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TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 60 – LABORATORIES AND MEDICAL EXAMINER

SUBCHAPTER 05 – STATE LABORATORY

PART 5 – Certifying Analytical Laboratories

5.1 Authority

These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-16.2-5(a), and are established for applying minimum standards for certification of analytical laboratories that analyze potable water, non-potable water, or other environmental matrices for the protection of the health, safety, and welfare of the public. The proper operation of analytical laboratories within the state is a matter of vital concern to the health and safety of the state. The determination and enforcement of proper standards is necessary to ensure the qualifications and competence of personnel and to ensure the adequacy of equipment, facilities, and quality assurance programs.

5.2 Incorporated Materials

A. These regulations hereby adopt and incorporate 40 C.F.R. Parts 122, 136, 141, 143, 430, 455, and 465 (July 1, 2003) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

B. These regulations hereby adopt and incorporate 40 C.F.R. Part 136, Docket Number EPA-HQ-OW-2010-0192 (March 6, 2013) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

C. These regulations hereby adopt and incorporate EPA Solutions to Analytical Chemistry Problems with Clean Water Act Methods, EPA 821-R-07-002 (March 2007) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

D. These regulations hereby adopt and incorporate EPA Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition, EPA 815-R-05-004 (January 2005) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

E. These regulations hereby adopt and incorporate EPA Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water. EPA 815-F-08-006 (June 2008) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

F. These regulations hereby adopt and incorporate APHA Standard Methods for the Examination of Water and Wastewater, American Public Health Association, 18th – 22nd editions (1992-2012) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

G. These regulations hereby adopt and incorporate Methods for the Chemical Analysis of Water and Wastes, U.S. Environmental Protection Agency, EPA-600/4-79-020 (March 1983) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

H. These regulations hereby adopt and incorporate Methods for the Organic Chemical Analysis of Municipal and Industrial Wastewater, USEPA, EPA 600/4-82-057 (July 1982) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

5.3 Definitions

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

1. “A2LA” means American Association for Laboratory Accreditation, a voluntary program for accrediting environmental lead laboratories and proficiency testing providers to the ISO/IEC 17025 standard.

2. “Accredited” means to be recognized as conforming to a standard by an accrediting organization (i.e., NELAP approved accrediting authorities, American Industrial Hygiene Association [AIHA], American Association for Laboratory Accreditation [A2LA]).

3. "Act" means R.I. Gen. Laws Chapter 23-16.2, entitled "Laboratories."

4. “AIHA” or “American Industrial Hygiene Association” means a voluntary program for accrediting environmental lead laboratories for the testing of Environmental Lead per the ISO/IEC 17025 standard.

5. "Analytical laboratory" means a facility for the biological, microbiological, chemical, physical, and radiochemical examination of potable water, non-potable water, or other environmental matrices.

6. “Analytical reagent grade”, “(AR) grade”, “ACS reagent grade”, and “reagent grade” means reagents that conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society (ACS).

7. “ASTM” means the American Society for Testing and Materials.

8. “Applicant” means a laboratory applying to the Department to become a certified analytical laboratory.

9. “Certification” means the determination by the Department of Health that an analytical laboratory can perform tests or analyses of environmental samples in accordance with the requirements of these rules and regulations.

10. “Certified thermometer” means a thermometer that has documentation from the manufacturer that it has been calibrated by NIST.

11. “Class ‘A’ glassware” means glassware satisfying the applicable requirements for Class A glassware established by NIST.

12. “Compliance analysis or testing” means the analysis of a sample that is required by law or regulation.

13. “Department” means the Rhode Island Department of Health.

14. "Director" means the Director of the Rhode Island Department of Health.

15. “Environmental lead” means lead in paint, dust, wipe and soil and/or water samples collected for laboratory testing to support the migration of lead hazard or exposure.

16. “EPA” means the United States Environmental Protection Agency.

17. “ISO/IEC 17025” means the International Organization for Standardization Standard 17025 used by laboratories that produce testing and calibration results.

18. “NELAP” means National Environmental Laboratory Accreditation Program, which implements the TNI standards and evaluates the accrediting authority programs.

19. “NPDES” means National Pollutant Discharge Elimination System, a program of the EPA.

20. “NIST” means National Institute of Standards and Technology, an agency that sets accuracy standards for laboratory equipment and accredits proficiency test providers.

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

22. “Proficiency testing sample” or “PT sample” means a subsample of a matrix containing analytes of a concentration unknown to the laboratory that is used to evaluate the performance of its analytical systems. Proficiency testing samples shall be obtained from a provider that is accredited by the TNI Proficiency Testing Provider Accreditation Program.

23. “Quality assurance” or “QA” means the integrated system of operations and measurements performed to assure that data meets defined standards of quality within a stated level of confidence.

24. “Quality control” or “QC” means the practice of standardized operations or measurements that determine or predict aspects of data quality.

25. “TNI” or “NELAC Institute” means a voluntary non-profit organization whose mission is to foster performance standards for the operation of environmental laboratories for the generation of environmental data of known and documented quality through process that is endorsed by the EPA. TNI also maintains the Proficiency Testing Provider Accreditor program.

5.4 Certification

5.4.1 General Requirements

A. It shall be unlawful for any analytical laboratory to perform testing or analyses of samples originating in this state, for which the Department requires certification, without obtaining certification pursuant to the Act and this Part.

B. Certification for specific analytes and methods shall be required for laboratory testing of potable water, non-potable water, and environmental samples for lead content. Certification for potable water is required whenever a laboratory performs analytical tests on drinking water supply samples. Certification for non-potable water is required whenever a laboratory performs analytical tests on water other than drinking water.

C. Certification is required for laboratories performing environmental lead analysis in accordance with the rules and regulations for Lead Poisoning Prevention (Part 50-15-3 of this Title). A certificate for environmental lead analysis shall be issued only to laboratories providing documentation of accreditation through a program recognized by the EPA’s National Environmental Lead Laboratory Accreditation Program (e.g., A2LA or AIHA).

D. An analytical laboratory shall represent itself in its advertisements, publications, or other forms of communication, as providing only those services for which it is certified and shall not advertise in a manner that tends to mislead the public.

5.4.2 Application for Certification

A. Application for certification to conduct laboratory testing of potable water, non-potable water, and environmental lead shall be made to the Department on forms provided for initial certification and for certification renewal.

B. Applications for certification renewal shall be submitted to the Department on or before the date specified by the Department.

C. Each application for certification and renewal thereof shall contain such information as the Department reasonably requires which may include affirmative evidence of ability to comply with the provisions of the Act and the rules and regulations herein.

D. Each application for certification or renewal thereof must be accompanied by the non-refundable fee as set forth in the rules and regulations pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title) for each category for which the laboratory is requesting certification, and made payable to the General Treasurer of the State of Rhode Island and submitted to the Department of Health.

E. The annual fee schedule per category for both in-state and out-of-state laboratory certification is as set forth in in the rules and regulations pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

5.4.3 Issuance of a Certificate & Renewal of Certification

A. No less than thirty (30) days after receipt of a satisfactorily completed application for initial certification, the Department shall issue a certificate if the applicant meets the requirements of the Act and this Part for certification. Said certification, unless sooner suspended or revoked, shall expire by limitation on the thirtieth (30th) day of December, of every year following the date of certification and shall be renewed annually.

B. Certificates shall not be issued to an analytical laboratory located in Rhode Island prior to an inspection and correction of any deficiencies in a manner acceptable to the Department as specified in § 5.4.4 of this Part. Further, said laboratory must comply with the proficiency testing requirements for initial certification as described in § 5.7.5 of this Part.

C. The Department may issue a certificate to an out-of-state laboratory provided the laboratory is:

1. Certified by the EPA in the analytes and methods it is to perform; or

2. Licensed, certified, or accredited by the state agency in the state where the laboratory is located, and provided the laws, rules and regulations for

licensure, certification or accreditation of said state agency are deemed equivalent to or exceed the Act and this Part, as determined by the Director; or

3. Accredited by NELAP for analytes and methods not offered by the state where the laboratory is located, but allowable by these rules.

D. Analytical laboratories in this state and out-of-state may receive samples from another laboratory for examination provided the laboratory is certified in this state pursuant to the Act and this Part.

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

F. The certificate issued to an analytical laboratory shall clearly identify the laboratory and those analytes and methods under each category for which the laboratory is certified. Such categories include:

1. Potable Water pertaining to the following subcategories:

a. microbiology,

b. organic chemistry, and

c. inorganic chemistry.

2. Non-Potable Water pertaining to the following subcategories:

a. microbiology,

b. organic chemistry, and

c. inorganic chemistry.

3. Radiochemistry

4. Environmental Lead

G. A certificate issued hereunder shall be the property of the state and loaned to the laboratory and shall be kept posted in a conspicuous place on the premises.

5.4.4 Inspections

A. The Director or authorized agent(s) or employees shall at all reasonable times have authority to enter upon 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 determining compliance with the provisions of the Act and this Part.

B. Each analytical laboratory shall be provided a written report by the Department of all deficiencies recorded as a result of an inspection or investigation within sixty (60) days of such inspection or investigation.

C. The analytical laboratory shall provide a plan of corrective action, including expected completion dates for all deficiencies listed on such report within thirty (30) days of receipt.

D. At the discretion of the Director, a follow-up inspection may be conducted to assure that all deficiencies have been corrected.

5.4.5 Denial, Suspension, or Revocation of Certificate

A. In addition to the grounds for revocation and suspension stated in R.I. Gen. Laws § 23-16.2-7, the Department may deny, revoke, or suspend the certificate of any analytical laboratory for engaging in conduct that includes but is not limited to:

1. making false or deceptive representation on any application for certification or renewal thereof;

2. failure to maintain professional and competent standards of practice;

3. making false or deceptive representation of any testing results and reports thereof;

4. engaging in false or deceptive advertising;

5. failure to maintain a quality assurance system and follow a quality assurance plan;

6. failure to perform proper managerial review and approval prior to issuance of reports of any testing results; and

7. for certified out-of-state laboratories, failure to comply with § 5.4.5(D) of this Part.

B. Lists of deficiencies noted in inspections and investigations conducted by the Department shall be maintained on file in the Department and shall be considered by the Department in rendering determinations to deny, suspend, or revoke the certificate of an analytical laboratory.

C. Whenever action shall be proposed to deny, suspend, or revoke the certificate or take another disciplinary action, the Department shall notify the facility by certified mail setting forth reasons for the proposed action, and the applicant or certified laboratory shall be given an opportunity for a prompt and fair hearing in accordance with R.I. Gen. Laws § 42-35-9, Practices and Procedures Before the Rhode Island Department of Health (Part 10-05-4 of this Title), and § 5.13 of this Part.

1. However, if the Department finds that public health, safety, and welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the Department may order summary suspension of certification pending proceedings for revocation or other action in accordance with R.I. Gen. Laws §§ 23-1-21 and 42-35-14(c).

D. Certified laboratories not located in Rhode Island shall notify the Department of changes in its accreditation, certification, or licensure status within fourteen (14) days of receiving a notification of such changes.

5.5 Organization, Management, and Personnel

5.5.1 Governing Body

A. 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. compliance with other relevant health and safety requirements, including this Part.

5.5.2 Management

A. Each analytical 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 laboratory director shall meet the following minimum qualifications:

1. be a person of good moral character; and

2. has earned, from a college or university accredited by a national or regional certifying authority; a doctorate in the chemical or biological sciences and a minimum of two (2) years analytical laboratory experience, or has earned a master's degree in the chemical or biological sciences and has a minimum of four (4) years of analytical laboratory experience, or has earned a bachelor’s degree in the chemical or biological sciences and has a minimum of five (5) years of analytical laboratory experience.

B. Exempt from § 5.5.2(A)(2) of this Part are directors of analytical laboratories that were in operation on October 25, 1987 and who meet all other qualifications set forth in this Part.

C. Directors of laboratories in municipal waste treatment facilities testing non-potable water for only fecal coliforms, Biochemical Oxygen Demand and total suspended solids shall be deemed to be qualified if they have earned an associate's degree in the biological or chemical sciences and have a minimum of two (2) years of laboratory experience; or they have earned a bachelor's degree in the chemical or biological sciences and have a minimum of one (1) year of laboratory experience.

D. The director of each analytical laboratory or his/her designee, who meets the qualifications of § 5.5.2(A)(2) of this Part shall furthermore be responsible for no less than the following:

1. 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;

2. to ensure the accurate performance of all tests in the laboratory including the submission of appropriate reports on all tests pursuant to § 5.6 of this Part.

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

4. to be available during the hours of operation for personal or telephone consultation with personnel;

5. to notify the Department within ten (10) days of any change in laboratory services or supervisory personnel;

6. to establish and adhere to written policies and procedures for a comprehensive quality assurance program; and

7. such other activity as may be deemed appropriate.

E. In the event the director of the laboratory is absent for a continuous period longer than one-month duration, the laboratory shall not operate unless a person who meets the qualifications of § 5.5.2(A)(2) of this Part is in attendance.

F. The laboratory director shall designate a quality assurance officer who has the responsibility for the laboratory's quality assurance plan and its implementation. The laboratory director may be the self-designated Quality Assurance Officer or a consultant may be designated to serve as the Quality Assurance Officer.

1. The quality assurance officer shall have earned at least a bachelor's degree in a chemical or biological science and two years of related laboratory experience. The quality assurance officer qualifications may be met if the person has previous laboratory quality assurance experience acceptable to the Department in a licensed, certified or accredited

laboratory, or possesses other qualifications acceptable to the Department.

2. The quality assurance officer shall:

   a. be responsible for the oversight of QC data, including establishing acceptance criteria and documenting/monitoring corrective action;

   b. where staffing allows, be independent of the technical areas for which he/she has QA oversight;

   c. have general knowledge of the methodologies for which data review is performed;

   d. have oversight of the laboratory's quality assurance system and conduct or arrange for annual internal audits of the technical operation and report findings to the laboratory director.

5.5.3 Personnel

A. 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.

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

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

   1. current background information pertaining to qualifications, to justify initial and continued employment;

   2. orientation, including an initial demonstration of capability for each method and/or instrument the analyst will be performing and/or operating;

   3. evidence of periodic evaluation of work performance; and

   4. such other data as may be deemed appropriate.

5.6 Records & Reports

A. Each analytical laboratory shall maintain appropriate records and reports, which shall be available for inspection by authorized representatives of the Department.

B. The certified laboratory shall create, control, and maintain records of raw data, chain-of-custody records, calculations, quality control data, and other essential documentation. All records shall be complete with signatures, units of

measurement, and documentation sufficient for verification of results. All records shall be retained in such a manner as to permit prompt retrieval. Such records shall include:

1. records of the operation and maintenance of all laboratory equipment;

2. records of all sample examinations in accordance with § 5.7.3 of this Part;

3. records of control values, standard values, calibration curves and calculations of standard deviations; and

4. reports of proficiency testing programs and of such other records as may be deemed necessary.

C. All records and reports shall clearly indicate which analytes have been analyzed by certified methods and which have not. If a report references a method for which the laboratory is certified, adherence to the method is required. All records and reports including correspondence related to reported results and compliance issues shall be retained a minimum of five (5) years and be available for review.

D. Laboratory reports shall clearly identify the name, address and Rhode Island analytical laboratory certification number 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.

E. Multipage reports shall be paginated.

F. All reports of laboratory analyses for compliance purposes shall be submitted to the Department by the certified laboratory contracted by the public water system to analyze the samples.

G. Any portion of the analysis sub-contracted to another certified laboratory shall be reported by the primary contracted laboratory. The primary contracted laboratory shall submit the final report to the Department.

H. Certified laboratories shall submit forms to the Department in a format approved by the Department, which includes hard copy or electronic forms.

I. Certified laboratories must report, to both their public water facility client and to the Department's Center for Drinking Water Quality, any priority test results no later than twenty-four (24) hours after the results are known, or the next business day if State offices are closed. Priority results include:

1. Positive total coliform results;

2. E. coli positive results;

3. Nitrate results exceeding the Maximum Contaminant Level as defined by Public Drinking Water (Part 50-05-1 of this Title);

4. Nitrite results exceeding the Maximum Contaminant Level as defined by Public Drinking Water (Part 50-05-1 of this Title); and

5. Lead results exceeding fifteen (15) parts per billion (ppb).

5.7 Quality Assurance and Quality Control Programs

5.7.1 General Requirements

A. Each analytical laboratory shall have clearly established internal and external quality controls to ensure high standards of performance and reliability of test results. These quality controls shall consider such factors as preventative maintenance, periodic inspection, testing for proper validation of methods, evaluation of reagents and volumetric equipment, surveillance of results, remedial action taken to correct deficiencies and quality control failures and such other equivalent factors as required in this Part and as may be deemed necessary.

B. The laboratory shall perform all analyses which will be used for compliance with state or federal regulations, using the prescribed methods incorporated above at §§ 5.2(A) through (H) of this Part.

C. The laboratory's quality assurance plan shall be accessible to all personnel in the laboratory. It shall include, but not be limited to:

1. sampling procedures (if performed by the laboratory);

2. laboratory sample handling procedures;

3. instrument calibration procedures;

4. a list of detailed analytical procedures or analytical references;

5. data reduction, validation, and reporting procedures including non-compliance action plan;

6. types and frequency of internal audit samples (quality control samples) and external audit samples (proficiency testing samples);

7. internal audit procedures and frequency;

8. preventative maintenance procedures and schedules;

9. procedures for determining accuracy and precision and method detection limits of all analytes and specified frequency;

10. control limits and corrective action policies;

11. laboratory organization, staff, and responsibilities; and

12. procedures for laboratory and managerial data review.

D. The method detection limit (MDL) shall be determined prior to placing a new method in service and annually thereafter for each analyte per 40 C.F.R. § 136 Appendix B incorporated above at § 5.2(A) of this Part, or other such MDL guidance as deemed appropriate by the Department.

1. Method Detection Limits determined by the laboratory for analytes in the potable water category must meet the detection limit criteria specified in 40 C.F.R. §§ 141.23 and 24 incorporated above at § 5.2(A) of this Part. If the laboratory cannot meet said criteria for an analyte, a request for a variance must be submitted pursuant to § 5.11 of this Part.

E. The laboratory shall follow the quality control requirements specified in "Standards Methods for the Examination of Water and Wastewater" incorporated above at § 5.2(F) of this Part.

F. The laboratory shall follow all applicable quality control activities described in the "EPA Manual for the Certification of Laboratories Analyzing Drinking Water" incorporated above at § 5.2(D) of this Part. This requirement applies to pertinent non-potable water testing as well.

5.7.2 Procedure Manual

A. Each analytical laboratory shall 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 certified. Furthermore, such manuals shall:

1. Specify the approved method employed;

2. Describe the quality control activities pertinent to the method;

3. Contain information concerning preparation and storage of media, reagents, control and calibration procedures and pertinent literature references;

4. Describe the laboratory's technical procedures for the collection, processing and examination of samples;

5. 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

6. Be approved, signed, and dated by the current laboratory supervisor/director and the QA Officer. Changes in procedures must be approved, signed, and dated by the current supervisor/director and QA Officer.

7. Required methodologies for testing can be found in EPA Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Standard Methods for the Examination of Water and Wastewater, Methods for the Chemical Analysis of Water and Wastes and, Methods for the Organic Chemical Analysis of Municipal and Industrial Wastewater incorporated at §§ 5.2(D) through (H) of this Part.

5.7.3 Collection, Identification & Examination of Samples

A. Information that accompanies samples shall be sufficiently detailed to permit identification and document chain of custody.

B. The laboratory shall not accept samples for examination unless there is sufficient documentation to verify proper collection, preservation, and other conditions as prescribed in the relevant methods, and to permit adherence to holding times.

C. The laboratory shall not accept samples for examination without sufficient sample volume to perform the requested analyses.

D. 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:

1. the laboratory number or other identification,

2. the name of the person or analytical laboratory that submitted the sample,

3. date of sample collection,

4. date of sample receipt,

5. condition of sample upon receipt,

6. type of test requested and performed,

7. the results and date of laboratory tests and date of reporting, and

8. the name and address of laboratory to which the sample(s) is forwarded for procedures not performed on the premises.

5.7.4 Other Applicable Regulations

An analytical laboratory certified in the category of radiochemistry shall comply with the Rules and Regulations for the Control of Radiation and shall obtain, as applicable, the appropriate radioactive materials license from the Department.

5.7.5 Proficiency Testing

A. Each laboratory shall participate in a proficiency testing program approved by the Department for each analyte (or group of analytes) and method for which the laboratory is certified or is requesting certification. Proficiency testing samples shall be procured from a provider of proficiency test samples accredited by a Proficiency Testing Provider Accreditor (PTPA) that meets the TNI requirements.

B. The laboratory shall analyze a PT sample annually for each analyte and matrix by each method and receive an acceptable evaluation from the PT provider for that analyte/method/matrix, with the following exceptions:

1. laboratories certified for environmental lead must maintain a proficient status according to their respective accrediting agency;

2. laboratories must receive an acceptable evaluation for at least eighty percent (80%) of the Regulated Volatile Organic Compounds and eighty percent (80%) of Haloacetic Acids, in potable water, to maintain certification for these analyte groups, (as defined in the reference incorporated above at § 5.2(A) of this Part); and,

3. laboratories certified for potable and non-potable water-microbiology must correctly analyze ninety percent (90%) of the samples in a shipment with no false negatives for qualitative microbiology proficiency testing, and for quantitative microbiology proficiency testing no more than one (1) of the target organisms in a sample set containing three (3) or more samples may be incorrectly quantified.

C. Proficiency test results shall be submitted directly from the accredited provider to the certification office by October 31 of each year. The Department shall be designated as the recipient of the laboratory results before the results are available to the laboratory.

D. Whenever a laboratory receives an unacceptable evaluation for an analyte in a study, it shall determine the cause for the failure, take corrective action, and participate in another PT study for the failed analyte. Documentation of the investigation and corrective action shall be maintained and a copy provided to the Department before the next proficiency testing study.

E. Failure to complete PT studies or failure to obtain an acceptable result in a PT study as specified in § 5.7.5(D) of this Part shall result in loss of certification for the analyte until two (2) consecutive PT studies resulting in acceptable evaluations have been completed. There shall be an interval of at least thirty (30) days between the two (2) studies.

F. All proficiency test samples shall be analyzed in the same manner and frequency as a real environmental sample using the same staff, procedures and equipment.

G. Laboratories shall not send a PT sample, or a portion thereof, to another laboratory for any analysis for which it is certified or seeks certification.

H. A laboratory shall not knowingly receive any PT sample, or a portion thereof, from another laboratory for any analysis for which the sending laboratory is certified or seeks certification.

I. Laboratory management or staff shall not communicate with any individual at another laboratory concerning a PT sample or attempt to obtain the assigned value from their PT provider.

J. All raw data obtained in analyzing PT samples shall be retained and be available for review for a minimum of five (5) years.

K. The use of supplemental PT samples shall be allowed only if the PT provider certifies, in writing, that PT samples meet the criteria specified by the EPA.

L. A laboratory not located in Rhode Island shall follow the proficiency testing requirements of the state in which it is located.

5.8 Physical Plant, Equipment, and Supplies

A. Each analytical laboratory shall be housed in well lighted, sanitary, properly vented quarters equipped with hot and cold running water, and toilet facilities and shall contain ample space to process and examine the samples commensurate with the total workload. Furthermore, said analytical 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, be well lighted and have sufficient water, gas, suction, electrical outlets and sinks;

3. have adequate and proper storage space for all chemicals including explosive, flammable, corrosive and caustic materials;

4. have flooring composed of non-porous material in laboratory areas where acids, caustics, and solvents are used;

5. have adequate temperature and humidity controls as may be required for proper performance of tests and operation of instruments affected by environmental conditions;

6. have adequate electrical supply; and

7. have adequate refrigeration for samples, standards, and reagents used in testing

    a. food for consumption may not be stored in refrigerators containing laboratory materials.

B. The laboratory shall possess suitable equipment required for certified analyses that shall meet the requirements of the methods. All instruments shall be physically located on site.

C. The laboratory shall have sufficient glassware and plastic labware necessary for the analyses. Glassware shall be borosilicate glass or other corrosion-resistant glass. It shall be free of cracks and chips. Markings and etchings shall be legible. Volumetric flasks, pipettes, and other glassware used for volumetric analysis shall be class “A”.

D. All precision equipment and instruments shall be calibrated and checked for accuracy at regular intervals as required by the method and the laboratory’s quality assurance policies. Documentation of calibration and accuracy checks shall be maintained. Records of service by a qualified instrument service organization shall be maintained.

E. Balance range and sensitivity shall be appropriate for the application for which it is used. Balances shall be kept clean and free of corrosion and spillage and shall be checked daily with weights meeting ASTM Type I, Class 1 or 2 specifications with values that bracket the laboratory’s weighing needs. Records shall be maintained that include acceptance criteria for the checks. ASTM weights shall be recalibrated every five (5) years or immediately if nicked or corroded. Non-reference weights may be used but shall be calibrated every six (6) months against ASTM type 1, 2 or 3 weights.

    1. All balances shall be calibrated annually by a professional balance service.

F. All incubators, refrigerators, ovens, and water baths shall contain calibrated thermometers.

G. Thermometer range and graduation increments should be appropriate for the application for which it is used. Glass thermometers shall be checked for accuracy annually, and other types of thermometers quarterly, by comparing with a NIST traceable thermometer at the temperatures of interest. Thermometers shall be tagged with the date of accuracy check and the correction factor (which may be zero). There shall be no separation in the liquid column of glass thermometers.

H. Analytical reagent grade chemicals are required for analyses unless otherwise allowed or specified by the analytical method.

I. Bottles of dehydrated microbiology media shall be dated when received and dated when opened. Media shall not be used beyond the manufacturer's expiration date or within one (1) year from opening, whichever is sooner. It shall be discarded immediately if caked or otherwise deteriorated. Prepared, prepackaged media are permitted.

J. All plastic labware used for microbiology shall be clear and non-toxic.

K. For chemical analyses, reagent water for general use shall be distilled or deionized and have a resistivity value greater than 0.5 megohms/cm or a conductivity value of less than 2 microhmos/cm at 25°C. Quality checks shall be made according to specified analytical method requirements, but at least monthly, with a conductivity meter. All such quality checks shall be recorded.

L. For microbiological analyses, reagent water shall meet all criteria listed in the following table:

PARAMETER	LIMITS	FREQUENCY
resistivity or	> 0.5 megohms/cm	monthly
conductivity	< 2 micromhos/cm	monthly
Pb, Cd, Cr, Cu, Ni, Zn	< 0.05 mg/L per contaminant and < 0.1 mg/L total	annually
total chlorine residual	none detectable	monthly
Heterotrophic plate count	< 500/mL	monthly
bacteriological quality of reagent water	Ratio of growth rate: 0.8 to 3.0 (see Standard Methods, Section. 9020B. This test is not required if laboratories use water that meets the criteria for Types I and II water as defined in Standard Methods, Section 1080).	annually

M. All reagents and solutions shall be labeled to indicate identity, concentration, storage requirements, expiration dates, and any other pertinent information.

N. All reagents and solutions shall be dated when received and opened. No materials shall be used beyond their expiration dates.

O. All laboratory prepared reagents and solutions must be labeled with preparation and expiration dates. No laboratory prepared materials shall be used beyond their expiration dates.

5.9 Safety & Security

A. Adequate safety and security precautions shall be established and maintained. Safety instructions shall be present in a laboratory safety manual for the protection of personnel from exposure to physical, chemical and biological hazards in laboratories. The laboratory safety manual shall include applicable procedures for the protection of employees and visitors.

B. Personnel shall be given a safety orientation reviewing policies and procedures in the safety manual.

C. Samples, standards, reagents, solvents, acids, chemicals and data must be kept in restricted access areas.

D. The laboratory must supervise visitors, repairmen, and maintenance workers in restricted areas.

5.10 Waste Disposal

A. The laboratory must manage medical waste pursuant to the Medical Waste Regulations (250-RICR-140-15-1).

B. The laboratory must manage hazardous waste pursuant to the Rules and Regulations for Hazardous Waste Management (250-RICR-140-10-1).

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

1. 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; and

2. Load packers must conform to the same restrictions required for dumpsters and shall be high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment and the loading section shall be construed and maintained to prevent rubbish from blowing away.

5.11 Variance Procedure

A. The Department 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 federal regulations, the public interest, public health, or health and safety of individuals.

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

C. Upon filing of such request with the Department and within a reasonable time thereafter, the Department 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.

5.12 Violations

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

5.13 Rules Governing Practices & Procedures

All hearings and reviews required under the provision of this Part will be held in accordance with Practices and Procedures Before the Rhode Island Department of Health (Part 10-05-4 of this Title) and Access to Public Records (Part 10-05-1 of this Title).

216-RICR-60-05-5

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 60 - LABORATORIES AND MEDICAL EXAMINER

SUBCHAPTER 05 - STATE LABORATORY

PART 5 - CERTIFYING ANALYTICAL LABORATORIES (216-RICR-60-05-5)

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