment;



2. Records of all specimen examinations in accordance with § 4.8.4(D) of this Part;
  3. Records of control values, standard values, calibration curves and calculations of standard deviations; and
  4. Reports of proficiency testing program results as well as copies of forms used by the laboratory to report results to the proficiency testing company;
  5. Policies and procedures that describe a comprehensive quality assurance program designed to monitor and evaluate the ongoing and overall quality of the total testing process; and
  6. Such other reports as may be deemed necessary.
- B. Clinical laboratory reports shall be based upon and confined to the findings of the laboratory examinations. Test results shall be submitted promptly to the licensed physician or other authorized medical personnel who requested the test(s).
1. No reports shall be worded to convey or simulate a diagnosis or prognosis or to specify or suggest specific medication, surgical manipulation or other form of treatment unless signed by a physician or other authorized medical personnel.
  2. Reports to physicians or other authorized medical personnel on specimens submitted by a licensed laboratory to a reference laboratory shall specify the name and address of the reference laboratory that shall be licensed in accordance with § 4.9.3(C) of this Part.
  3. Each clinical laboratory shall report communicable diseases in accordance with the rules and regulations pertaining to Reporting and Testing of Infectious, Environmental and Occupational Diseases (Part 30-05-1 of this Title).
- C. Each station shall maintain a record(s) in chronological sequence indicating the daily collection of specimens.
- D. Each clinical laboratory and station shall maintain a record indicating the processing of specimens, each of which shall be uniquely identified. The records of specimens shall contain no less than:
1. The unique laboratory identifier;
  2. The name and other identification of the person from whom the specimen was obtained;
  3. The name of the licensed physician or other authorized person or clinical laboratory that submitted the specimen;

4. Date of the collection and source of the specimen;
  5. Condition of specimen upon receipt (e.g., broken, turbid, etc.);
  6. The date and time of specimen receipt;
  7. The type of test requested and performed;
  8. The results of laboratory tests or cross reference to results;
  9. The date of reporting;
  10. The identity of the testing personnel; and
  11. The name and address of laboratory to which specimen(s) are referred if procedure(s) are not performed on the premises.
- E. Reports and records shall be retained for no less than five (5) years, except for histopathology reports that shall be retained for ten (10) years from the date the reports were issued.
- F. Laboratories shall retain all cytology slide preparations for five years from the date of examination and all histologic slide preparations for ten (10) years from the date of examination.

## **4.9 Quality Assurance Program**

### **4.9.1 General Requirements**

Each clinical laboratory or station shall have clearly established internal and external quality control programs to ensure high standards of performance and reliability of test results. These programs shall consider such factors as preventive maintenance, periodic inspection, testing for proper operation of equipment and instruments as may be appropriate, validation of methods, evaluation of reagents and volumetric equipment, surveillance results, remedial action taken to correct deficiencies and such other relevant factors as required in these rules and regulations and as may be deemed necessary.

### **4.9.2 Procedural Manual**

- A. Each clinical laboratory shall have available at all times in the immediate bench area of personnel engaged in conducting clinical laboratory testing, a procedure manual that includes a detailed compilation of all automated and manual methods and procedures for all clinical tests that are performed by the laboratory and for which it is licensed. Furthermore, such manual shall:
1. Contain information concerning preparation and storage of reagents, control and calibration procedures and pertinent literature references;

2. Describe the laboratory's technical procedures for the collection, processing and examination of specimens based on current standards of practice;
  3. For those tests that are normally performed on automated test equipment, provide for alternate methods or for storage of the test specimens, in the event the automated equipment becomes inoperable; and
  4. Procedures shall be approved, signed, and dated by the laboratory director. Procedures shall be re-approved, signed and dated if the directorship of the laboratory changes. Each change in a procedure shall be approved, signed, and dated by the current director of the laboratory.
- B. Each station shall have available at all times a procedure manual that includes a detailed compilation of methods and procedures for the collection, processing, and transmission of specimens including preparation of patients, based on current practices.

#### **4.9.3 Collection, Identification and Examination of Specimens**

- A. No specimen shall be examined if unsuitable for testing as a result of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection and examination, or for such other reason(s) that would render findings of doubtful validity.
- B. Specimens shall be examined only at the documented request of a licensed physician or other authorized medical personnel, pursuant to statutory provisions of this state.
- C. Clinical laboratories in state and out of state may receive reference specimens for examination provided the reference laboratory is licensed in this state, pursuant to R.I. Gen. Laws Chapter 23-16.2 and this Part.
- D. Whenever a clinical laboratory licensed by the state of Rhode Island isolates any one of the specified microorganisms identified in the rules and regulations pertaining to Reporting and Testing of Infectious, Environmental and Occupational Diseases (Part 30-05-1 of this Title), the original culture or a subculture shall be submitted to the Rhode Island Department of Health Laboratory for confirmation, typing, or banking in accordance with the aforementioned regulations.
1. All specimens shall be accompanied by identifying data such as name of the patient, physician or other authorized medical personnel, and laboratory.
- E. A clinical laboratory collecting blood for lead analysis and/or performing blood lead analyses shall do so in accordance with the regulations of Reporting and

Testing of Infectious, Environmental and Occupational Diseases (Part 30-05-1 of this Title) and Lead Poisoning Prevention (Part 50-15-3 of this Title).

#### **4.9.4 Radiobioassay, Pathological, and Cytological Examinations**

- A. A clinical laboratory licensed in the category of radiobioassay shall comply with the applicable rules and regulations for Radiation (Chapter 40 Subchapter 20 of this Title).
- B. Pathological examination of specimens of excised tissue(s) shall be performed only by a physician licensed in this state who is either qualified for certification, or is certified in anatomic pathology by the American Board of Pathology.
- C. Cytological examination of specimens shall be performed only under the supervision of a physician licensed in this state who is either qualified for certification, or is certified in anatomic pathology or cytopathology by the American Board of Pathology.

#### **4.9.5 Methodologies for Quality Control**

- A. Each clinical laboratory shall establish an internal program of quality control covering each type of analysis performed for the verification and assessment of accuracy, measurement of precision, and detection of error. The factors that constitute the quality control provisions shall be based on current acceptable standards of practice such as those promulgated in the most current version of the rules and regulations of the Department of Health and Human Services' "Clinical Laboratory Improvement Amendments of 1988."
- B. Each clinical laboratory shall furthermore be required to participate in an external proficiency testing program to assess the accuracy and reliability of testing performance for each category and subcategory of clinical specialties for which the laboratory is licensed.
  - 1. Appropriate proficiency testing programs shall be those approved by the U.S. Department of Health and Human Service or such as those the Director may deem appropriate based upon national standards.
  - 2. A determination of satisfactory performance on proficiency testing shall be made by the licensing agency based on the passing score for each analyte as established by the proficiency testing program.

### **4.10 Physical Plant and Equipment**

#### **4.10.1 Physical Facility, Equipment, and Supplies**

- A. General Requirements: Clinical Laboratories and stations shall be maintained in a manner that protects the health and safety of personnel and the public in accordance with all applicable state and local laws and codes. Where there is a

difference between codes, the code having the more stringent standard shall apply.

- B. Clinical Laboratories: Each clinical laboratory shall be housed in well-lighted, sanitary, properly ventilated quarters, equipped with hot and cold running water, toilet facilities and shall include adequate space to process and examine the specimens commensurate with the total workload. Furthermore, clinical laboratories shall:
1. Be in distinct and separate locations from living quarters unless provisions exist for separate entrances and plumbing fixtures;
  2. Have ample workbench space, well-lighted and conveniently located to sink, water, gas and suction and electrical outlets as necessary;
  3. Have adequate and proper storage space for volatile chemicals and inflammable solvents, located in non-hazardous areas in accordance with "Rhode Island State Fire Safety Code", R.I. Gen. Laws Chapter 23-28.1.
  4. Have adequate temperature humidity controls as may be required for proper performance of tests and operation of instruments affected by variations in temperatures;
  5. Have sufficient, consistent voltage levels at electrical sources to which automated equipment is connected;
  6. Have adequate refrigerated storage facilities for reagents used in testing. Said facilities shall be conveniently located to the testing area(s);
  7. Have on hand and readily available on the premises, all equipment, reagents and glassware necessary for the accurate performance of the clinical laboratory work;
  8. Calibrate all precision equipment at regular intervals and maintain calibration logs that provide evidence of calibrations. Or, documentation of calibration by a qualified laboratory instrument service organization shall be acceptable; and
  9. Have sharps containers assembled according to manufacturer's intended use(s) and shall ensure the use of biohazard containers at the point of generation of the medical waste.
- C. Stations: each station shall be located in well-lighted, sanitary quarters with hot and cold running water, toilet facilities and shall have:
1. A blood drawing chair or cot;
  2. A telephone; and

3. A procedure manual outlining steps to be taken in the event of an emergency;
4. A procedure manual, as required in § 4.9.2(B) of this Part; and
5. Have sharps containers assembled according to manufacturer's intended use(s) and shall ensure the use of biohazard containers at the point of generation of the medical waste.

#### **4.10.2 Fire and Safety**

- A. Adequate fire and safety precautions shall be established and maintained. Safety instructions shall be posted for the protection of personnel and patients against physical, chemical, and biological hazards.
  1. Personnel shall be given an orientation to the safety policies and procedures that shall be compiled in a safety manual and available at all times to all personnel.

#### **4.10.3 Medical Waste Disposal**

Medical waste as defined in the Medical Waste Regulations of the Rhode Island Department of Environmental Management, 250-RICR-140-15-1, shall be managed in accordance with the provisions of the aforementioned regulations.

### **4.11 Practices and Procedures, and Violations**

#### **4.11.1 Variance Procedure**

- A. The licensing agency may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such variance will not be contrary to the public interest, public health and/or health and safety of patients. The provisions of this section shall not be applicable to the requirements of §§ 4.8.2(A) and (B) of this Part pertaining to the director of the clinical laboratory.
- B. A request for a variance shall be filed by an applicant in writing setting forth in detail the basis upon which the request is made.
  1. Upon the filing of each request for variance with the licensing agency and within a reasonable time thereafter, the licensing agency shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the station or clinical laboratory appeals the denial.

#### **4.11.2 Violations**

In addition to revocation or suspension of licenses granted, any person who violates the statutory or regulatory provisions herein shall be subject to the sanctions of R.I. Gen. Laws § 23-16.2-13.

#### **4.11.3 Rules Governing Practices and Procedures**

All hearings and reviews required under the provisions of this Part herein shall be held in accordance with the rules and regulations regarding Practices and Procedures Before the Department of Health (Part 10-05-4 of this Title) and Access to Public Records (Part 10-05-1 of this Title).

**216-RICR-60-05-4**

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