RULES AND REGULATIONS

FOR LICENSING

ANALYTICAL LABORATORIES

(R23-16.2-A/LAB)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

September 1984

As Amended:
September 1987
November 1996
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

INTRODUCTION

These amended rules and regulations are promulgated pursuant to the authority conferred under section 23-16.2-5 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimum standards for licensure of analytical laboratories for the protection of the health, safety and welfare of the public.

The proper operation of laboratories and stations within the state is a matter of vital concern to the health and safety of the state. The determination and enforcement of proper standards to insure qualifications of personnel in the laboratories and stations and to insure the adequacy of equipment and facilities are necessary to the operation of the laboratories and stations in order to promote the general welfare.

Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following issues were considered in arriving at the amended regulations: (1) alternative approach; (2) duplication or overlap with other state regulations; and (3) significant economic impact which would be placed on facilities through the amended regulations. No alternative approach, duplication or overlap was identified. Furthermore, the protection of the health, safety and welfare of the public necessitates the adoption of these amended regulations, despite the economic impact may be incurred as a result.

These amended regulations shall supersede all previous *Rules and Regulations for Licensing Analytical Laboratories* promulgated by the Department of Health and filed with the Secretary of State.

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PART I ***Licensing Procedure & Definitions***

Section 1.0 ***Definitions***

Wherever used in these rules and regulations the following terms shall be construed to mean:

1.1 ***"Act"*** means the Laboratory Act of Chapter 23-16.2 of the General Laws of Rhode Island, as amended, entitled, "Laboratories."

1.2 ***"Analytical laboratory"*** means a facility for the biological, microbiological, chemical, physical and radiochemical examination of food, surface water, recreational water, air, wastewater, potable water, and sewage, swimming pools, solid waste, hazardous waste, minerals, soil, sediment or other matrices.

1.3 ***"Director***" means the Director of the Rhode Island Department of Health.

1.4 "***Licensing agency***" means the Rhode Island Department of Health.

1.5 ***"Persons***" means any individual, firm, partnership, corporation, company, association, or joint stock ownership.

1.6 "***State agency"*** means the Rhode Island Department of Health.

Section 2.0 ***General Requirements***

2.1 It shall be unlawful for any person, corporation or other form of business entity to perform analytical laboratory services on samples collected in this state, or to own, conduct or maintain an analytical laboratory in this state without a license pursuant to the requirements of section 23-16.2-4 of the Act, and the rules and regulations herein, unless exempt in accordance with section 2.1.1 (below).

2.1.1 The provisions of these rules and regulations shall apply to all analytical laboratories and stations performing analytical laboratory services on specimens collected in this state except food preparation or processing establishments performing analysis to determine the quality of their own products.

2.2 An analytical laboratory 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.

Section 3.0 ***Application for License***

3.1 Application for a license to establish, conduct, maintain or operate an analytical laboratory shall be made to the licensing agency on forms provided by the licensing agency for initial licensure and for license renewal.

3.1.1 Applications for license renewal must be submitted to the licensing agency on or before the first day of April prior to the expiration date of the license.

3.1.2 Each application for license and renewal thereof shall contain such information as the licensing agency reasonably requires which may include affirmative evidence of ability to

comply with the provisions of the Act and the rules and regulations herein.

3.1.3 Each application for license or renewal thereof as an analytical laboratory must be accompanied with the fee of five hundred dollars ($500.00) for each category for which the laboratory is approved and made payable to the General Treasurer of the State of Rhode Island and submitted to the Department of Health.

Section 4.0 ***Issuance & Renewal Of License***

4.1 No less than thirty (30) days after receipt of a satisfactorily completed application for an initial license, the licensing agency shall issue a license if the applicant meets the requirements of the Act and the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire by limitation on the 30th day of June, a year following its issuance and may be renewed biennially.

4.1.1 The licensing agency will issue a license to an out-of-state laboratory provided the laboratory is:

a) certified by a federal agency in the categorical specialties it is to perform;

or

b) licensed by the state agency in the state where 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 herein as determined by the Director of Health.

4.2 Analytical laboratories in this state and out-of-state may receive referred samples for examination provided the laboratory is licensed in this state pursuant to these rules and regulations and Chapter 23-16.2 of the Rhode Island General Laws, as amended.

4.3 A license shall be issued only for the premises and persons named in the application and shall not be transferable or assignable.

4.4 The license issued to an analytical laboratory shall clearly identify the type of laboratory and those categorical tests which the laboratory is licensed to provide. Such categories may include:

a) *Microbiology* pertaining to the following subcategories:

1. Dairy
2. Water
3. Wastes
4. Foods

b) *Chemistry* pertaining to the following subcategories:

1. *Inorganic chemistry* pertaining to the following subcategories:

i) Food
ii) Surface water

iii) Air
iv) Waste water
v) Potable water
vi) Sewage
vii) Soil
viii) Dust
ix) Paint chips

2. *Organic chemistry* pertaining to the following subcategories:

i) Food
ii) Surface water
iii) Air
iv) Waste water
v) Potable water
vi) Sewage

c) Bioassay

d) Radiochemistry

e) Physical

4.5 A license issued hereunder 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.

Section 5.0 ***Inspections***

5.1 The Director or his duly authorized agent(s) or employees shall at all reasonable times have authority to enter upon any and all parts of the premises on which any analytical laboratory is located and of the premises appurtenant thereto, to make any examination or investigation whatsoever for the purpose of determining compliance with the provisions of the Act and the rules and regulations herein.

5.2 Each analytical laboratory shall be given prompt notice by the licensing agency of all deficiencies recorded as a result of an inspection or investigation.

Section 6.0 ***Denial, Suspension Or Revocation Of License***

6.1 The licensing agency may revoke or suspend the license of any analytical laboratory for conduct by or chargeable to said laboratory as follows:

a) failure to observe any term of such license;

b) failure to observe any order may under authority of the Act or under the statutory authority vested in the Department of Health;

c) engaging in, aiding, abetting, causing or permitting any action prohibited under the Act; and

d) failure to comply with any regulations promulgated by the Department of Health.

6.2 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 an analytical laboratory.

6.3 Whenever action shall be proposed to deny, suspend or revoke a license or take another 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 section 42-35-9 of the General Laws of Rhode Island, as amended, and the *Rules and Regulations Governing Practices and Procedures (R42-35-PP)* of the Rhode Island Department of Health, pursuant to section 21.0 herein.

6.3.1 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 licensure pending proceedings for revocation or other action in accordance with sections 23-1-21 and 42-35-14(c) of the General Laws of Rhode Island, as amended.

6.4 ***Compliance with the Rules and Regulation*****s** - In addition to those aspects of section 6.1 above, an analytical laboratory in order to maintain its license must:

a) not make false and deceptive representation of any application for licensure or renewal thereof;

b) maintain professional and competent standards of practice;

c) not make false and deceptive representation of any testing results and reports thereof;

d) not engage in false or deceptive advertising.

PART II *Organization & Management*

Section 7.0 *Governing Body & Management*

7.1 Each analytical laboratory 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) other relevant health and safety requirements, including the rules and regulations herein.

Section 8.0 *Director Of Laboratory*

8.1 Each analytical laboratory shall have a 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:

a) be a person of good moral character;

b) possess an earned doctorate in the biological or chemical sciences and a minimum of two (2) years analytical laboratory experience; or hold a master's degree in the chemical or biological sciences and a minimum of four (4) years of analytical laboratory experience; or possess a bachelor's degree in the biological or chemical sciences and a minimum of five (5) years of analytical laboratory experience.

i) Exempt from section 8.1 (b) are directors of analytical laboratories which were in operation on the effective date of these regulations (October 25, 1987) and who meet all other qualifications set forth in these rules and regulations.

8.2 The director of each analytical laboratory or his/her designated supervisor who meets the qualifications of section 8.1 (b) herein shall furthermore be responsible for no less than the following:

a) to 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;

b) to ensure the accurate performance of all tests in the laboratory including the submission of appropriate reports on all tests pursuant to section 10.0 herein;

c) to ensure the supervision of all personnel in the laboratory and for hiring adequately trained personnel commensurate with the workload;

d) to be available at all times during the hours of operation for personal or telephone consultation with personnel;

e) to notify the licensing agency within ten (10) days of any change in laboratory services or personnel;

f) to establish and follow written policies and procedures for a comprehensive quality assurance program; *and*

g) such other activity as may be deemed appropriate.

8.3 In the event the director of the laboratory is absent for a continuous period of time longer than one month duration, the laboratory shall not operate unless a person who meets the qualifications of section 8.1 (b) herein is in attendance.

Section 9.0 ***Personnel***

9.1 Each analytical laboratory shall employ a sufficient number of qualified personnel commensurate with the workload to ensure that services are provided effectively and safely and in accordance with prevailing laboratory standards and practices.

9.1.1 A job description for each classification of position shall be established, clearly delineating qualifications, duties and responsibilities inherent in each position.

9.1.2 Personnel records shall be maintained for each employee which contain no less than:

a) current background information pertaining to qualifications, to justify initial and continued employment;

b) evidence of periodic evaluation of work performance; and

c) such other data as may be deemed appropriate.

Section 10.0 ***Records & Reports***

10.1 Each analytical laboratory shall maintain appropriate records and reports which shall be available for inspection by authorized representatives of the licensing agency. Such records and reports shall include:

a) records of the operation and maintenance of all laboratory equipment;

b) records of all sample examinations in accordance with section 13.3 herein;

c) records of control values, standard values, standard curves and calculations of standard deviations; *and*

d) reports of proficiency testing programs and of such other as may be deemed necessary.

10.2 Laboratory reports shall clearly identify the name and address of the laboratory (which may be a subcontracted laboratory) actually performing the test(s), and shall include the results and the date of the reporting.

PART III ***Quality Assurance Program***

Section 11.0 ***General Requirements***

11.1 Each analytical laboratory shall have clearly established internal and external quality controls to ensure high standards of performance and reliability of test results considering such factors as

preventive maintenance, periodic inspection, testing for proper validation of methods, evaluation of reagents and volumetric equipment, surveillance results, remedial action taken to correct deficiencies and such other equivalent factors as required in these rules and regulations and as may be deemed necessary.

11.2 The laboratory must perform all analyses of samples, the results of which will be used for compliance with state or federal regulations, using methods that are currently approved by the appropriate state or federal regulatory agency. (See Appendix "A" for a sample listing of approved methods).

Analyses of samples relating to public health or safety (i.e., not for compliance purposes) may be performed by in-house methods established in writing. Evidence must be available that these methods have been verified by the laboratory for precision and accuracy. These methods must comply with the quality assurance requirements described herein.

Section 12.0 ***Procedure Manual***

12.1 Each analytical laboratory must have available, at all times, in the immediate bench area of personnel engaged in conducting analytical laboratory testing, a procedure manual which includes a detailed compilation of all automated and manual methods and procedures for all analytical tests which are performed by the laboratory and for which it is licensed. Furthermore, such manuals must:

12.1.1 contain information concerning preparation and storage of reagents, control and calibration procedures and pertinent literature references;

12.1.2 describe the laboratory's technical procedures for the collection, processing and examination of samples based on current practices;

12.1.3 for those tests which are normally performed on automated test equipment, provide for alternate methods or for storage of test samples, in the event the automated equipment becomes inoperable; *and*

12.1.4 be approved, signed and dated by the current laboratory supervisor/director. Changes in procedures must be approved, signed, and dated by the current supervisor/director.

Section 13.0 ***Collection, Identification & Examination Of Samples***

13.1 *Analytical laboratories:* - information that accompanies samples shall be sufficiently detailed to permit positive identification of the sample. Such information shall contain no less than:

a) source of the sample;
b) date of collection; *and*
c) such other data as may be deemed necessary.

13.2 No sample 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 reasons(s) which would render findings of doubtful validity.

13.3 Each analytical laboratory shall maintain a record indicating the daily accession of samples, each of which shall be numbered or otherwise appropriately identified. The records of samples shall contain no less than:

a) the laboratory number or other identification;
b) the name of the person or analytical laboratory which submitted the sample;
c) date of collection of sample;
d) condition of sample upon receipt;
e) the date and type of test requested and performed;
f) the results of laboratory tests or cross reference to results and date of reporting; *and*
g) the name and address of laboratory to which sample(s) is forwarded in procedure(s) not performed on the premises.

Section 14.0 ***Other Applicable Regulations***

14.1 An analytical laboratory licensed in the category of radiochemistry shall comply with the *Rules and Regulations for the Control of Radiation*, promulgated by the Rhode Island Department of Health; and, must obtain, as applicable, the appropriate radioactive materials license from the Office of Occupational and Radiological Health, Rhode Island Department of Health.

14.2 A licensed analytical laboratory, which performs the analysis of asbestos, shall comply with the *Rules and Regulations for Asbestos Control*, promulgated by the Rhode Island Department of Health; and, must obtain the appropriate certification from the Office of Occupational and Radiological Health, Rhode Island Department of Health.

14.3 A licensed analytical laboratory, which performs the analysis of radon, shall comply with the *Rules and Regulations for Radon Control*, promulgated by the Rhode Island Department of Health; and, must obtain the appropriate certification from the Office of Occupational and Radiological Health, Rhode Island Department of Health.

Section 15.0 ***Methodologies For Quality Control***

15.1 Each laboratory shall establish an acceptable internal program of quality control covering each test performed for the verification and assessment of accuracy, measurement of precision, and detection of error. The factors constituting these provisions shall be based on current acceptable standards of practice.

15.2 Each analytical laboratory shall be required to successfully participate in an external proficiency testing program for every test performed for which proficiency testing is available.

15.2.1 The Director shall designate such appropriate proficiency testing program.

15.2.2 Satisfactory performance shall be determined by the licensing agency based on the passing score for each constituent.

15.2.3 Failure of performance may be considered grounds for suspension, revocation or other disciplinary action at the discretion of the Director.

PART IV ***Physical Plant And Equipment***

Section 16.0 ***Physical Facility, Equipment & Supplies***

16.1 Each analytical laboratory shall be housed in well lighted, sanitary, properly vented quarters equipped with hot and cold running water, toilet facilities and shall contain ample space to process and examine the samples commensurate with the total workload. Furthermore, said analytical laboratories shall:

16.1.1 be in distinct and separate locations from living quarters unless provisions exist for separate entrances, plumbing fixtures;

16.1.2 have ample workbench space, well lighted and conveniently located to sink, water, gas, suction, and electrical outlets as needed;

16.1.3 have adequate and proper storage space for volatile chemicals and inflammable solvents, located in non-hazardous areas;

16.1.4 have adequate temperature and humidity controls as may be required for proper performance of tests and operation of instruments affected by variations of temperature;

16.1.5 have voltage levels at electrical sources to which analytical equipment is connected, monitored and recorded periodically;

16.1.6 have adequate refrigeration for reagents used in testing; (Food for consumption may not be stored in refrigerators containing laboratory materials);

16.1.7 have on-hand and readily available on the premises, all equipment, reagents, glassware necessary for the satisfactory performance of the required work; *and*

16.1.8 calibrate all precision equipment at regular intervals satisfactory to the surveyor(s) and maintain calibration logs with documentation of calibration. Documentation by a qualified instrumentation service organization may also be deemed acceptable.

Section 17.0 ***Fire & Safety***

17.1 Adequate fire and safety precautions shall be established and maintained. Safety instructions shall be present in a laboratory safety manual for the protection of personnel from physical, chemical and biological hazards. The laboratory safety manual shall include applicable programs for the protection of employees as outlined in the *Code of Federal Regulations* (29 CFR Part 1910), including, but not limited to, the Occupational Safety and Health Administration standards for bloodborne pathogens, hazard communication, and occupational exposure to hazardous chemicals in laboratories.

17.1.1 Personnel will be given a safety orientation reviewing policies and procedures in the safety manual.

Section 18.0 ***Waste Disposal***

18.1 *Infectious Waste:*

Infectious waste as defined in the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92*) of the Rhode Island Department of Environmental Management shall be managed in accordance with the provisions of the aforementioned regulations.

18.2 *Other Waste:*

Wastes which are not classified as infectious waste, hazardous wastes or which are not otherwise regulated by law or rule may be disposed in dumpsters or load packers provided the following precautions are maintained:

a) Dumpsters shall be tightly covered, leak proof, inaccessible to rodents and animals, and placed on concrete slabs preferably graded to a drain. Water supply shall be available within easy accessibility for washing down of the area. In addition, the pickup schedule shall be maintained with more frequent pickups when required. The dumping site of waste materials must be in sanitary landfills approved by the Department of Environmental Management.

b) Load packers must conform to the same restrictions required for dumpsters and in addition, load packers shall be:

   i) high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment; *and*

   ii) the loading section shall be construed and maintained to prevent rubbish from blowing from said area site.

PART V *Practices & Procedures, Violations & Severability*

Section 19.0 *Variance Procedure*

19.1 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 specific instances where it is found that literal enforcement of such provisions will result in unnecessary hardship to the applicant and such variance will not be contrary to the public interest, public health, or health and safety of individuals.

19.2 A request for variance shall be made in writing, setting forth in detail the basis of the request.

19.2.1 Upon filing of such request with the licensing agency and within thirty (30) days thereafter, the licensing agency shall notify the applicant by certified mail of its approval, or in case of a denial, a hearing date, time, and place may be scheduled if the applicant appeals the decision.

Section 20.0 *Violations*

20.1 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 section 23-16.2-13 of the General Laws of Rhode Island, as amended.

Section 21.0 *Rules Governing Practices & Procedures*

21.1 All hearings and reviews required under the provision of the rules and regulations herein should be held in accordance with the *Rules and Regulations Governing the Practices and Procedures Before the Rhode Island Department of Health (R42-35-PP).*

Section 22.0 *Severability*

22.1 If any provisions of these rules and regulations or the application thereof to any persons or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.

APPENDIX "A"

Laboratories must perform all analyses in accordance with the current methods specified in the appropriate edition of:

- *Standard Methods for the Examination of Water and Wastewater*, American Public Health Association, 18th edition, 1992, 1015 Fifteenth Street, NW, Washington, D.C. 20005.

- *Methods for the Chemical Analysis of Water and Wastes*, U.S. Environmental Protection Agency, EPA-600/4-79-020, March 1983.

- *Guidelines Establishing Test Procedures for the Analysis of Pollutants*, Title 40, EPA Part 136 Federal Register, vol. 60, no. 64, April 4, 1995.

- *Methods for the Organic Chemical Analysis of Municipal and Industrial Wastewater, USEPA, EMSL, Cincinnati, OH, EPA 600/4-82-057*.

- *Air Pollution Methods*, as published in the *Federal Register* as *Reference for Equivalent Method*s by the U.S. Environmental Protection Agency, CFR 40, Parts 53--60, July 1988. U.S. Government Printing Office, Washington, D.C. 20402.

- *Standard Methods for the Examination of Dairy Products*, 16th edition, 1992 APHA, 1015 Fifteenth Street, NW, Washington, D.C. 20005.

- The *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

- SW-846 *Test Methods for Evaluating Solid Waste*, U.S. Environmental Protection Agency, Third edition (1986) and updates. Office of Solid Waste and Emergency Response, Washington, D.C. 20460.

REFERENCES

1. *Rules & Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92*), Rhode Island Department of Environmental Management, April 1994.

2. *Rules & Regulations for the Control of Radiation (R23-1.3-RAD*), Rhode Island Department of Health, June 1995.

3. *Rules & Regulations for Radon Control (R23-61-RC),* Rhode Island Department of Health, August 1994.

4. *Rules & Regulations for Asbestos Control (R23-24.5-ASB),* Rhode Island Department of Health, February, 1992.