

STATE OF MAINE

**MAINE COMPREHENSIVE AND LIMITED ENVIRONMENTAL
LABORATORY ACCREDITATION RULE**



10-144 Code of Maine Rules

Chapter 263

Department of Health and Human Services

jointly with

06-096 Code of Maine Rules

Chapter 263

Department of Environmental Protection

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SUMMARY STATEMENT

This rule is promulgated by the Department of Health and Human Services (DHHS) and the Department of Environmental Protection (DEP) for the accreditation of laboratories producing compliance data for programs administered by DHHS and DEP.

TABLE OF CONTENTS

SECTION 1.	
ADMINISTRATION	1
A. Purpose and scope	1
B. Exceptions	1
C. Authority	1
 SECTION 2.	
DEFINITIONS	3
 SECTION 3.	
METHODS REQUIRED FOR ACCREDITATION	9
A. Scope	9
B. Wastewater Program	9
C. Drinking Water Program	10
D. Resource Conservation Recovery Program	10
E. Oil Program or Leaking Underground Storage Tanks (LUST) Program	10
F. Environmental Lead Program	10
G. Other required methods	10
 SECTION 4.	
APPLICATION PROCESS	11
A. Application requirements	11
B. Applications for renewal of accreditation	12
C. Requirements for mobile laboratories	12
D. Changes in scope of accreditation	12
E. Application processing	13
F. Decision on application	13
 SECTION 5.	
LABORATORY INSPECTION	14
A. Laboratory inspection	14
B. Equivalency of laboratories in other states	15
 SECTION 6.	
FEES	17
A. Payment	17
B. Fee table	17
 SECTION 7.	
ACCREDITATION	19
A. Levels of accreditation	19
B. Awarding accreditation	19

C.	Denial of accreditation	20
D.	Downgrading of accreditation to provisional status.....	20
E.	Suspension and reinstatement of accreditation after suspension.....	20
F.	Revocation of accreditation.....	21
G.	Appeal of administrative decision.....	23
H.	Voluntary withdrawal of accreditation.....	24
SECTION 8.		
QUALITY SYSTEMS		
A.	Laboratory organization	26
B.	Duty to notify	26
C.	Personnel requirements - laboratory technical director.....	27
D.	Personnel requirements - quality assurance officer (QAO)	28
E.	Responsibilities of laboratory management	28
F.	Internal audits.....	30
G.	Management reviews.....	30
H.	Data integrity training	31
I.	Data integrity investigations.....	32
J.	Corrective action	32
K.	Demonstration of capability	33
L.	Sample handling, receipt and acceptance.....	34
M.	Standards, reagents and bacteriological media.....	37
N.	Calibration of support equipment.....	39
O.	Calibration of analytical instruments	42
P.	Reporting.....	45
Q.	Documents and records	47
SECTION 9.		
LABORATORY POLICIES AND PROCEDURES		
A.	Quality Assurance Manual	50
B.	Standard operating procedures	51
SECTION 10.		
PROFICIENCY TESTING REQUIREMENTS.....		
A.	Obtaining proficiency test samples	54
B.	Availability of proficiency test samples.....	55
C.	Proficiency testing requirements to obtain or maintain accreditation	56
D.	Proficiency test sample analysis requirements	56
E.	Proficiency test sample reporting requirements	57
F.	Proficiency test sample study record retention.....	58
G.	Evaluation of results.....	58
H.	Questionable proficiency test samples	58
I.	Corrective actions for unacceptable results.....	59
J.	Grounds for suspension of accreditation	59
K.	Requirements for reinstatement of accreditation after suspension.....	59
L.	Additional samples for compliance.....	60
SECTION 11.		
QUALITY CONTROL CRITERIA		
A.	Quality control criteria for chemistry.....	61
B.	Quality control criteria for bacteriology.....	66
C.	Quality control criteria for radiochemistry.....	71

SECTION 12.

WASTE MANAGEMENT77

A. SOP for waste management77

STATUTORY AUTHORITY78

SECTION 1. ADMINISTRATION

A. Purpose and scope

The purpose of this rule is to establish quality guidelines for laboratory data received by the DHHS and the DEP. The rule establishes procedures for accrediting laboratories by creating minimum criteria for laboratory operations, performance, and administration. This rule is intended for the accreditation of all laboratories, including industrial, commercial, academic and governmental, that analyze samples under the following regulations: Safe Drinking Water Act; Clean Water Act; Resource Conservation and Recovery Act; and Leaking Underground Storage Tanks (LUST) Program for the DHHS and/or the DEP. The Maine Laboratory Accreditation Program (MLAP) within Maine Center for Disease Control and Prevention (Maine CDC) will accredit laboratories for drinking water, non-potable water, air, and solid and chemical materials, including tissues and septage, in accordance with this rule.

B. Exceptions

1. Treatment plants with in-house drinking water laboratories involved in limited analysis required for system or treatment surveillance, but deemed by the United States Environmental Protection Agency (EPA) and the MLAP as analytes not required for analysis by an accredited laboratory under 10-144 CMR ch. 231 § 7, Rules Relating to Drinking Water, do not need to be accredited.
2. Laboratories operated by wastewater discharge facilities licensed pursuant to 38 MRS § 413 may analyze wastewater discharges for total suspended solids, total dissolved solids, settleable solids, biological or biochemical oxygen demand (BOD), chemical oxygen demand, carbonaceous BOD, pH, chlorine residual, fecal coliform, *E. coli*, conductivity, color, temperature, turbidity, and dissolved oxygen without being certified under this rule.
 - a. This exception is limited to a laboratory testing its own samples for pollutants listed on its permit or license, pretreatment samples, and samples from other wastewater treatment plants for up to 60 days of analysis per year.
 - b. A day of analysis is defined as analyzing one or more samples for one or more parameters, all with the same sampling date. When analyzing multiple samples for one or more parameters spanning two or more sampling dates, the count of the different sampling dates will define the days of analysis.
3. This rule does not address the management of waste streams or the use of hazardous or toxic substances. Laboratories should consult with the DEP regarding any such rules that may apply to their facility or operations.

C. Authority

1. 22 MRS ch. 157-A authorizes the director of the Maine CDC to establish a State accreditation program for laboratories that generate data pursuant to specific statutory requirements for programs of the DHHS and the DEP. This rule for Maine Comprehensive and Limited Environmental Laboratory Accreditation is hereby promulgated to implement portions of 22 MRS ch. 157-A.
2. The director of the Maine CDC is responsible for implementation of this accreditation rule. The director shall designate an accreditation officer to manage the accreditation program.

SECTION 2: DEFINITIONS

- A. Definitions in this rule are in addition to definitions in the statute. As used in this rule, unless the context otherwise indicates, the following terms have the following meanings.
1. **Acceptance criteria** means the specified limits placed on characteristics of an item, process, or service defined in requirement documents.
 2. **Accreditation** means the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.
 - a. **Primary Accreditation** means the accreditation awarded by an approved accrediting body having the responsibility of assessing a laboratory's total quality system, providing on-site assessments and tracking proficiency testing (PT) performance for fields of accreditation.
 - b. **Secondary Accreditation** means the accreditation granted to a laboratory for a field of accreditation based on recognition of accreditation from a primary accreditation body for the same field of accreditation.
 3. **Accreditation officer** means the person designated by the director of the Maine CDC to manage the MLAP.
 4. **Accuracy** means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.
 5. **Analyst** means the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.
 6. **Analytical uncertainty** means a subset of measurement uncertainty that includes all laboratory activities performed as part of the analysis.
 7. **Approved provider or approved proficiency testing provider** means a provider of proficiency testing samples that the accreditation officer has determined meet the requirements of Section 10 of this rule.
 8. **Assessment** means the evaluation process used to measure or establish the performance effectiveness and conformance of an organization and/or its systems to defined criteria and standards and requirements of laboratory accreditation.
 9. **Audit** means a systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and reporting aspects of a system to determine whether quality assurance, quality control and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.
 10. **Batch** means the environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of at least one and no more than 20 environmental sample(s) of the same quality

systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples, unless the method requirements are more stringent.

11. **Bias** means the systematic or persistent distortion of a measurement process, which causes errors in one direction (e.g., the expected sample measurement is different from the sample's true value).
12. **Blank** means a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and may be used to adjust or correct routine analytical results. Blanks include field blanks, instrument blanks, method blanks, and trip blanks.
 - a. **Field blank** means a clean sample (e.g., distilled water) carried to the sampling site, exposed to sampling conditions, returned to the laboratory and treated as an environmental sample.
 - b. **Instrument blank** means a clean sample processed through the instrumental steps of the measurement process and used to determine instrument contamination.
 - c. **Method blank** means a sample of a matrix similar to the batch of associated samples when available that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.
 - d. **Trip blank** means a clean sample of a matrix that is carried to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.
13. **Calibration** means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

In calibration of support equipment, the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).

In calibration according to methods, the values realized by standards are typically established through the use of reference materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

14. **Calibration curve** means the mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.
15. **Calibration standard** means a substance or reference material used for calibration.

16. **Certified reference material (CRM)** means reference material, accompanied by a certificate, having a value, measurement of uncertainty and stated metrological traceability chain to a national metrology institute.
17. **Chain-of-custody form** means a record, either paper-based or electronic, that documents the possession of the samples from the time of collection to receipt in the laboratory in accordance with chain-of-custody protocol. This record, at a minimum, must include the sample location, the number and types of containers, the mode of collection, the collector, the date and time of collection, preservation, and requested analyses. See also Legal Chain of Custody Protocols.
18. **Corrective action** means an action taken by the laboratory to eliminate or correct the causes of an existing nonconformance to prevent the recurrence of the nonconformance.
19. **Corrective action plan** means a report, including specific corrective actions and a specific date of completion, generated by a laboratory in response to deficiencies.
20. **Data reduction** means the process of transforming the number of data items by arithmetic or statistical calculation, standard curves and concentration factors, and collating them into a more useful form.
21. **Deficiency or deviation** means a failure of the laboratory to meet any of the requirements in this rule.
22. **Demonstration of capability** means a procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.
23. **Director** means the director of Maine CDC or the director's designee.
24. **Field of testing (FOT)** means those programs, matrices, methods or analyte combinations for which accreditation is offered.
25. **Internal standard** means a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.
26. **Laboratory control sample (LCS)** means a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes and taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a reference method. It may be used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system; however named, such as laboratory fortified blank, spiked blank or quality control (QC) check sample.
27. **Legal chain-of-custody protocols** means the procedures developed and employed by the laboratory to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a chain of custody form that documents the collection, transport and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.

28. **Limit(s) of detection (LOD)** means an estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably be detected in the laboratory.
29. **Limit(s) of quantitation (LOQ)** means the minimum levels, concentrations or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.
30. **Limited laboratory accreditation** means a laboratory with limited accreditation that reports no more than a total of five analytes for no more than two methods.
31. **Managing agent** means the person legally authorized to direct the activities of a laboratory and commit the appropriate resources to comply with this rule.
32. **Matrix or matrices** means the substrate of a test sample.
33. **Matrix duplicate** means a replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision.
34. **Matrix spike** means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound.
35. **Measurement system** means a method, as implemented at a particular laboratory, which includes the equipment used to perform the test and the name(s) of the analyst(s).
36. **Method** means a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis or quantification), systematically presented in the order in which they are to be executed.
37. **Method analyte table (MAT)** means the table used to identify methods, analytes, programs and matrices available for accreditation.
38. **Method detection limit (MDL)** means the minimum measured concentration of a substance that can be reported with 99 percent confidence that the measured analyte is distinguishable from method blank results.
39. **Mobile laboratory** means a portable, enclosed structure with necessary and appropriate accommodations and environmental conditions for a laboratory, within which testing is performed. Examples include, but are not limited to the following: trailers, vans and skid-mounted structures configured to house testing equipment and personnel.
40. **National Institute of Standards and Technology (NIST)** means a federal agency of the United States Department of Commerce's Technology Administration that is designated as the National Metrology Institute (NMI).
41. **Nonconformance or noncompliance** means a failure of a laboratory to meet any requirement in this rule.
42. **Owner** means a person who is a sole proprietor of a laboratory; holds a partnership interest in a laboratory; or owns five percent or more of the shares in a corporation that owns a laboratory.

43. **Precision** means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision serves as a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.
44. **Preservation** means any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis.
45. **Proficiency testing (PT)** means a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.
46. **Proficiency test sample or PT sample** means a sample, the composition of which is unknown to the laboratory provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.
47. **Protocol** means the detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.
48. **Quality assurance (QA)** means an integrated system of management activities involving planning, implementation, assessment, reporting and quality improvement to ensure that a process, item or service is of the type and quality needed and expected by the client.
49. **Quality control (QC)** means the overall system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that they meet the stated requirements established by the client; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.
50. **Quality control sample** means a sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as certified reference materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.
51. **Quality manual** means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability and implementation of an agency, organization or laboratory, to ensure the quality of its product and the utility of its product to its users.
52. **Quality system** means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability and implementation plan of an organization for ensuring quality in its work processes, products (items) and services. The quality system provides the framework for planning, implementing and assessing work performed by the organization and for carrying out required QA and QC activities.
53. **Quantitate** means to undertake the arithmetic process of determining the amount of analyte in a sample.

54. **Raw data** means the documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, un-tabulated sample results, QC sample results, chromatograms, instrument outputs and handwritten records.
55. **Reagent water** for chemical analysis means water with no detectable concentration of the analyte to be analyzed at the detection limit of the analysis.
56. **Reference material** means a material or substance, one or more of which the property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
57. **Replicate** means two or more substantially equal aliquots analyzed independently for the same parameter.
58. **Reporting limit (RL)** means the lowest level of an analyte that can be accurately recovered from the matrix of interest (e.g., the level of quantitation).
59. **Revocation** means a determination by the accreditation officer to invalidate in part, or in total, a laboratory's accreditation.
60. **Sampling date** means the date that a sample was taken in the field, which will be reported as such when reporting the sample results to laboratory clients or regulatory programs.
61. **Scope of accreditation** means the sum of all fields of testing for which a laboratory has been granted accreditation by the accreditation officer.
62. **Second source** means a different vendor or manufacturer, or different lots from the same vendor or manufacturer, usually in reference to standards.
63. **Selectivity** means the ability to analyze, distinguish and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system.
64. **Sensitivity** means the capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.
65. **Solid** means a matrix that includes: soils, sediments, solid waste and sludges.
66. **Standard** means the certified reference materials produced by NIST or other equivalent organization and characterized for absolute content, independent of analytical method or the dilutions made from these certified reference materials for the purposes of calibration or determining accuracy of a test method.
67. **Standard operating procedure (SOP)** means a written document that details the method for an operation, analysis or action, with thoroughly prescribed techniques and steps. SOPs are officially approved by the laboratory's senior management as the methods for performing certain routine or repetitive tasks.

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- 68. Surrogate standard** means a non-target analyte that has similar chemical properties to the analyte of interest. The surrogate standard is added to the sample in a known amount and used to evaluate the response of the analyte to preparation and analysis procedures.
- 69. Suspension** means the temporary invalidation, in part or in total, of a laboratory's accreditation for a defined period of time according to Section 7(E), to allow a laboratory time to correct deficiencies or areas of noncompliance to comply with this rule.
- 70. Target or target analyte** means an analyte or list of analytes within a test method that may be analyzed and for which the laboratory has obtained accreditation from the accreditation officer to test as part of a field of testing.
- 71. Technology** means a specific arrangement of analytical instruments, detection systems and/or preparation techniques.
- 72. Traceability** means the ability to trace the history, application or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.
- 73. Verification** means the confirmation by examination of and provision of objective evidence that specified requirements have been fulfilled. Verification is the process of examining a result of a given activity to determine conformance with this rule.

SECTION 3: METHODS REQUIRED FOR ACCREDITATION**A. Scope**

1. The laboratory must use appropriate methods and procedures for all tests within its scope. These methods and procedures include sampling, handling, transport, storage and preparation of samples as well as statistical techniques for analysis of test data.
2. The laboratory must retain instructions on the use and operation of all relevant equipment and on the handling and preparation of samples. All instructions, standards, manuals and reference data relevant to the work of the laboratory must be kept current and must be made readily available to personnel. Deviations from test methods may occur only if the deviation has been documented, technically justified, authorized, accepted by the client and allowed by regulation. Deviations from Drinking Water methods are not permitted.
3. Laboratories must observe appropriate methodologies for conducting analyses.

B. Wastewater Program

1. Methods for the Wastewater Program test category are as provided in 40 CFR Part 136, including 40 CFR § 136.3, Tables IB, IC and ID; § 136.4; § 136.5; § 136, Appendices A, B, and C; and 40 CFR Part 503, updated in the Annual Edition of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017. The CFR is available online at the website of the US Government Publishing Office, Code of Federal Regulations (Annual Edition). The Federal Register is available online by searching the citation.
2. Unless prohibited by a federal regulation, alternative methods may be used for Maine-specific testing if the state agency administering the permit, program or rule grants written approval, citing the laboratory's name and the title, revision date and revision number of the procedure that is receiving DEP approval.
3. The laboratory must submit a copy of the approval for alternative methods to the accreditation officer, along with an application, as required under Section 4 and fees as required under Section 6.
 - a. The laboratory must validate standard methods used outside its published scope to confirm that the methods are appropriate for the intended use.
 - b. Modifications to methods are allowed, only if the modified method produces equivalent performance for the analyte(s) of interest, as determined by the accreditation officer, and the equivalent performance is documented.

C. Drinking Water Program

1. Methods for the Drinking Water Program test category are in 40 CFR Part 141, including Subpart C, Appendix A and 40 CFR §§ 141.21(f), 141.23(k), 141.24(e), 141.131(b), 141.131(c), 141.131(d), 141.74(a), and 40 CFR § 143.4(b) updated in the Annual Edition of July 1, 2017.
2. In the absence of an applicable federal regulation, alternative methods may be used for Maine-specific testing, if the Maine State agency administering the permit, program or rule grants written approval that cites the laboratory's name and the title, revision date and revision number of the procedure receiving agency approval.

D. Resource Conservation Recovery Program

1. Methods for the Resource Conservation Recovery Program test category are as provided under 40 CFR Part 261, as amended up to July 1, 2017 and “Test Methods for Evaluating Solid Waste: Physical/Chemical Methods,” Publication SW-846 and the *Methods Innovation Rule*, 40 CFR Parts 63, 258, 260, 261, 264, 265, 266, 268, 270, 271 and 279, updated in the Annual Edition of July 1, 2017.
2. In the absence of an applicable federal regulation, alternative methods may be used for Maine-specific testing if the Maine State agency administering the permit, program or rule grants written approval, citing the laboratory’s name and the title, revision date and revision number of the procedure that is receiving DEP approval.
3. The laboratory must submit a copy of the approval of alternate methods to the accreditation officer, along with an application, as required under Section 4 and fees as required under Section 6.
 - a. The laboratory must validate methods used outside its published scope to confirm that the methods are fit for the intended use.
 - b. Modifications to methods are allowed only if the modified method produces equivalent performance for the analyte(s) of interest, as determined by the accreditation officer, and the equivalent performance is documented.

E. Oil Program or Leaking Underground Storage Tanks (LUST) Program

1. The laboratory must be accredited under this rule for organic compounds analysis in either the Wastewater Program or Resource Conservation and Recovery Program.
2. In the absence of an applicable federal regulation, alternative methods may be used for Maine-specific testing, if the Maine State agency administering the permit, program or rule grants written approval that cites the laboratory's name and the title, revision date and revision number of the procedure receiving DEP approval.

F. Environmental Lead Program

1. A certificate will be issued to any laboratory providing documentation of accreditation through a program recognized by the EPA’s National Lead Laboratory Accreditation Program (NLLAP).
2. In the absence of an applicable federal regulation, alternative methods may be used for Maine-specific testing, if the Maine State agency administering the permit, program, or rule grants written approval that cites the laboratory's name and the title, revision date and revision number of the procedure receiving agency approval.

G. Other required methods

The analytical methods, as well as the verification of preservation procedures used for samples required to be analyzed under a permit, program or rule administered by a Maine State agency must meet the requirements specified by the permit, program or rule.

SECTION 4: APPLICATION PROCESS

- A. Application requirements.** These requirements pertain to all laboratories applying for accreditation, including those seeking limited accreditation or renewal of accreditation.
- 1.** A laboratory may request to be accredited for the use of methods and analytes eligible for accreditation according to Section 3. The accreditation officer will maintain a MAT of methods and analytes by program and matrix, available for accreditation.
 - 2.** Out-of-state laboratories may not apply for programs, matrices, methods or analytes in which they do not have primary certification or accreditation by another approving body.
 - 3.** A laboratory must specify the fields of testing for which it seeks accreditation using the MAT maintained by the accreditation program. No laboratory may receive initial accreditation without approval of at least one field of testing.
 - 4.** A laboratory must apply using the appropriate form (Initial or Renewal Application) provided by MLAP. The laboratory must supply:
 - a.** The name of the laboratory;
 - b.** The physical location, postal mailing address and email address of the laboratory;
 - c.** The name(s) of the owner(s) of the laboratory;
 - d.** The name(s) and telephone number(s) of designated contact person(s) as well as the laboratory director and quality assurance officer;
 - e.** The applicable fees, including a nonrefundable base accreditation fee and fees for each test method in which the laboratory seeks accreditation;
 - f.** A QA manual meeting the standards of Section 9(A);
 - g.** SOPs for methods requested for laboratory accreditation meeting the standards of Section 9(B). Out-of-state laboratories are required to submit SOPs only at the request of the accreditation program;
 - h.** The most recent proficiency testing result for each field of testing for which the laboratory seeks accreditation. The proficiency testing samples must be supplied by an approved provider and be analyzed within six months of the date that the application is received by the accreditation officer;
 - i.** An accurate copy of the MAT including the laboratory's detection limits and reporting limits for each field of testing for which the laboratory is requesting accreditation; and
 - j.** If the laboratory is an out-of-state laboratory, a copy of the most recent on-site assessment report with final responses and current copies of all relevant certificates and scopes.

5. A laboratory that owns or manages laboratory facilities at different locations must submit a separate application for each laboratory location except as provided for mobile laboratories in Section 4(C).

B. Applications for renewal of accreditation

1. Applications must be received no later than 60 days before the expiration of accreditation.
2. The application must meet the criteria of Section 4(A).
3. If a laboratory fails to submit a renewal application before the expiration of accreditation, the accreditation officer must notify the regulatory authorities that the laboratory did not renew its accreditation.
4. The laboratory must not report results as accredited after its accreditation expires.

C. Requirements for mobile laboratories

1. A mobile laboratory is equivalent to a fixed laboratory location and is subject to all requirements, including application requirements, of this rule.
2. In addition to the requirements under Section 4(A), a mobile laboratory must submit a vehicle identification number, license plate number or other uniquely identifying information.
3. A mobile laboratory must designate which fields of testing, equipment and personnel are associated with the mobile laboratory. Changes to the numbers and types of equipment within the mobile laboratory may require reapplication according to Section 4(A). The operator of a mobile laboratory must maintain a record or log, documenting the actual location where the testing is performed, as well as the arrival and departure times of the mobile laboratory. This information must be known by the laboratory director or quality assurance officer.

D. Changes in scope of accreditation

1. The accreditation officer will approve a laboratory's application to add a field of testing at any time other than the time of renewal if the laboratory:
 - a. Submits passing proficiency test for the requested program, matrices, methods or analytes as specified in Section 10;
 - b. Completes the Revision Application;
 - c. Submits the applicable Method/Analyte Table sections with MDL/RL data;
 - d. Provides documentation demonstrating current, primary certification or accreditation for the requested parameter (applies to out-of-state laboratories only); and
 - e. Submits applicable fees according to Section 6.
2. Changes to the scope will include applicable fees for each test method added. See exception below in Section 4(D)(3). The request for methods or analytes must include current MDL/RL data in the MAT.

3. Notice of Availability
 - a. Requests to add fields of testing for analytes, in response to a notice of availability by the MLAP, do not require payment of additional fees if:
 - (i) The laboratory holds an accreditation for that test method;
 - (ii) The laboratory applies for a newly available analyte within the same test method; and
 - (iii) The laboratory submits the request within 180 days of the notice of availability.
 - b. Requests for the addition of fields of testing received more than 180 days after the notice of availability is posted by the MLAP are subject to fees according to Section 6.
4. There is no fee for relinquishing methods or analytes from the scope of accreditation.

E. Application processing

1. The MLAP shall not process an application until a complete application is received.
2. If the application is not complete when filed, the MLAP shall send the applicant written notice of what is needed to complete the application.
3. Upon notifying an applicant that the application is incomplete, the MLAP shall suspend further processing of the application pending receipt of the information required to complete the application.
4. Upon determining that an application is complete, the MLAP shall review it and proceed to make a decision on the application.

F. Decision on application

The MLAP shall approve an application and grant accreditation only if:

1. The applicant has submitted a complete application, required documentation and payment, as applicable, for primary or secondary accreditation.
2. The criteria listed in Section 4, for primary or secondary accreditation, as applicable, have been met.

SECTION 5: LABORATORY INSPECTION

A. Laboratory inspection

1. The accreditation officer must conduct a comprehensive on-site inspection of each laboratory located within the State of Maine, prior to granting accreditation. In addition, an on-site inspection of each Maine accredited laboratory should be completed every two years.
2. The accreditation officer may notify the laboratory prior to arrival at the facility or may conduct an inspection without prior notice at any time during normal business hours to verify compliance with this rule.
3. When the accreditation officer determines, after inspection that a Maine accredited laboratory does not comply with applicable provisions of this rule, the accreditation officer must notify the laboratory of the deficiencies in writing within 30 days of inspection by issuing a notice referred to as the initial on-site assessment report.
4. Additional on-site inspections, scheduled or unannounced, may be conducted to resolve problems indicated by deficiencies found during prior on-site inspections or when there is a change of location, key personnel or equipment, or to resolve a complaint. If the deficiencies listed in a previous on-site inspection report are substantial or numerous, an additional on-site inspection may be conducted before a final decision for accreditation is made.
5. A laboratory must remedy any deficiencies and provide documentation of the correction to the accreditation officer.
 - a. Within 30 days of receiving the initial on-site assessment report of deficiencies, the laboratory must submit responses and documentation of corrective actions implemented and planned.
 - i. If the laboratory does not provide responses within 30 days, the accreditation officer must notify the laboratory that its accreditation may be suspended in total or in part.
 - ii. If the laboratory does not provide any documentation of deficiency corrections within 30 days following the notification of possible suspension, the accreditation officer will notify the laboratory that its accreditation is revoked in total.
 - b. When the accreditation officer determines, after review of the laboratory responses to the initial on-site assessment report and review of documentation of corrective actions, that the corrective actions do not comply with applicable provisions of this rule, the accreditation officer will notify the laboratory, in writing, of the deficiencies within 30 days of the receipt of laboratory responses and documentation. This notice issued by accreditation officer's notice is referred to as the follow-up report.
 - c. Within 30 days of receiving the follow-up report from the accreditation program, the laboratory must submit responses and documentation of corrective actions. If the laboratory does not provide acceptable documentation of corrective actions within 30 days of receiving the follow-up report, the accreditation officer will notify the laboratory that its accreditation may be suspended in total or in part pursuant to 5 MRS § 10051 or as otherwise provided for by law.

If the laboratory does not provide any documentation within 30 days of notification of possible suspension, the accreditation officer may institute suspension or revocation proceedings, in total or in part, pursuant to 5 MRS § 10051 or as otherwise provided for by law.

- d.** When all deficiencies indicated in the initial on-site assessment report have been addressed satisfactorily, the MLAP will acknowledge the closing of the assessment in writing with an Acceptable Corrective Action Plan (ACAP) letter.
- 6.** A laboratory may not reapply for accreditation after suspension or revocation until it has corrected all deficiencies. After all deficiencies are corrected, the laboratory may apply for accreditation according to Section 4. With its new application, the laboratory must submit written documentation of the steps employed to correct the deficiencies.
 - 7.** At the discretion of the accreditation officer, third-party assessors may be used for inspection purposes by the MLAP.

B. Equivalency of laboratories in other states

- 1.** A laboratory in another state may request accreditation in Maine. This request is performed through an equivalency determination of the program of the state in which the laboratory is located or through equivalency determination of the federal agency which accredits or certifies the laboratory. A laboratory in another state must submit the resident state or federal agency's accreditation or certification program requirements for review prior to the accreditation request.
 - a.** If the resident state does not offer the specific program for which the laboratory is requesting accreditation, the accreditation officer may consider equivalency through another accreditation or certification which the laboratory holds. This accreditation program must be with a state or federal entity.
- 2.** The accreditation officer shall determine if the accrediting or certifying program of federal agencies and agencies of other states are substantially equivalent. Equivalency will be based on a comparison between this rule and the laboratory's resident state or federal agency's accreditation or certification program requirements. For a program to be determined equivalent, the program's criteria must be at least as stringent as stated in this rule.
- 3.** An accreditation or certification program is not considered equivalent if:
 - a.** Inspections of accredited or certified laboratories are performed at intervals exceeding two years; or
 - b.** The accrediting or certifying agency does not require an acceptable corrective action response with supporting documentation from the laboratory as required under Section 8; or
 - c.** The accrediting or certifying agency is not the primary authority to initiate necessary enforcement actions, such as suspension or revocation of the laboratory's accreditation/certification.
- 4.** When a program is deemed equivalent, the accreditation officer will accredit an out-of-state laboratory that:

- a.** Submits an application meeting the requirements of Section 4;
 - b.** Submits the appropriate fees;
 - c.** Provides a copy of current accreditation or certification from the resident state or federal agency;
 - d.** Provides a copy of the accrediting or certifying authority's most recent inspection report and complete responses; and
 - e.** Fulfills proficiency testing requirements of Section 10.
- 5.** When a program is not deemed equivalent, the accreditation officer may accredit an out-of-state laboratory that meets the requirements of this rule as determined by:
 - a.** A review of an application meeting the requirements of Section 4;
 - b.** Submission of the appropriate fees, including an on-site inspection fee for out-of-state laboratories;
 - c.** Inspection under the requirements of Section 5; and
 - d.** Fulfillment by the laboratory of proficiency testing requirements.
- 6.** A laboratory accredited under this sub-section must notify the accreditation officer within 14 days after any enforcement action is assessed by the laboratory's primary accrediting or certifying authority.
- 7.** A laboratory accredited under this sub-section must notify the accreditation officer within 14 days after any adverse change in accreditation or certification status is assessed by the laboratory's primary accrediting or certifying authority. The notification from the laboratory must contain an indication of the changes to the list of analytes.
- 8.** Laboratories accredited under equivalency must comply with the applicable requirements of this rule. Only fixed-base laboratories may apply for equivalency.
- 9.** Out-of-state laboratory inspection. If a laboratory located in another state is accredited by MLAP and is not scheduled for inspection by the laboratory's primary accrediting or certifying authority of that state prior to the period specified in that state's rules, MLAP must be notified 60 days prior to the two-year anniversary of the last complete inspection of the laboratory.

SECTION 6: FEES**A. Payment**

1. When a laboratory requests accreditation in Maine, the laboratory must submit all applicable fees with the application.
2. All applications or requests to change the scope of accreditation must be accompanied by the applicable fees specified in this section.
3. Application fees apply to the addition of methods for reinstatement after revocation or denial of accreditation.
4. No fee will be assessed for the addition of fields of testing in response to a notice of availability when an application is submitted under the conditions specified in Section 4, or for the addition of analytes to a test method which the laboratory maintains accreditation.
5. Payment of fees must be in the form of a check or money order, made payable to the “Treasurer, State of Maine.”

B. Fee table

1. The total biennial accreditation fee includes the base fee, the test method fees, and when applicable, the on-site inspection fee. Accreditation may be awarded biennially or annually.
 - a. The accreditation fees include the following:
 - (i) Base accreditation fee of \$1,250 (for both biennial and annual accreditation); and
 - (ii) Test method category accreditation fees are reduced by half for annual accreditation.

TEST METHOD CATEGORIES	BIENNIAL ACCREDITATION FEE
Bacteriology Methods	\$50 per method
Inorganic Chemistry Methods	\$50 per method
Metals Methods	\$125 per method
Organic Compounds Methods	\$150 per method
Radiochemistry Methods	\$200 per method

- b. The limited laboratory accreditation fee is \$650 for biennial or annual accreditation.
 - c. The environmental lead program fee is \$600 for biennial or annual accreditation.
2. A change fee will be assessed if a laboratory requests additional methods at any time other than when applying for or renewing its certification.
3. Refunds or credits will not be made for analytes or methods requested but not approved.

4. Accreditation of a laboratory will not be awarded until all fees are paid.
5. The MLAP will assess a fee for an on-site inspection for out-of-state laboratories. This fee will be based on the established hourly rate of the laboratory accreditation officer inclusive of preparation time, travel time and inspection time, as well as associated travel expenses (transportation, meals, lodging and other associated travel expenses) incurred. The minimum fee assessed will be \$1,500 and the maximum fee will be \$3,750.

SECTION 7: ACCREDITATION

A. Levels of accreditation

1. Accredited – a laboratory that meets the regulatory performance criteria as explained in this rule and as specified by the 40 CFR Part(s) 141, as amended up to July 1, 2017, and/or 40 CFR Part 136, as updated in the Annual Edition of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017 and all other applicable regulatory requirements.
2. Provisionally Accredited – a laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified by the 40 CFR Part(s) 141, as amended up to July 1, 2017, and/or 40 CFR Part 136, as updated in the Annual Edition of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017, and within the policies required by this rule. A provisionally accredited laboratory may analyze samples for compliance purposes, if clients are notified in writing of its provisional status and affected methods/analytes are notated on reports as “provisionally accredited.” Provisional accreditation may not be given if the accreditation officer believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations.
3. Not accredited – a laboratory that possesses deficiencies and, in the opinion of the accreditation officer, cannot consistently produce valid data.

B. Awarding accreditation

1. Documentation of a laboratory's accreditation must include:
 - a. A certificate acknowledging the laboratory's compliance with base accreditation requirements; and
 - b. The scope of accreditation for the laboratory.
2. The certificate and scope of accreditation must include the:
 - a. Seal of the State of Maine (certificate only);
 - b. Name of the laboratory;
 - c. Physical address of the laboratory;
 - d. Laboratory identification number;
 - e. Effective date of the accreditation certificate; and
 - f. Expiration date of the accreditation certificate.
3. If a laboratory's scope of accreditation changes, the accreditation officer shall issue a new scope of accreditation.
4. A laboratory's accreditation is valid for one or two years from the date of awarding base accreditation or renewal of base accreditation, unless conditions warrant initiation of

suspension or revocation by proceedings pursuant to 5 MRS § 10051 or as otherwise provided for by law.

5. A laboratory must return its certificate and scope of accreditation to the accreditation officer upon revocation of accreditation.
6. An accredited laboratory must not misrepresent its accreditation on any document, including laboratory reports, catalogs, advertising, business solicitations, proposals, quotations or other materials.
7. A laboratory must make available its current certificate and corresponding scope of accreditation, upon the request of a client, accreditation authority or regulatory agency. The laboratory must not supply a copy of its current certificate without the accompanying copy of its scope of accreditation.

C. Denial of accreditation

1. The MLAP may deny a laboratory's request for accreditation, including a request for renewed accreditation, if:
 - a. The application does not meet the requirements of Section 4;
 - b. The laboratory's current or prior accreditation has been downgraded or revoked; or
 - c. The laboratory or one of its owners or employees is currently in violation of this rule.
2. A laboratory with its request for accreditation denied may reapply after deficiencies are corrected and/or violations resolved. The application and all required documentation must be accompanied with the applicable fees.
3. The accreditation officer will not refund a base accreditation fee if an application is denied.

D. Downgrading of accreditation to provisional status

1. For deficiencies not affecting the laboratory's ability to produce valid data, the MLAP may downgrade a laboratory's accreditation status to provisional, in total or in part, for a period not to exceed 90 calendar days. If the MLAP determines that there are grounds for downgrading, the MLAP shall notify the laboratory in writing by certified mail.
2. If the laboratory does not correct the deficiencies related to the accreditation status downgrade within 90 calendar days, accreditation, in full or in part, will be revoked.
3. A laboratory that has had its accreditation downgraded to provisional status may request reinstatement once deficiencies have been corrected, as long as corrections are completed within the time period prescribed in the notification of downgrading and is done in accordance with the requirements of Section 4.

E. Suspension and reinstatement of accreditation after suspension

1. Grounds for suspension of accreditation are:

- a. Failure to produce acceptable results in two consecutive proficiency testing studies for the same field of testing; and/or
 - b. Failure to submit an acceptable corrective action report in response to an inspection or unacceptable proficiency testing results.
2. When the accreditation officer determines that there are grounds for suspension, the accreditation officer must notify the laboratory in writing and may initiate suspension proceedings pursuant to 5 MRS § 10051 or as otherwise provided for by law. A laboratory's accreditation may be suspended in total, or in part, for a period not to exceed 180 days or extend beyond the expiration date of the current accreditation.
 3. Notice of suspension
 - a. The effective date of suspension is the date that the laboratory receives the suspension as a result of proceedings pursuant to 5 MRS § 10051 or as otherwise provided for by law.
 - b. Upon receiving the suspension pursuant to 5 MRS § 10051 or as otherwise provided for by law, the laboratory must return to the client or subcontract to another Maine accredited laboratory, samples for the field of testing for which the laboratory is suspended.
 - c. During the suspension period, notification to clients whose samples are subcontracted or returned is required for all fields of testing for which the laboratory's accreditation has been suspended. The notification from the laboratory must be in writing.
 - d. At the time the notification is sent to the client, the laboratory must submit to the accreditation officer a list of clients who received the notification and one copy of the form letter used for the notification. The laboratory must retain an electronic copy of each notification sent to the client that may be reviewed by the accreditation officer.
 4. Reinstatement after suspension for failure to submit corrective action

A laboratory that has had its accreditation suspended may have the accreditation reinstated after acceptable corrective action has been received by the MLAP. Repayment of fees is not required for reinstatement if the laboratory corrects the deficiencies within the time-frame required by the accreditation officer, not to exceed 180 days or the expiration date of the current accreditation, whichever is sooner. If a laboratory takes corrective action before the end of the suspension period, accreditation for the suspended fields of testing or for the base accreditation and fields of testing must be restored if the corrective actions satisfactorily address the deficiencies cited in the notice of suspension. If the laboratory fails to correct the causes of suspension within the specified time frame, the accreditation officer will revoke in total, or in part, the laboratory's accreditation.
 5. Reinstatement After Proficiency Testing Failure Suspension

A laboratory with a suspended accreditation, due to unacceptable proficiency testing results must submit acceptable proficiency testing results according to Section 10.

F. Revocation of accreditation

The MLAP may initiate proceedings pursuant to 5 MRS § 10051 or as otherwise provided for by law to revoke a laboratory's accreditation, in total or in part, if it determines that there are grounds for revocation. The MLAP shall notify the laboratory in writing of the initiation of revocation proceedings pursuant to 5 MRS § 10051 or as otherwise provided for by law.

- 1.** Grounds for Revocation are:
 - a.** Failure to comply with applicable standards of this rule;
 - b.** Failure to pass an inspection;
 - c.** Failure to respond to deficiencies;
 - d.** Failure to correct the deficiencies cited in a notice of suspension within the time frame specified by the accreditation officer;
 - e.** Failure to implement corrective action related to any deficiencies found during a laboratory inspection;
 - f.** Failure to report compliance data to a public water system, the Drinking Water Program, the DEP or other responsible party in a timely manner or interfering with the reporting of such data produced by other entities;
 - g.** Failure to complete proficiency testing studies and maintain a history of successful proficiency testing studies at the frequency specified in Section 10;
 - h.** Failure to implement corrective action in response to an unacceptable proficiency testing result;
 - i.** Revocation of accreditation or certification by an approving body with which the accreditation officer has deemed equivalent;
 - j.** Careless, inaccurate or falsified reporting of analytical measurements and supporting documentation;
 - k.** Operating the laboratory in such a manner so as to endanger public health or safety;
 - l.** Making an intentionally false oral statement or written statement on any document issued by the laboratory or on any document associated with accreditation;
 - m.** Failure to notify the MLAP in writing within the prescribed time frames, pursuant to Section 8(B), regarding any change in ownership, laboratory name, laboratory location, personnel, equipment or any other factor that could impair the analytical, reporting or operational capability of the laboratory;
 - n.** Unethical conduct in the operation of the laboratory;
 - o.** Fraudulent or deceptive practices;
 - p.** Reporting sample results without indicating whether or not the laboratory is accredited for that analysis;

- q.** Failure to use an approved method or to follow the approved method for sample analysis where the report issued for the analysis indicates that the analysis was conducted in accordance with program accreditation standards;
 - r.** Denial of entry during normal business hours for an inspection, unless circumstances endangering safety or welfare prohibit entry; or
 - s.** Failure to pay the inspection fee for out-of-state laboratories requiring an on-site inspection.
- 2.** Notice of Revocation
 - a.** The effective date of revocation is the date that the laboratory receives the revocation as a result of proceedings pursuant to 5 MRS § 10051 or as otherwise provided for by law.
 - b.** Upon revocation pursuant to 5 MRS § 10051 or as otherwise provided for by law, the laboratory must return to the client or subcontract to another Maine accredited laboratory, samples for the fields of testing of the revocation.
 - c.** Notification to the client is required for all fields of testing for which the laboratory's accreditation has been revoked. The notification from the laboratory must be in writing.
 - d.** The laboratory must retain an electronic copy of each notification sent to the client, for review by the accreditation officer.
 - e.** At the time that the notification is sent to the client, the laboratory must submit a list of clients who received the notification and one copy of the form letter used for the notification to the accreditation officer.
- 3.** A laboratory that has had its accreditation revoked must not advertise itself as accredited and when possible, must remove or replace any advertisements that indicate that the laboratory is accredited.
- 4.** A laboratory with a revoked accreditation may not reapply for accreditation until it has corrected all written deficiencies. The laboratory must provide documentation of the steps implemented to correct the deficiencies before applying for accreditation according to Section 4.
- 5.** A successor in interest of a laboratory with a revoked accreditation may not apply for re-accreditation until all conditions for re-application after revocation are met.

G. Appeal of administrative decision

- 1.** The accreditation officer will notify a laboratory in writing of the reasons for the administrative decision to deny an application for accreditation or make an accreditation provisional.
- 2.** A laboratory has 30 days from the date of receiving the decision to appeal the decision. A request for an administrative hearing to appeal the decision must:
 - a.** Be in writing;

- b. Indicate the facts that the laboratory disputes; and
 - c. Be signed by the laboratory director.
3. Adjudicatory Proceedings shall be conducted pursuant to 5 MRS, Ch. 375, Sub-Chapter 4.
- a. Appeals by a laboratory are limited to appeals contending that a decision by the Department misapplies applicable laws, procedures or rules; or is based upon a significant factual error to the detriment of the laboratory.
 - b. Administrative hearing requests shall state the specific issues being appealed and requests shall be directed to:

Maine Center for Disease Control and Prevention
11 State House Station
Augusta, ME 04333-0011
 - c. Within 14 days of its receipt, the request for an administrative hearing accompanied by an administrative hearing report shall be forwarded to:

Chief Hearings Officer, Office of Administrative Hearings
11 State House Station
Augusta, ME 04333-0011
 - d. A hearing officer shall conduct the administrative hearing.
 - e. The hearing will be conducted pursuant to the rules of the Office of Administrative Hearings, as set forth in the Administrative Hearing Manual, and in conformity with the *Maine Administrative Procedures Act*, 5 M.R.S §§ 9051-9064.
 - f. A notice will inform the persons of the time, date and place of the hearing. The hearing will be held in Augusta, unless otherwise noted.
 - g. The hearing officer or the Commissioner will issue a written decision of the administrative hearing to all parties.
 - h. Any person or party dissatisfied with the hearing officer's or the Commissioner's decision has the right of judicial review under the Maine Rules of Civil Procedure, Rule 80C.

H. Voluntary withdrawal of accreditation

- 1. If a laboratory chooses to withdraw its application for accreditation or its current accreditation in total, or in part, the laboratory must notify the accreditation officer in writing and specify the effective date of withdrawal.
- 2. The accreditation officer will consider that a laboratory has chosen to voluntarily withdraw its accreditation if the laboratory has not submitted a complete renewal application by the expiration date of its current accreditation. In this situation, the effective date is the expiration date of the laboratory's current accreditation.

- 3.** By the effective date of the withdrawal of accreditation, in total or in part, the laboratory must notify current clients and regulatory agencies of its intent to withdraw its accreditation and must indicate the effective date of the withdrawal. Notification is required for all fields of testing for which the laboratory has chosen to voluntarily withdraw accreditation. The notification from the laboratory to the client(s) must be in writing. The laboratory must submit to the accreditation officer, at the time the lab is sending notice to clients, one copy of the notification and a list of clients to whom the notice was sent.
- 4.** The accreditation officer will not refund fees if a current accreditation is voluntarily withdrawn by the laboratory.

SECTION 8: QUALITY SYSTEMS**A. Laboratory organization**

The laboratory must:

1. Be an entity that can be held legally responsible;
2. Carry out its testing activities in such a way as to meet the requirements of this rule and to satisfy the needs of clients and the regulatory authorities;
3. Have technical management and personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the management system and to initiate actions to prevent or minimize such departures;
4. Use personnel employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory must ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system;
5. Have a written policy that, as indicated by signature, ensures management and personnel are free from any undue internal and external commercial, financial and other pressures, and influences that may adversely affect the quality of their work or diminish confidence in its competence, impartiality, judgement or operational integrity;
6. Define the organization and management structure of the laboratory, its place in any parent organization and the relationships between quality management, technical operations and support services;
7. Define the responsibilities of key personnel in the organization that have an involvement or influence on the testing, if the laboratory is part of an organization performing activities other than testing, in order to identify potential conflicts of interest;
8. Have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
9. Maintain records of the relevant authorization(s), demonstration(s) of capability, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information must be readily available and include the date on which authorization and/or competence is confirmed; and
10. Maintain initials and signatures of anyone analyzing or reviewing data so that the records can be traced back to the individual approving the data.

B. Duty to notify

1. A laboratory must notify the accreditation officer in writing within 30 days of a change in the:
 - a. Name of the laboratory;

4. A valid treatment plant operator's certificate or license may be substituted for the above qualifications for a laboratory technical director of a drinking water or wastewater treatment facility engaged in the analysis of bacteriology samples or chemistry, other than radiochemistry, collected within the State. The certificate or license must meet or exceed the classification for the drinking water or wastewater treatment facility in which the laboratory is located.
5. When the laboratory engages in more than one analytical category (chemistry, bacteriology and/or radiochemistry), one or more persons may complement the laboratory technical director, provided that each meets the applicable qualifications for the analytical category as specified in paragraphs (1), (2) and (3) above.
6. An individual is not permitted to be laboratory technical director of more than one Maine accredited laboratory without authorization from the MLAP. Circumstances to be considered for authorization include, but will not be limited to:
 - a. Operating hours of the laboratories;
 - b. Adequacy of supervision; and
 - c. Availability of environmental laboratory services in the area.

D. Personnel requirements - Quality Assurance Officer (QAO)

1. Each laboratory must appoint a QAO, however named. The QAO is the person responsible for the laboratory's quality assurance program and its implementation.
2. The QAO must review laboratory quality control data, conduct annual internal laboratory audits and notify laboratory management of deficiencies found in the laboratory's quality system. The QAO must be free from internal and external influences when evaluating data and conducting audits.
3. The QAO must have documented training and/or experience in QA and QC procedures and must have knowledge of the approved analytical methods and quality system requirements. The QAO must maintain the laboratory's QA documents up to date.
4. The QAO duties and responsibilities may also be carried out by the laboratory technical director.
5. The QAO must have direct access to laboratory management.
6. The QAO should (when possible) have functions independent from laboratory operations for which they have quality assurance oversight.

E. Responsibilities of laboratory management

1. Personnel documentation

Laboratory management must:

- a. Ensure the laboratory has sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions;

- b.** Specify and document the responsibility, authority and interrelationships of all personnel, who manage, perform or verify work affecting the quality of the tests;
- c.** Establish job descriptions to include the minimum level of qualifications, experience and basic laboratory skills necessary for all positions in the laboratory;
- d.** Appoint a member of staff as QAO (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times;
- e.** Appoint a deputy when the laboratory technical director is absent from the laboratory for more than 15 consecutive calendar days. The appointed deputy must meet the qualifications for laboratory technical director. The laboratory management must notify the MLAP in writing when the absence of the laboratory technical director exceeds 65 consecutive calendar days; and
- f.** Authorize specific personnel to perform particular types of sampling and environmental testing, issue test reports, give opinions and interpretations and operate particular types of equipment.

2. Personnel training and supervision

The laboratory management must:

- a.** Provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures;
- b.** Formulate goals with respect to the education and training skills of the laboratory personnel. The laboratory must have policies and procedures for identifying training needs and providing training of personnel. The training program must be relevant to the present and anticipated tasks of the laboratory staff;
- c.** Ensure all technical laboratory staff has demonstrated capability in the activities for which they are responsible; and
- d.** Ensure that the training of the laboratory personnel is kept up to date (on-going) by providing the following:
 - (i)** Documentation that each employee has read, understands and uses the latest version of the laboratory's quality documents;
 - (ii)** Training documentation on equipment, techniques and/or procedures;
 - (iii)** Training in ethical and legal responsibilities, as stated in Section 8; and
 - (iv)** Documentation of each analyst's continued performance at least once per year according to Section 8.

3. Quality control

The laboratory management must:

- a. Be responsible for documenting the quality of all data reported;
- b. Ensure that all personnel are responsible for complying with all QA and QC requirements that pertain to their organizational and technical function; and
- c. Ensure that all sample acceptance criteria are verified and samples are logged into the sample tracking system and are properly labeled and stored.

4. Communication

Laboratory management must:

- a. Ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the laboratory management system; and
- b. Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the laboratory management system.

F. Internal audits

1. The laboratory shall, at least annually and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the laboratory management system and this rule. The laboratory's internal audit program shall address all elements of the laboratory management system, including testing and/or calibration activities.
2. It is the responsibility of the QAO to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.
3. When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action and shall notify clients in writing if investigations show that the laboratory results may have been affected. The laboratory shall:
 - a. Have a policy that specifies the time frame for notifying clients of events that cast doubt on the validity of the results; and
 - b. Ensure that these actions are discharged within the agreed-upon time frame.
4. Audit reports shall document the focus of the audit, the audit findings and corrective actions that arise from them.
5. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

G. Management reviews

1. In accordance with a predetermined schedule and procedure, the laboratory's senior management shall conduct an annual review of the laboratory's management system and laboratory testing to ensure their continuing suitability and effectiveness and to introduce

necessary changes or improvements. Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed time frame.

2. The review shall take account of:
 - a. The suitability of policies and procedures;
 - b. Reports from managerial and supervisory personnel;
 - c. The outcome of recent internal audits;
 - d. Corrective actions;
 - e. Assessments by external bodies;
 - f. The results of interlaboratory comparisons or proficiency tests;
 - g. Changes in the volume and type of the work;
 - h. Client feedback;
 - i. Complaints;
 - j. Recommendations for improvement; and
 - k. Other relevant factors, such as QC activities, resources and staff training.

H. Data integrity training

1. The data integrity training must:
 - a. Be provided as a formal part of new employee orientation;
 - b. Be provided on an annual basis for all current employees;
 - c. Be provided in writing and available to all trainees; and
 - d. Have a signature attendance sheet or other form of documentation that demonstrates that each staff person has received the training and understands their obligations related to data integrity.
2. Key topics covered during training must include:
 - a. The organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, as well as how and when to report data integrity issues and record keeping;
 - b. Proper procedures to ensure data integrity, recognition and prevention of improper laboratory practices, the promotion of objectivity and impartiality in the generation and reporting of analytical data;

2. Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

3. Additional audits

Where the identification of nonconformities or departures casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with this rule, the laboratory shall ensure that the appropriate areas of activity are audited. Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

K. Demonstration of capability**1. Initial demonstration of capability**

- a.** The laboratory must demonstrate that it can properly perform all methods before conducting tests. An initial demonstration of capability must be completed each time there is a change in instrument, personnel or method.
- b.** The demonstration of capability must be performed by spiking a known standard into a clean matrix which duplicates that used for routine analysis (e.g., drinking water, soil). In addition, for analytes which do not lend themselves to spiking, the demonstration of capability may be performed using QC samples.
- c.** All demonstrations must be documented. All data applicable to the demonstration must be retained for a minimum of five years and available. The laboratory must set reasonable criteria for acceptability of the demonstration of capability.
- d.** When an analyte that is not currently found on the laboratory's list of accredited analytes, the laboratory must perform an initial evaluation before adding the analyte to the list.

2. Procedure for initial demonstration of capability

- a.** A QC sample must be prepared by the laboratory using stock standards that are not used in instrument calibration (e.g., calibration verification standard).
- b.** The analyte(s) must be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration of the mid-level standard.
- c.** At least four aliquots must be prepared and analyzed according to the test method either concurrently or over a period of days.
- d.** Using all of the results, the laboratory must calculate the mean recovery in the appropriate reporting units and the sample standard deviations for each parameter of interest must be calculated. Recovery for each analyte in each aliquot and the calculated standard deviation must be within the limits specified by the applicable approved method or by the applicable permit, program or rule. When it is not possible to determine mean and standard deviations, such as for presence or absence

and logarithmic values, the laboratory must assess performance against established and documented criteria.

- e. It is the responsibility of the laboratory to document that other approaches to the demonstration of capability are adequate. The documentation must be provided within the laboratory's Quality Manual (e.g., for Bacteriology).

3. Continuing demonstration of capability

After the initial demonstration of capability has been completed, the laboratory is required to continue demonstrating method performance through one of the following:

- a. Acceptable performance of a blind sample;
- b. Another demonstration of capability;
- c. Successful analysis of a blind performance sample on a similar method using the same technology;
- d. Analysis of at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; or
- e. If one of the above cannot be performed, the analysis of environmental samples that have been analyzed by another trained analyst with statistically indistinguishable results.
- f. Results of all continuing demonstration of capability determinations must be documented in writing.

L. Sample handling, receipt and acceptance

1. Handling samples

- a. A laboratory must have procedures for the collection, transportation (if a function of the laboratory), receipt, handling, protection, storage, retention and disposal of samples. The procedures must include provisions necessary to protect the integrity of the sample and to protect the interests of the laboratory and the client.
- b. A laboratory must have a system for identifying samples. The sample's identification must be retained throughout the life of the sample in the laboratory. The identification system must be designed and operated so as to ensure that samples cannot be confused physically or when referred to in laboratory documentation. The identification of samples must accommodate a subdivision of groups of samples and the transfer of samples between laboratories.
- c. Upon receipt of samples, the condition, including any abnormalities or departures from specified conditions as described in the laboratory's QA manual, must be recorded. When there is doubt as to the suitability of a sample for environmental testing, when a sample does not conform to the description provided, when an insufficient amount of sample is received or when the environmental test required is not specified in sufficient detail, the laboratory must consult the client for further instructions before proceeding and must maintain a record of the discussion.

- d.** A laboratory must have procedures and appropriate facilities for avoiding deterioration, contamination, and loss or damage to the sample during storage, handling, preparation and testing.
- e.** When samples require storage under specified environmental conditions, the conditions must be maintained, monitored and recorded. When a sample or a portion of a sample is to be held secure, a laboratory must have arrangements for storage and security that protect the condition and integrity of the secured samples and/or sample portions.
- f.** Samples, sample fractions, extracts, leachates and other products of sample preparation must be kept in storage units, such as cabinets, refrigerators or freezers, which are separate from the storage units for all standards, reagents, food and other potentially contaminating sources. Samples must be stored in such a manner as to prevent contamination between samples.

2. Sample receipt protocols

The following information must be verified and the results documented:

- a.** Samples received for drinking water analysis must be verified and documented per the following:
 - i.** All samples that require thermal preservation are considered acceptable if the arrival temperature is verified and within the range required by either the approved method or by the applicable permit, program or rule.
 - ii.** Samples that do not arrive at the proper temperature may be analyzed without client notification, or qualifying the report for temperature, if the sample is received within a reasonable timeframe after collection and there is evidence of an attempt to thermally preserve.
 - iii.** Samples that are not received shortly after collection (e.g., received through the mail), that do not arrive at the proper temperature may be analyzed, at the client's discretion, if the following criteria are met:
 - (1)** The sample arrived with evidence of an attempt to thermally preserve;
 - (2)** The client is notified that the sample did not arrive at the proper temperature and the outcome of the conversation is documented; and
 - (3)** The report is annotated to indicate that the sample arrived outside of the acceptable range and was run at the client's request.
- b.** Samples received for any programs other than the Drinking Water Program must be verified and documented per the following:
 - i.** All samples that require thermal preservation are considered acceptable if the arrival temperature is verified and within the range required by either the approved method or by the applicable permit, program or rule.

- ii.** Sample temperature must be recorded at the time of sample receipt.
- iii.** Samples that do not arrive at the proper temperature may be analyzed at the client's discretion, if the following criteria are met:
 - (1)** The sample arrived with sufficient coolant to indicate adequate support for the thermal cooling process;
 - (2)** The client is notified that the sample did not arrive at the proper temperature and the outcome of the conversation is documented; and
 - (3)** The report is annotated to indicate the temperature of the sample at the time of sample receipt, that the sample arrived outside the acceptable range and was run at the client's request.
- c.** All samples that require chemical preservation are considered acceptable if the laboratory verifies that the preservation meets the requirements of the approved method. A laboratory must implement procedures for checking chemical preservation before sample preparation or analysis, except for methods where post-analysis preservation checks are required, to ensure that sample integrity is not compromised. When specified in permit, program or rule, chemical preservation must be verified upon receipt.
- d.** A laboratory must maintain chronological records, either paper-based or electronic, such as a log book or database, to document receipt of all samples, including the number and types of containers received for each field of testing. The records must include the following:
 - (i)** The client and project name, if applicable;
 - (ii)** The date and time of laboratory receipt;
 - (iii)** A unique laboratory-assigned identification code;
 - (iv)** The signature, initials or equivalent electronic identification of the person making the entries;
 - (v)** The field identification code, which identifies each container, linked to the laboratory-assigned identification code in the sample receipt log;
 - (vi)** The date and time of sample collection, linked to the sample container and to the date and time of receipt in the laboratory;
 - (vii)** The requested field of testing, linked to the laboratory-assigned identification code; and
 - (viii)** Any comments resulting from inspection for sample rejection, linked to the laboratory-assigned identification code.

3. Sample Acceptance Policy

- a.** A laboratory must have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted or rejected by the laboratory. Data from samples that do not meet the laboratory's criteria must be recorded in an unambiguous manner clearly defining the nature and substance of the deviation from acceptable procedures.
- b.** A laboratory's sample acceptance policy must be made available to sample collection personnel and must address, at a minimum:
 - (i)** Documentation on the chain of custody must include sample identification; location, date and time of collection; collector's name; preservation type; sample type; and any special remarks concerning the sample;
 - (ii)** Sample labeling, to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;
 - (iii)** The use of appropriate sample containers;
 - (iv)** Adherence to specified holding times;
 - (v)** Adequate sample volume to perform the requested tests and relevant QC determinations; and
 - (vi)** Procedures to be used when samples show signs of damage, contamination, inadequate preservation or loss of integrity.
- c.** If the sample does not meet the sample receipt acceptance criteria listed in the laboratory's QA manual, the laboratory must retain correspondence and records of conversations concerning the final disposition of rejected samples or fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.
- d.** The report of samples analyzed without meeting the sample acceptance criteria must indicate, at a minimum, the condition of the samples on the chain of custody and the transmittal form or the laboratory receipt documents in addition to appropriately qualifying the analysis data on the final report.
- e.** Additional requirements - legal chain of custody protocols

Legal chain of custody protocols are used for evidentiary or legal purposes. A laboratory shall have a written SOP that describes the protocols for carrying out legal chain of custody if a client specifies that the sample is to be used for evidentiary purposes.

M. Standards, reagents and bacteriological media

- 1.** Reference standards that are used in the laboratory must be obtained, when available, from an accredited third party or a National Metrology Institute (e.g., NIST) and be traceable to the SI, International System of Units.
- 2.** A laboratory must retain records for all standards, reagents and bacteriological media. The records must include:

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- a.** Identification of the manufacturer or vendor;
 - b.** Certificate of analysis or purity, if supplied;
 - c.** Lot number;
 - d.** Date of receipt or preparation;
 - e.** Preparer's initials, if applicable;
 - f.** Method of preparation, when prepared in the laboratory;
 - g.** Recommended storage conditions; and
 - h.** Expiration date after which the material must not be used unless its reliability is verified by the laboratory.
 - 3.** All containers of reagents, standards and bacteriological media must be assigned a unique identification linked to records containing the documentation required in this section.
 - 4.** All reagents, standards and bacteriological media must be laboratory verified before use.
 - a.** Reagents are to be analyzed by use of a method blank before use.
 - b.** Standards are to be verified against a lot number previously determined fit for use by the laboratory.
 - c.** Bacteriological media must be verified by positive and negative controls before use.
 - 5.** All water must be appropriate for use.
 - a.** Reagent water for chemical analysis:
 - (i)** May be American Society for Testing Materials (ASTM) Type I, Type II or Type III based on the appropriateness for the analysis; or
 - (ii)** May be Standard Methods for the Examination of Water and Wastewater, American Water Works Association, 22nd Edition, 2012 medium-quality or high-quality water based on the appropriateness for the analysis.
 - b.** Results of these analyses must meet the specifications of the required method and records of analyses must be maintained for five years.
 - c.** Reagent water used for bacteriological analysis must meet the following requirements:

Test	Monitoring Frequency	Maximum Acceptable Limit
Chemical Tests:		
Conductivity	Monthly*	<2 μ mhos/cm (μ msiemens/cm) at 25°C
Total organic carbon	Monthly	<1.0 mg/L
Heavy metals, single (Cd, Cr, Cu, Ni, Pb, and Zn)	Annually †	<0.05 mg/L
Heavy metals, total	Annually †	<0.10 mg/L
Total chlorine residual	Monthly or with each use	<0.10 mg/L
Bacteriological Tests:		
Heterotrophic plate count	Monthly	<500 CFU/mL
Use test (see SM 9020B.5f2)	For a new source	Student's $t \leq 2.78$
Water quality test (see SM 9020B.5f1) ‡	Annually	0.8-3.0 ratio

*Monthly, if meter is in-line or has a resistivity indicator light; otherwise with each new batch of reagent water.

† Or more frequently if there is a problem.

‡ This bacteriological quality test is not needed for Type II water or better, as defined in Standard Methods (18th and 19th Editions), Section 1080C, or medium-quality water or better, as defined in Standard Methods (20th, 21st and Online Editions), Section 1080C.

N. Calibration of support equipment

1. Scope

This section applies to all devices that may not be the actual test instrument, but that are necessary to support laboratory operations, if quantitative results are dependent on their accuracy. Such devices include, but are not limited to, the following: balances; ovens; refrigerators; freezers; incubators; water baths; temperature-measuring devices, including thermometers and thermistors; thermal/pressure sample preparation devices; autoclaves; and volumetric dispensing devices, such as Eppendorf or automatic diluter/dispensing devices.

2. Requirements

- a. Equipment must be operated by trained personnel. Up-to-date instructions on the use and maintenance of equipment, including any relevant manuals provided by the manufacturer of the equipment, must be readily available for use by the appropriate laboratory personnel.
- b. All equipment must be properly maintained, including inspection, calibration and cleaning. Maintenance procedures must be documented. Calibration of balances, weights, temperature recording devices, light sources and detectors must be appropriate to the required precision and accuracy of the method. Calibrations must be performed at least annually and must be traceable to appropriate standards.

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- c.** Records must be maintained for each major component of equipment, including software. The records must include:
- (i)** The identity of the component of equipment, including software;
 - (ii)** The manufacturer's name, type, identification and serial number or other unique identification;
 - (iii)** Documentation that equipment complies with the manufacturer's specification;
 - (iv)** The current location within the laboratory;
 - (v)** The manufacturer's instructions, if available;
 - (vi)** Dates, results and copies of reports and certificates of all calibrations, adjustments and acceptance criteria and the due date of the next calibration;
 - (vii)** The maintenance plan and maintenance carried out to date, documentation on all routine and non-routine maintenance activities and reference material verifications;
 - (viii)** Any damage, malfunction, modification or repair to the equipment;
 - (ix)** Date received and date placed in service or the date on which its first use or repair was recorded; and
 - (x)** If available, condition when received, such as new, used or reconditioned.
- 3.** Frequency of calibration
- a.** All support equipment must be calibrated or verified at least annually, using references from an accredited third party or a National Metrology Institute (e.g., NIST) which are traceable to the SI.
 - b.** On each working day, balances, ovens, water baths, refrigerators and freezers must be checked in the expected use range with thermometers from an accredited third party or a National Metrology Institute (e.g., NIST) which are traceable to the SI.
 - c.** Mechanical volumetric dispensing devices including burettes, except Class A glassware, must be checked for accuracy at least quarterly. All glassware, including glass microliter syringes used for calibration, must be checked for accuracy and documented before its first use in the laboratory if the glassware does not come with a certificate attesting to established accuracy.
 - d.** For chemical and biological tests using an autoclave, the temperature, cycle time and pressure of each run must be documented by the use of appropriate chemical indicators, temperature recorders and pressure gauges.
 - e.** Volumetric equipment must be calibrated as follows:

- (i) Equipment with movable parts, such as automatic dispensers, dispensers/diluters and mechanical hand pipettes, must be calibrated quarterly.
 - (ii) Equipment such as filter funnels, bottles, non-Class A glassware and other marked containers must be calibrated once per lot prior to first use.
 - (iii) The volume of the disposable volumetric equipment such as sample bottles, disposable pipettes and micropipette tips must be checked once per lot prior to first use.
- f.** The accuracy of all temperature measurement devices shall be verified by comparing the reading of each device with that of a certified reference thermometer (e.g., NIST) which is traceable to the SI.
- (i) The thermometer shall be graduated in degree increments no larger than those of the device whose accuracy is being verified;
 - (ii) If a thermometer graduated in 0.5 °C increments or less differs from the certified reference thermometer by more than 1 °C, its use must be discontinued;
 - (iii) The accuracy of thermometers must be verified as follows:
 - (1) Glass and electronic thermometers must be verified annually;
 - (2) Metal thermometers must be verified quarterly;
 - (3) Infrared detection devices must be verified every six months; and
 - (4) Certified reference thermometers must be verified at least once every five years.
 - (iv) The correction factor and date of verification of accuracy must be indicated on the thermometers. The laboratory shall maintain a record that includes:
 - (1) Identification number of each thermometer;
 - (2) Temperatures displayed on both the certified reference thermometer and the thermometer being verified;
 - (3) Any applicable correction factor;
 - (4) Date each check was performed; and
 - (5) Signature of the analyst who performed each check.

4. Acceptance criteria

- a.** The results of calibrations must be within the specifications required of the application for which the equipment is used.

- b.** The acceptability for use or continued use must be according to the needs of the analysis or application for which the equipment is being used.
- c.** When the results of calibration of support equipment are not within the required specifications, the laboratory must remove the equipment from service until repaired.
- d.** Records must be retained to document equipment performance.

O. Calibration of analytical instruments

1. Scope

This section applies to all devices that are the actual test instrument used to quantify the test results.

2. Requirements

- a.** Equipment must be operated by trained personnel. Up-to-date instructions on the use and maintenance of equipment, including any relevant manuals provided by the manufacturer of the equipment, must be readily available for use by the appropriate laboratory personnel.
- b.** All equipment must be properly maintained, including inspection, calibration and cleaning. Maintenance procedures must be documented. Calibration of instruments must be appropriate to the required precision and accuracy of the method. Calibrations must be performed at least annually and must be traceable to appropriate standards.
- c.** Records must be maintained for each major component of equipment, including software. The records must include the following:
 - (i)** The identity of the component of equipment, including software;
 - (ii)** The manufacturer's name, type, identification and serial number or other unique identification;
 - (iii)** Documentation that equipment complies with the manufacturer's specification;
 - (iv)** Date received and date placed in service or the date on which its first use or repair was recorded;
 - (v)** If available, condition when received, such as new, used or reconditioned;
 - (vi)** The current location within the laboratory;
 - (vii)** The manufacturer's instructions;
 - (viii)** Dates, results and copies of reports and certificates of all calibrations, adjustments and acceptance criteria and the due date of the next calibration;

- (ix) The maintenance plan and maintenance carried out to date, documentation on all routine and non-routine maintenance activities and reference material verifications; and
- (x) Any damage, malfunction, modification or repair to the equipment.

3. Initial calibration

- a.** Sufficient records must be retained to permit reconstruction of the instrument calibration, such as calibration date, approved method identification, instrument, analysis date, each analyte name, the manual or electronic identification of the analyst performing the test, concentration and response, calibration curve or response factor or unique equation or coefficient used to reduce instrument responses to concentration.
- b.** Sample results must be quantitated from the most recent instrument calibration and may not be quantitated from any earlier instrument calibration verification.
- c.** All instrument calibrations must be verified with a standard obtained from a second source such as a different manufacturer, when available. Traceability must be to a national standard, when available.
- d.** Criteria for the acceptance of an instrument calibration must be established, such as correlation coefficient or relative standard deviation. The criteria used must be appropriate to the calibration technique employed and must be documented in the laboratory's SOP.
- e.** If allowed in the permit, program or rule, results of samples outside of the concentration range established by the calibration must be reported with defined qualifiers, flags or explanations estimating the quantitative error.
- f.** The following must occur for methods employing standardization with a zero point and a single point calibration standard:
 - (i) Before the analysis of samples, the linear range of the instrument must be established by analyzing a series of standards, one of which must encompass the single point quantitation level;
 - (ii) A zero point and a single point calibration standard must be analyzed with each analytical batch;
 - (iii) A standard corresponding to the RL must be analyzed with each analytical batch and must meet established acceptance criteria;
 - (iv) The linearity must be verified at a frequency established by the method or the manufacturer; and
 - (v) If allowed in the permit, program or rule, a sample result within an analytical batch, higher than its associated single point standard, can be reported if the following conditions are met:

- (1) A standard with a concentration at or above the analyte concentration in a sample must be analyzed and must meet established acceptance criteria for validating the linearity;
 - (2) The sample must be diluted such that the result falls below the single point calibration concentration; or
 - (3) The data must be reported with an appropriate data qualifier or an explanation in the narrative of the test report.
 - g.** If the instrument calibration results are outside established acceptance criteria, corrective actions must be performed and all associated samples reanalyzed. If reanalysis of the samples is not possible, data associated with an unacceptable instrument calibration must be appropriately qualified on the test report.
 - h.** Calibration standards must include concentrations at or below the limit specified in the permit, program or rule.
 - i.** If an approved method does not specify the number of calibration standards, the minimum number is three, one of which must be at the RL, not including blanks or a zero standard, with the exception of instrument technology for which it has been established by methodologies and procedures that a zero and a single point standard are appropriate for calibrations. The laboratory must have an SOP that documents the protocol for determining the number of points required for the instrument calibration employed and the acceptance criteria for calibration.
 - j.** It is prohibited to remove data points from within a calibration range while still retaining the extreme ends of the calibration range.
- 4.** Calibration verification
- a.** When an instrument calibration is not performed on the day of analysis, the instrument calibration must be verified before analysis of samples by analyzing a calibration standard with each batch.
 - b.** If calibration verification is not described in the approved method, calibration verification must be repeated at the beginning of each batch, after every tenth sample, excluding QC samples, and at the end of each batch.
 - c.** Sufficient raw data records must be retained to permit reconstruction of the calibration verification, such as: test method; instrument; analysis date; each analyte name, concentration and response; calibration curve or response factor; or unique equations or coefficients used to convert instrument responses into concentrations. Calibration verification records must explicitly connect the verification data to the instrument calibration.
 - d.** Criteria for the acceptance of calibration verifications must be established and evaluated using the same technique used to evaluate the instrument calibration.
 - e.** If the calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then the laboratory must either demonstrate performance

after corrective action by performing one successful calibration verification or perform a new instrument calibration. If the laboratory has not demonstrated acceptable performance after the corrective action, sample analyses must not occur until a new instrument calibration is established and verified. Sample data associated with unacceptable calibration verification may be reported as qualified data under the following special conditions if allowed in the permit, program or rule:

- (i) When the acceptance criteria for the calibration verification are exceeded high (high bias) and all associated samples contain analytes below the RL, those sample results may be reported.
 - (ii) When the acceptance criteria for the calibration verification are exceeded low (low bias), the sample results may be reported if the concentration exceeds a maximum regulatory limit as defined by the permit, program or rule.
- f. When allowed by permit, program or rule, verification procedures may result in a set of correction factors. If correction factors are employed, the laboratory must have procedures to ensure that copies of all data records, such as in computer software, are correctly updated.
 - g. Test equipment, including both hardware and software, must be safeguarded from adjustments that would invalidate the test results.

P. Reporting

1. No accredited or provisionally accredited laboratory shall report analytical results as a Program-accredited laboratory unless:
 - a. The laboratory conducted the analytical measurements at the laboratory's address as stated in its current certificate;
 - b. The laboratory clearly distinguishes in the report between those analyses for which it is accredited, provisionally accredited or not accredited; and
 - c. For those analyses for which it is accredited or provisionally accredited, the laboratory clearly distinguishes in the report between those analyses that it conducted in accordance with the MLAP accreditation standards and those that it did not conduct in accordance with the MLAP accreditation standards.
2. For non-compliance analysis (e.g., private wells), no accredited or provisionally accredited laboratory may report analytical results as such, if the criteria required for program accreditation are not followed (e.g., use of an accredited method, proper sample handling, acceptable quality control). Analytical results for non-compliance samples that are generated using non-accredited procedures must be annotated as such on reports.
3. Analytical results must be reported accurately, legibly, objectively and according to any specific instructions in the laboratory's standard operating procedures or quality assurance manual.
4. The test report must include the following:
 - a. A title (e.g., "Test Report" or "Laboratory Results");

- b.** The name and address of the laboratory and the location where the tests were carried out, if different from the address of the laboratory;
- c.** The laboratory's EPA identification number;
- d.** The name and telephone number of a contact person;
- e.** The information in paragraph b above for the subcontracted laboratory and the phrase, "This report contains data that were produced by a subcontracted Maine accredited laboratory accredited for the fields of testing performed," if data were produced by a laboratory other than the laboratory reporting the results;
- f.** A unique identification of the test report, such as a serial number, an identification on each page to ensure that the page is recognized as a part of the test report and a clear identification of the end of the test report;
- g.** The name of the client and project name, if applicable;
- h.** Identification of the approved method used;
- i.** A description, the condition and unambiguous identification of the sample, including the client's identification code;
- j.** Date and time of sample collection;
- k.** The date and time of receipt of the sample(s) when critical to the validity and application of the results;
- l.** Time of sample preparation and time of sample analysis when critical to the validity of the sample result;
- m.** Date of analysis of the environmental test;
- n.** The test results with the units of measurement, when appropriate; whether data are calculated on a dry weight or an "as received" basis; the reporting or detection limit for each analyte with appropriate units of measurement; and the counting error for each radiochemistry sample;
- o.** The name, function and signature or equivalent electronic identification of the person authorizing the test report and the date of issue;
- p.** A statement to the effect that the results relate only to the samples;
- q.** A statement that the report must not be reproduced, except in full, without the written approval of the laboratory;
- r.** Deviations from the SOP, such as failed QC, additions to or exclusions from the test method and information on specific test conditions, such as environmental conditions and any nonstandard conditions that may have affected the quality of results, including the use and definitions of data qualifiers;

- s. Test results that do not meet the requirement or for which the laboratory is not accredited, documentation explaining why the result does not meet the requirements and justification as to why the result was reported; and
 - t. QC information required by the applicable permit, program or rule.
5. When the laboratory analyzes samples by a procedure other than as written, the laboratory records and reports must include:
 - a. The sample identification traceable to the client;
 - b. The modification to the procedure;
 - c. The reason for the modification; and
 - d. The client's authorization or acknowledgment of the modification.
 6. When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in test reports.
 7. Electronic reporting of data
 - a. If electronic reporting is required by the MLAP or this rule, sample results must be reported in the electronic format acceptable to the MLAP.
 - b. If electronic reporting is required, sample results must be reported in the electronic format acceptable to the associated program. This includes the reporting of all required laboratory quality control information and associated acceptance limits.

Q. Documents and records

1. Document approval and issuance
 - a. All documents issued to personnel in the laboratory as part of the quality system must be reviewed and approved for use by authorized personnel prior to issuance. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system must be established and be readily available to preclude the use of invalid and/or obsolete documents.
 - b. The procedure(s) adopted must ensure that:
 - (i) Authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;
 - (ii) Documents are periodically reviewed and where necessary, revised to ensure continuing suitability and compliance with applicable requirements;
 - (iii) Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; and

- j.** All records must be signed or initialed by personnel designated by the laboratory as responsible for the task performed. All changes must be clearly indicated in the records. The laboratory must have procedures for recording changes and identifying the personnel making the change.
- k.** All observations used to calculate the final result must be recorded immediately. If the record is handwritten, the record must be legible and in permanent ink.
- l.** Entries in records must not be obliterated by methods such as erasures, overwritten files or markings. All corrections to records on paper must be made by one line marked through the error. The individual making the correction must sign or initial and date the handwritten or electronic correction.
- m.** A laboratory must maintain a record-keeping system that includes procedures for protecting the integrity and security of the data.
- n.** A laboratory must supply any documentation or data within seven calendar days of the date that the accreditation officer requests the information.

SECTION 9: LABORATORY POLICIES AND PROCEDURES**A. Quality assurance manual**

1. A laboratory must possess and follow a written manual of quality assurance.
2. The manual may include separate procedures or incorporate documents by reference.
3. The manual or its separate procedures must contain the following:
 - a. Document title;
 - b. Identification on each page to ensure that the page is recognized as part of the manual and clear identification of the end of the manual;
 - c. The laboratory's name and address;
 - d. Identification of the laboratory's approved signatories;
 - e. A revision number;
 - f. A date indicating when the revision became effective;
 - g. A table of contents, applicable lists of references, glossaries and appendices;
 - h. All maintenance, calibration and verification procedures used by the laboratory in conducting tests;
 - i. Major equipment, support equipment and reference measurement standards (e.g., NIST traceable thermometers and weights);
 - j. Verification practices, which may include proficiency testing programs, use of reference materials, internal QC processes and inter-laboratory comparisons;
 - k. Procedures for reporting analytical results;
 - l. The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;
 - m. Procedures to ensure that all records required under this rule are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all SOPs, manuals or documents clearly indicate the time period during which the procedure or document was utilized;
 - n. Job descriptions of key staff and reference to the job descriptions of other laboratory staff;
 - o. Procedures for achieving traceability of measurements;
 - p. A list of all methods under which the laboratory performs its accredited or provisionally accredited testing;

- q.** Procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;
 - r.** Procedures for handling samples, including subcontract testing;
 - s.** Procedures for collection and transportation of samples, if the laboratory provides this service;
 - t.** Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected or departures from documented policies and procedures occur;
 - u.** Policy for permitting departures from documented policies and procedures or from standard specifications;
 - v.** Procedures for handling complaints;
 - w.** Procedures for protecting confidentiality (including national security concerns) and proprietary rights;
 - x.** Procedures for data review and internal audits;
 - y.** Procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out, as well as procedures for providing necessary training;
 - z.** A policy addressing the use of unique electronic signatures, where applicable; and
 - aa.** A description of how data accuracy and precision are determined for each accredited method and analyte within each test category; for example, establishing control limits, preparing control charts and performing calculations.
- 4.** The manual must be reviewed periodically and updated when necessary. Documentation of the review process must include the scope of the review, identification and signature of the reviewer, as well as the date the review was completed.

B. Standard operating procedures

1. Written procedures required

A laboratory must possess written SOPs used by laboratory personnel for the analysis of samples. A laboratory must prepare written procedures for all laboratory activities including, but not limited to, sample acceptance, sample analysis, operation of instrumentation, generation of data and performance of corrective action. Only the laboratory director or quality assurance officer may approve changes in SOPs. Such changes shall be effective only when documented in writing.

2. Quality control (QC)

Actual practice must conform to the written procedures. The laboratory must maintain copies of the methods from which the procedures are developed. A laboratory must ensure that the applicable requirements are incorporated into each procedure. All quality control measures

must be assessed and evaluated on an ongoing basis. QC acceptance criteria in the laboratory's QA manual must be used to determine the validity of the data.

3. Standard operating procedure requirements

a. All SOPs must contain the following:

- (i) A table of contents;
- (ii) A unique identification of the SOP, such as a serial number, an identification on each page to ensure that the page is recognized as a part of the manual and a clear identification of the end of the manual;
- (iii) Pagination;
- (iv) The laboratory's name; when several separate procedures are included in the manual the name must appear on each procedure;
- (v) A revision number; and
- (vi) A date indicating when the revision became effective.

b. Each analytical method SOP shall include or reference the following topics where applicable:

- (i) Identification of the method;
- (ii) Applicable matrix or matrices;
- (iii) Limits of detection and quantitation;
- (iv) Scope and application, including parameters to be analyzed;
- (v) Summary of the method;
- (vi) Definitions;
- (vii) Interferences;
- (viii) Safety;
- (ix) Equipment and supplies;
- (x) Reagents and standards;
- (xi) Sample collection, preservation, shipment and storage;
- (xii) QC;
- (xiii) Calibration and standardization;
- (xiv) Procedure;

- (xv) Data analysis and calculations;
- (xvi) Method performance;
- (xvii) Pollution prevention;
- (xviii) Data assessment and acceptance criteria for QC measures;
- (xix) Corrective actions for out-of-control data;
- (xx) Contingencies for handling out-of-control or unacceptable data;
- (xxi) Waste management;
- (xxii) References; and
- (xxiii) Any tables, diagrams, flowcharts and validation data.

4. Availability

A copy of each written procedure must be available to all personnel that engage in that particular activity.

5. Required use

An analyst must use the laboratory's SOP beginning on the effective date for all laboratory activities for the analysis of samples for which accreditation is required.

6. Effective dates

A laboratory must maintain a record of effective dates for all procedures. A copy of the procedure and the record of effective dates must be maintained for the same period of time that records of the data generated by those procedures are required to be maintained.

7. Copy to accreditation officer

A laboratory must submit an electronic copy of its laboratory SOPs to the accreditation officer at the time of application.

8. Changes

All changes to the SOPs must be documented. Changes to the SOPs must be incorporated at least annually. All updated SOPs must include the signature of the managing agent upon revision.

SECTION 10: PROFICIENCY TESTING REQUIREMENTS

A. Obtaining proficiency test samples

A laboratory must obtain proficiency test samples from an approved provider meeting the criteria below:

1. Approved providers of proficiency test samples
 - a. The National Environmental Laboratory Accreditation Program (NELAP) Institute, also known as The NELAP Institute (TNI);
 - b. EPA; or
 - c. Other proficiency test providers that are also accreditation bodies.

2. Criteria for approval

The accreditation officer must approve a proficiency testing provider, if the proficiency testing provider:

- a. Is compliant with a national or international standard and is a recognized proficiency testing provider acceptable for use by TNI;
- b. Clearly defines the scope of each proficiency testing study;
- c. Evaluates results from all proficiency testing studies using the acceptance criteria described in national or international standards or those specified by the accreditation officer;
- d. Scores each result as either "acceptable," "not acceptable," "satisfactory," "unsatisfactory," "pass," "fail," "no evaluation" or "not reported;"
- e. Provides to participant laboratories reports that include:
 - (i) The provider name in the header;
 - (ii) The laboratory name, laboratory address (physical location), EPA laboratory ID number in the header, and the name, title and telephone number of the laboratory point of contact in the header or cover letter;
 - (iii) The study number and study type in the header;
 - (iv) The shipment date and closing date of the study in the header;
 - (v) The date of any amended report, if applicable, in the header;
 - (vi) Analyte name for each analyte included in the sample;
 - (vii) Method description;
 - (viii) Laboratory value as reported;

- (ix) Assigned values and acceptance values reported to three significant figures, except for tests requiring reports of presence or absence of the analyte;
 - (x) The acceptable/not acceptable status;
 - (xi) A "no evaluation" score for reported values containing alpha characters;
 - (xii) An indication of the length of the report presented by either "page X of Y" or the total number of pages with each page numbered consecutively; and
 - (xiii) For amended reports, an indication of the amended results, including a brief description of the reason for the amendment.
- f. Sends reports of results no later than 21 calendar days after the study closing date;
 - g. Maintains the overall effectiveness of the provider's quality system to indicate that samples provided for testing are verifiable, homogeneous and stable;
 - h. Makes available to the accreditation officer and any participating laboratory, upon request, a complete report of the provider's analytical data and documentation of the provider's quality system, which relates to the assigned values, homogeneity and stability of a particular proficiency testing study;
 - i. Makes available to the accreditation officer, upon request, a report listing the total number of participating laboratories and the number of laboratories scoring "not acceptable" for each analyte;
 - j. Supplies reports to the accreditation officer in an electronic format acceptable to the accreditation officer; and
 - k. Supplies the laboratory with a proficiency test sample formulated from a lot that has not been previously sent to the laboratory. If the lot was previously used in a proficiency test sample or its assigned values sent to any laboratory, the original proficiency test sample tracking ID must be obliterated and the new sample tracking ID must be unique.

B. Availability of proficiency test samples

1. The accreditation officer must determine that a proficiency test sample for a particular field of testing is not available if:
 - a. None of the approved providers list the proficiency test sample through published catalogs, websites or other widely distributed literature; or
 - b. None of the approved providers make the proficiency test sample available in a form similar to routine samples. For example, proficiency test samples may be considered unavailable if the preparation instructions require the laboratory to perform pretreatment steps not normally associated with the requirements of the approved methods. In this context, dilution of the proficiency test sample is not considered pretreatment.
2. If the accreditation officer determines that no approved provider has proficiency test samples for a field of testing, the accreditation officer must request written documentation from the

laboratory of QC data, meeting the minimum requirements under this rule to evaluate the capability of the laboratory to perform testing.

C. Proficiency testing requirements to obtain or maintain accreditation

1. A laboratory seeking to obtain accreditation must successfully complete at least one proficiency test sample, unless a proficiency test is not available, for each requested field of testing, no more than six months before the date the laboratory submits its application.
2. When a laboratory is granted accreditation status, it must continue to complete proficiency testing studies for each field of testing and maintain a history of at least one acceptable evaluation for each field of testing out of the most recent two proficiency test sample results submitted to the proficiency test provider.
3. When a laboratory has attained accreditation and requests to add a field of testing to its scope of accreditation, the laboratory must submit acceptable proficiency testing results for that field of testing, analyzed no more than six months before the date that the laboratory submits its application.
4. To maintain accreditation, a laboratory must complete the annual study, and any corrective action study required, by October 31.
5. If the laboratory is accredited by the MLAP through equivalency, and maintains accreditation or certification by another approving body, proficiency test sample results for all analytes and programs must be sent at the request of the accreditation officer.

D. Proficiency test sample analysis requirements

1. A laboratory shall analyze proficiency test samples in the same manner as used for routine environmental samples, using the same staff, sample tracking, sample preparation and analysis methods, SOPs, calibration techniques, QC procedures and acceptance criteria. The laboratory must follow sample preparation steps for the proficiency test sample as instructed by the approved proficiency test provider for which the proficiency test sample was obtained.
2. Laboratories under the same ownership are not to participate in the same study by the same approved proficiency test provider for the same fields of testing, except when a study is not again available for that field of testing by any approved proficiency test provider within the calendar year.
3. Prior to the closing date of a study, laboratory personnel, including corporate personnel, shall not:
 - a. Communicate with any individual at another laboratory concerning the analysis of the proficiency test sample prior to the closing date of the study;
 - b. Subcontract the analysis of any proficiency test sample or a portion of a proficiency test sample to another laboratory for any analysis;
 - c. Knowingly receive and analyze any proficiency test sample or portion of a proficiency test sample from another laboratory for which the results of the proficiency test sample are intended for use for initial or continued accreditation; and

- d. Attempt to obtain the assigned value of any proficiency test sample.

E. Proficiency test sample reporting requirements

The laboratory shall evaluate and report the analytical result for accreditation as follows:

1. For instrument technology that employs a multi-point calibration, the working range of the calibration under which the proficiency test sample is analyzed shall be the same range as used for routine samples.
 - a. A result for any proficiency test at a concentration above or equal to the lowest calibration standard shall be reported as the resultant value.
 - b. A result for any proficiency test at a concentration less than the lowest calibration standard shall be reported as less than the value of the lowest calibration standard.
 - c. A result for any proficiency test greater than the highest calibration standard shall be diluted to fall within the range of the calibration curve.
2. For instrument technology (e.g., ICP-AES or ICP-MS) that employs standardization with a zero point and a single point calibration standard, the laboratory shall evaluate the analytical result in the same range as used for routine samples.
 - a. A result for any proficiency test at a concentration above or equal to the RL shall be reported as the resultant value.
 - b. A result for any proficiency test at a concentration less than the RL shall be reported as less than the value of the RL.
 - c. A result for any proficiency test greater than the high calibration standard shall be diluted to be within the working range.
3. A laboratory must ensure that the proficiency test results include the correct physical address of the laboratory.
4. The laboratory shall report the analytical results for accreditation to the proficiency test provider on or before the closing date of the study using the reporting format specified by the proficiency test provider.
5. On or before the closing date of the study, the laboratory shall authorize the proficiency test provider to release the laboratory's final evaluation report directly to the laboratory's primary approving body. The MLAP shall evaluate only results received directly from the proficiency test provider.
6. A laboratory must supply results by authorizing the approved proficiency test provider to release all accreditation and corrective action results to the accreditation officer by an electronic format specified by the accreditation officer.
7. For programs other than drinking water, a laboratory may use one proficiency test sample to analyze and report results for multiple methods by the same technology, provided the sample is analyzed under analytical conditions which satisfy all technologies reported and the most stringent method QC requirements are fulfilled.

8. Errors in reporting the proper matrix, the method used or the tested analytes in the proficiency test study by the laboratory shall be graded as “not acceptable” by the MLAP.
9. A laboratory may not request a revised report from the proficiency test provider when the revisions to the report are due to any error on the part of the laboratory.
10. Laboratories also accredited under NELAP must designate one of the two annual proficiency test studies performed to be sent to the MLAP. Additional proficiency test studies received will be evaluated and subject to the same corrective action requirements found in Sub-Section I of this Section.

F. Proficiency test sample study record retention

1. The laboratory shall maintain copies of all written, printed and electronic records pertaining to proficiency test sample analyses for five years or for as long as is required by the applicable regulatory program, whichever is greater.
2. Proficiency test records shall include, but not be limited to:
 - a. Bench sheets;
 - b. Instrument strip charts or printouts;
 - c. Data calculations;
 - d. Data reports; and
 - e. Proficiency test study report forms used by the laboratory to record proficiency test results.
3. The laboratory shall make all retained records available to assessors during on-site assessments of the laboratory.

G. Evaluation of results

1. All study data released from the proficiency test provider will be scored for compliance with this rule.
2. A laboratory must demonstrate acceptable performance, as determined by the approved provider, for each field of testing reported.
3. For the purpose of initial or continuing accreditation, the accreditation officer shall deem unacceptable any reported results not meeting the criteria under this Section.
4. Proficiency test samples analyzed or reported after the study closing date are not valid for compliance with the proficiency testing requirements under this Section.

H. Questionable proficiency test samples

Upon notice from a laboratory and verification by the approved provider that a proficiency test sample did not meet the requirements in this Section, the accreditation officer may determine that the affected laboratory must analyze another proficiency test sample for that field of testing.

I. Corrective actions for unacceptable results

1. When an approved provider notifies a laboratory that a proficiency test sample result for any reported field of testing is unacceptable, the laboratory shall:
 - a. Review each “not acceptable” result to determine:
 - (i) Cause of the error; and
 - (ii) Corrective action(s) the laboratory need(s) to take to correct the problem.
 - b. Document the cause(s) and corrective action(s) the laboratory has taken to correct each problem that caused or contributed to the “not acceptable” result;
 - c. Submit the results of the laboratory’s investigation in a corrective action report to the MLAP within 30 days after receiving the notification of unacceptable results from the approved provider and before requesting a supplemental proficiency test study; and
 - d. Within 30 days of the close of the corrective action report, the laboratory must ensure that results of all proficiency test samples are received by the accreditation officer. These results are to be submitted directly by the proficiency test provider.

J. Grounds for suspension of accreditation

The following constitute grounds for suspension of accreditation:

1. Failure to produce acceptable results in two consecutive proficiency testing studies for the same field of testing; or
2. Failure to submit an acceptable corrective action report in response to an unacceptable proficiency testing result.

K. Requirements for reinstatement of accreditation after suspension

1. The following requirements must be met for reinstatement of accreditation following a PT related suspension:
 - a. The laboratory must complete a corrective action report within 30 days of the suspension;
 - b. The laboratory must pass two unique, successive proficiency test studies, analyzed at least one day apart; and
 - c. The proficiency tests must be completed within 180 days of the suspension or before the expiration of the current certificate, whichever is sooner, to restore accreditation.
2. To reinstate accreditation after suspension for failure to submit corrective action, refer to Section 7.

L. Additional samples for compliance

The accreditation officer may require Maine accredited laboratories to test additional proficiency test samples at any time to determine compliance with this rule.

SECTION 11: QUALITY CONTROL CRITERIA**A. Quality control criteria for chemistry****1. Scope**

- a.** This section applies to laboratories performing testing under the inorganic chemistry, metals, volatile organic compounds and other organic compounds test categories unless otherwise indicated.
- b.** All requirements in this Section must be incorporated into the laboratory's procedures, unless otherwise directed by the approved method. The quality control requirements specified by the laboratory's standard operating procedures must be followed.
- c.** All quality control measures must be assessed and evaluated on an ongoing basis and quality control acceptance criteria must be used to determine the validity of the data.

2. Method blanks

- a.** A method blank must be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure.
- b.** The method blank must be analyzed at a minimum of one per batch.
- c.** Procedures must be in place to determine whether a method blank is contaminated. Any affected samples associated with a contaminated method blank must be reprocessed for analysis or the results must be reported with appropriate data qualifying codes.
- d.** Each contaminated method blank must be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch. The source of contamination must be investigated and measures taken to minimize or eliminate the problem. Affected samples must be reprocessed or data must be appropriately qualified if:
 - (i)** The concentration of a target analyte in the blank is at or above the reporting limit as established by the test method or by regulation and is greater than one-tenth of the amount measured in any sample; or
 - (ii)** The blank contamination otherwise affects the sample results according to test method requirements or the individual project data quality objectives.

3. Laboratory control sample

- a.** A LCS must be used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Results of the LCS must be compared to established criteria and, if found to be outside of established criteria, must indicate that the analytical system is "out of control." Any affected samples associated with an out of control LCS must be reprocessed for reanalysis or the results must be reported with appropriate data qualifying codes.

- b.** A LCS must be analyzed at a minimum of one per preparation batch, except for:

 - (i)** Analytes for which no spiking solutions are available; or
 - (ii)** When the method specifically states that the LCS is not necessary.
 - c.** All analyte concentrations must be within the calibration range of the instrument calibration. The components to be spiked must be as specified by the permit, program or rule requirement. In the absence of permit, program, rule or method requirements, the laboratory must spike as follows:

 - (i)** For those components that interfere with an accurate assessment, such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike must be chosen that represents the chemistries and elution patterns of the components to be reported.
 - (ii)** The number of analytes selected is dependent on the number of analytes reported. The analytes selected for the spiking solution must be representative of all analytes reported. The following criteria must be used for determining the minimum number of analytes to be spiked:

 - (1)** For methods that include one to ten analytes, spike all components.
 - (2)** For methods that include 11 to 20 analytes, spike at least ten components or 80 percent of the analytes, whichever is greater.
 - (3)** For methods with more than 20 analytes, spike at least 16 components.
 - d.** The results of the analytes included in the LCS are calculated in percent recovery or a measure that allows comparison to established acceptance criteria. The laboratory must document the calculation. The individual LCS is compared to the acceptance criteria as published in the approved method or as specified in client-specified assessment criteria within a permit, program or rule requirement. When there are no established criteria, the laboratory must determine its own criteria and document the method used to establish the limits or utilize client-specified assessment criteria within a permit, program or rule requirement.
 - e.** A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with a LCS determined to be "out of control" must be considered suspect. The samples must be reprocessed and reanalyzed or the data must be reported with appropriate data qualifying codes.
- 4.** Matrix spike and matrix spike duplicates
- a.** The frequency of the analysis of matrix spikes and matrix spike duplicates must be determined as part of a systematic planning process or as specified by the required approved method, when applicable. Where no requirement is stated, the laboratory must prepare and analyze at least one matrix spike and one matrix spike duplicate with each batch, unless the lab has not been provided a sufficient sample amount. The matrix spikes must be prepared from samples contained in the batch.

- b.** When internal standards are recommended or required by the test method, such as mass spectrometry techniques, a laboratory must add the internal standards to all samples, standards, blanks and QC samples before analysis.
 - c.** When specified in the test method, a laboratory must use the internal standards mandated in the test method. If internal standards are not recommended in the method, then the analyst must select one or more internal standards that are similar in analytical behavior to the compounds of interest and not expected to be found in the samples otherwise.
 - d.** A laboratory must monitor and document the results from analysis of internal standards.
 - e.** Results of internal standards must be compared to the acceptance criteria as published in the approved method. When there are no established criteria, the laboratory must determine its own criteria and document the procedure used to establish the limits or utilize client-specified assessment criteria within a permit, program or rule requirement.
- 7.** Method detection limits
- a.** Each laboratory shall experimentally determine the MDL for analysis of each analyte, except pH, for each matrix in which the laboratory is accredited.
 - b.** The laboratory must document its procedure for determining the MDL.
 - c.** MDL procedures must be conducted as follows:
 - (i)** Drinking Water Program methods: The laboratory must use the procedure for determining the MDL that is described in the analytical method being used. If the analytical method does not include a procedure for the determination of MDLs, then the laboratory must determine the MDL using the procedure described in 40 CFR Part 136, Appendix B, updated in the Annual Edition of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017.
 - (ii)** Wastewater Program methods: The laboratory must use the procedure for determining the MDL using the procedure described in 40 CFR Part 136, Appendix B, updated in the Annual Edition of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017.
 - d.** Calculations and supporting documentation used in determining limits must be available for inspection.
 - e.** MDLs shall be expressed in appropriate units.
 - f.** The laboratory must achieve the MDLs required by the applicable regulations or program.
 - g.** Sample preparation and analysis for the MDL calculation must be made over a period of at least three days.

on organic tests, such as pesticides, herbicides or acid-extractable compounds or when recommended by the analytical test method, except when the analysis involves the use of a mass spectrometer or Fourier transform infrared spectrometer (FTIR). All confirmations must be documented.

- d.** A confirmation must be performed to verify the compound identification when positive results are detected in a sample from a location that has not been previously tested. The confirmations must be performed on organic tests, such as pesticides, herbicides or acid-extractable compounds, or when recommended by the analytical test method, except when the analysis involves the use of a mass spectrometer or FTIR. A confirmation is not required on positive results for samples analyzed for diesel range organics and gasoline range organics, Extractable Petroleum Hydrocarbons (EPH), Volatile Petroleum Hydrocarbons (VPH) or Total Extractable Petroleum Hydrocarbons (TEPH) under the Underground Storage Tank Program. All confirmations must be documented.
- e.** A laboratory must document acceptance criteria for mass spectral tuning. The laboratory must ensure that the tuning criteria meet the specifications in the approved method or as established by the client, whichever is more stringent.

10. Manual integrations

- a.** If the integrations are not calculated exclusively by the equipment's software, a laboratory must document acceptable use of manual integrations and must have in place a system for review of manual integrations performed to verify adherence to the policies and procedures of the laboratory.

11. Consistent test conditions

- a.** A laboratory must ensure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.
- b.** A laboratory must ensure that glass and plastic containers are cleaned so that they meet the sensitivity of the test method. Any cleaning and storage procedures that are not specified by the test method must be documented in laboratory records and the laboratory SOPs manual.

B. Quality control criteria for bacteriology

1. Scope

This Section applies to laboratories performing tests under the bacteriological test category unless otherwise indicated. All requirements in this Section must be incorporated into the laboratory's procedures unless otherwise directed by the approved method. The QC requirements specified by the laboratory's SOPs must be followed. All QC measures must be assessed and evaluated on an ongoing basis and QC acceptance criteria must be used to determine the validity of the data.

2. Sterility and Autofluorescence Checks

- a.** Each lot of pre-prepared, ready-to-use media, including chromofluorogenic reagent and each lot of media prepared in the laboratory must be checked for sterility. Chromofluorogenic media must also be checked for autofluorescence. The media

check must be run using a container and water that has passed a sterility check. The analysis must be done before first use of each lot of media.

- b.** For filtration technique:
 - (i)** A laboratory must conduct one beginning and one ending sterility check for each filtration unit used in a filtration series. The filtration series may include single or multiple filtration units that have been sterilized before beginning the series.
 - (ii)** For pre-sterilized, single-use funnels purchased, a sterility check must be performed on one funnel per lot before use.
 - (iii)** The filtration series is considered ended when more than 30 minutes elapse between successive filtrations.
 - (iv)** During a filtration series, filter funnels must be rinsed with three 20 to 30 milliliter portions of sterile rinse water after each sample filtration.
 - (v)** Laboratories must insert a sterility blank after every ten samples per filtration unit or sanitize filtration units by ultraviolet light after each sample filtration.
- c.** For pour-plate technique, a sterility check of the media must be made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and one for each lot of media prepared in the laboratory.
- d.** Sterility checks on sample containers and Quanti-Trays[®] must be performed on at least one container for each lot of purchased, pre-sterilized containers. For containers sterilized in the laboratory, a sterility check must be performed on one container per sterilized batch, using nonselective growth media. Sample containers used for chromofluorogenic methods must also be checked for autofluorescence. The analysis must be done before first use.
- e.** A sterility check must be performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water using nonselective growth media. The analysis must be done before first use.
- f.** At least one filter from each new lot of membrane filters must be checked for sterility by filtering 20 to 30 milliliters of sterile dilution water through the filter and testing for growth. The analysis must be done before first use.

3. Positive controls

Each pre-prepared, ready-to-use lot of media, including chromofluorogenic reagent, and each lot of media prepared in the laboratory must be tested with at least one pure culture of a microorganism known to elicit a positive reaction. This must be done before first use of each lot of media.

4. Negative controls

Each pre-prepared, ready-to-use lot of selective media, including chromofluorogenic reagent and each lot of selective media prepared in the laboratory must be analyzed with one or more

known negative culture controls (e.g., non-target microorganisms) that should not grow on the test media, as appropriate to the method. This analysis must be done before first use of each lot of media.

5. Test variability

For test methods that specify colony counts, such as methods using membrane filters or plated media, duplicate counts must be performed and documented monthly on at least one positive sample for each month that the test is performed. With respect to this test for variability, if the laboratory has two or more analysts, each analyst must count typical colonies on the same plate and counts must be within a ten-percent difference between analysts to be acceptable. In a laboratory with only one bacteriology analyst, the same plate must be counted twice by the analyst, with no more than a five-percent difference between the counts.

6. Method evaluation

A laboratory must demonstrate proficiency with the test method before first use, by comparison to a method already approved for use in the laboratory, by analyzing a minimum of ten spiked samples with a matrix representative of those normally submitted to the laboratory or by analyzing and passing one proficiency test series provided by an approved proficiency sample provider. The laboratory must maintain documentation of the proficiency demonstration, as long as the method is in use and for at least five years after the date of last use.

7. Test performance

To ensure that analytical results are accurate, those laboratories using commercially prepared media with manufacturer shelf-lives of greater than 90 days shall run positive and negative controls each quarter, in addition to running these controls and sterility checks on each new lot of media.

8. Quality of standards, reagents and media

- a.** Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use, unless otherwise indicated in the approved method. Media may be prepared by the laboratory from basic ingredients when commercial media are not available or when it can be demonstrated that commercial media do not provide adequate results. Media prepared by the laboratory from basic ingredients must be tested for performance, such as for selectivity, sensitivity, sterility, growth promotion and growth inhibition, before first use. Detailed testing criteria information must be defined in the laboratory's SOPs manual or QA manual.
- b.** Reagents, commercial dehydrated powders and media must be used within the shelf life of the product. The specifications of the reagent, powder or media must be documented according to the laboratory's QA manual.
- c.** Distilled, deionized or reverse-osmosis produced water that is free from bactericidal and inhibitory substances must be used in the preparation of media, solutions and buffers. The quality of the water must meet the requirements as listed in Section 8.

- d.** Media, solutions and reagents must be prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method. Documentation for media prepared in the laboratory must include the:
 - (i)** Date of preparation;
 - (ii)** Preparer's initials;
 - (iii)** Type and amount of media prepared;
 - (iv)** Manufacturer and lot number;
 - (v)** Final pH of the media after sterilization; and
 - (vi)** Expiration date.

- e.** Documentation for media purchased pre-prepared and ready-to-use must include the:
 - (i)** Manufacturer;
 - (ii)** Lot number;
 - (iii)** Type and amount of media received;
 - (iv)** Date of receipt;
 - (v)** Expiration date of the media; and
 - (vi)** Verification of the pH of the liquid.

9. Selectivity

- a.** To ensure identity and traceability, reference cultures used for positive and negative controls must be obtained from a recognized national organization.
- b.** Microorganisms may be single-use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.
- c.** Reference cultures may be revived, if freeze-dried or transferred from slants and sub-cultured once to provide reference stocks. The reference stocks must be preserved by a technique that maintains the characteristics of the strains. Reference stocks must be used to prepare working stocks for routine work. If reference stocks have been thawed, they must not be refrozen and reused.
- d.** Working stocks must not be cultured sequentially more than five times and must not be sub-cultured to replace reference stocks.

10. Temperature measuring devices

- a.** Temperature measuring devices such as liquid-in-glass thermometers, thermocouples and platinum resistance thermometers used in incubators, autoclaves

and other equipment must be of the appropriate quality to meet specifications in the test method.

- b.** The temperature measuring devices must be graduated in 0.5°C increments (0.2°C increments for tests which are incubated at 44.5°C) or less, except as noted for hot air ovens and refrigerators. These devices must be calibrated against thermometers from an accredited third party or a National Metrology Institute (e.g., NIST), traceable to the SI, International System of Units. All measurements must be recorded.

11. Autoclaves

- a.** The performance of each autoclave must be evaluated initially by establishing its functional properties and performance (e.g., heat distribution characteristics with respect to typical uses). Autoclaves must meet specified temperature tolerances. Pressure cookers must not be used for sterilization of growth media.
- b.** Demonstration of sterilization temperature must be provided by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle. Appropriate biological indicators must be used once per month to determine effective sterilization. Temperature-sensitive tape must be used with the contents of each autoclave run to indicate that the autoclave contents have been processed.
- c.** Records of autoclave operations must be maintained for every cycle. Records must include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (which may be recorded as time in and time out) and operator's initials.
- d.** Autoclave maintenance, either internally or by service contract, must be performed annually or must include a pressure check and calibration of the temperature device. Records of the maintenance must be maintained in equipment logs.
- e.** The autoclave's mechanical timing device must be checked quarterly against a stopwatch and the actual time elapsed must be documented.

12. Ultraviolet instruments

- a.** Ultraviolet (UV) instruments used for sterilization must be tested quarterly for effectiveness with an appropriate UV light meter or by plate counts on agar spread plates.
- b.** Bulbs must be replaced if output is less than 70 percent of original for light tests or if count reduction is less than 99 percent for a plate containing 200 to 300 organisms.

13. Incubators, water baths and ovens

- a.** The stability and uniformity of temperature distribution and the time required after test sample addition to reestablish equilibrium conditions in incubators and water baths must be documented. Calibration-corrected temperature of incubators and water baths must be documented twice daily, at least four hours apart, on each day of use.

- b.** Ovens used for sterilization must be checked for sterilization effectiveness monthly with appropriate biological indicators. Records must be maintained for each cycle and include the date, cycle time, temperature, contents and analyst's initials.

14. Labware, glassware and plasticware

- a.** A laboratory must have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use must be used.
- b.** Glassware must be made of borosilicate or other noncorrosive material, free of chips and cracks and must have readable measurement marks.
- c.** Labware that is washed and reused must be tested for possible presence of residues that may inhibit or promote growth of microorganisms by performing the inhibitory residue test annually and each time the laboratory changes the lot of detergent or washing procedures.
- d.** At a minimum, one piece of washed labware must be tested daily, each day of washing, for possible acid or alkaline residue. Labware must be tested with a suitable pH indicator (e.g., Bromothymol blue). Records of tests must be documented.

15. Quanti-Tray[®] sealer

When the Quanti-Tray[®] or Quanti-Tray[®] 2000 test is utilized, the sealer must be checked monthly by adding a dye (e.g., Bromocresol purple) to the water. If the dye is observed outside of the wells, maintenance must be performed or another sealer utilized.

C. Quality control criteria for radiochemistry

1. Scope

- a.** This Section applies to laboratories performing radiochemistry testing on environmental samples. All requirements in this Section must be incorporated into the laboratory's SOPs unless otherwise directed by the approved method.
- b.** The quality control requirements specified by the laboratory's SOPs must be followed. All quality control measures must be assessed and evaluated on an ongoing basis and quality control acceptance criteria must be used to determine the validity of the data.

2. Method blanks

- a.** A laboratory must analyze at least one method blank per batch. The method blank result must be evaluated according to the acceptance criteria in the laboratory's standard operating procedures.
- b.** When the method blank acceptance criteria are not met, a laboratory must take corrective action. The occurrence of a failed method blank and the actions taken must be noted in the laboratory report.

- a.** Matrix spikes must be performed at a frequency of one per batch for those methods that do not utilize an internal standard or carrier, for which there is a chemical separation process and when there is sufficient sample to do so.
 - b.** Gross alpha, gross beta and tritium require matrix spikes for aqueous samples. The result of the analysis must be one of the QC measures used to assess sample acceptability. The matrix spike result must be assessed against the specific acceptance criteria specified in the laboratory SOPs.
 - c.** When the specified matrix spike acceptance criterion is not met, the corrective actions specified in the laboratory's SOPs must be followed. The occurrence of a failed matrix spike acceptance criterion and the actions taken must be noted in the laboratory report. The lack of sufficient sample aliquot size to perform a matrix spike must also be noted in the laboratory report.
 - d.** The activity of the analytes in the matrix spike must be greater than 10 times the MDL.
 - e.** The laboratory standards used to prepare the matrix spike must be from a source independent of the laboratory standards used for instrument calibration, if available.
 - f.** The matrix spike must be prepared by adding a known activity of target analyte. When a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope, such as Plutonium, Pu 238 and Pu 239, using alpha spectrometry, only one of the analyte isotopes needs to be included in the matrix spike sample. When more than one analyte isotope is added to the matrix spike, each isotope must be assessed against the specified acceptance criteria.
 - g.** When gamma spectrometry is used to identify and quantitate more than one analyte isotope, the laboratory control sample and matrix spike must contain isotopes that represent the low (Americium-241), medium (Cesium-137) and high (Cobalt-60) energy range of the analyzed gamma spectra. As indicated by these examples, the isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.
 - h.** The matrix spike sample must be prepared with similar aliquot size to that of the routine samples of analyses.
- 5.** Tracer

 - a.** For those approved methods that allow or require the use of a tracer (e.g., internal standard), each sample result must have an associated tracer recovery calculated and reported. The tracer recovery for each sample result must be one of the QC measures used to assess the associated sample result acceptance.
 - b.** The tracer recovery must be assessed against the specific acceptance criteria specified in the laboratory SOPs. When the specified tracer recovery acceptance criteria are not met, corrective actions specified in the laboratory's SOPs must be followed. The occurrence of a failed tracer recovery and the corrective actions taken must be noted in the laboratory report.
- 6.** Carrier

- a.** Calibration verification checks must be performed using appropriate check standards and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the calibration has not changed.
 - b.** The same check standards used in the preparation of the tolerance chart or control chart at the time of calibration must be used in the calibration verification of the instrument.
 - c.** The check standards must provide adequate counting statistics for a relatively short count time. The sources must be sealed or encapsulated to prevent leakage and contamination of the instrument and laboratory personnel.
 - d.** For alpha and gamma spectroscopy systems, the instrument calibration verification must include checks on the counting efficiency and the relationship between channel number and alpha or gamma ray energy.
 - e.** For gamma spectroscopy systems, the calibration verification checks for efficiency and energy must be performed at least weekly along with performance checks on peak resolution.
 - f.** For alpha spectroscopy systems, the calibration verification check for energy must be performed at least weekly and the performance check for counting efficiency must be performed at least monthly for each day the instrument is used for sample analysis.
 - g.** For gas-proportional and scintillation counters, the calibration verification check for counting efficiency must be performed each day of use.
- 10.** Background radiation measurement
 - a.** Background radiation measurements must be performed on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required data quality objectives.
 - b.** Background radiation measurement values must be subtracted from the total measured activity in the determination of the sample activity.
 - c.** For gamma spectroscopy systems, background radiation measurements must be performed at least monthly.
 - d.** For alpha spectroscopy systems, background radiation measurements must be performed at least monthly.
 - e.** For gas-proportional counters, background radiation measurements must be performed at least weekly.
 - f.** For scintillation counters, background radiation measurements must be performed each day of use.
- 11.** Instrument contamination monitoring

A laboratory must have a written procedure for monitoring radiation measurement instrumentation for radioactive contamination. The procedure must indicate the frequency of the monitoring and must indicate criteria that initiate corrective action.

12. Method detection limits

- a.** Detection limits must be determined before sample analysis and must be re-determined each time there is a significant change in the test method or instrument type.
- b.** The procedures employed must be documented and consistent with published references.

13. Quality of standards and reagents

- a.** The QA manual must describe the procurement, use and storage of radioisotope standards.
- b.** Reference standards that are used in a radiochemical laboratory must be obtained from an accredited third party or a National Metrology Institute (e.g., NIST) and be traceable to the SI, International System of Units.
- c.** Reference standards must be accompanied with a certificate of calibration that describes traceability to the SI, International System of Units, from an accredited third party or a National Metrology Institute (e.g., NIST) when appropriate.
- d.** Laboratories must consult with the supplier if the laboratory's assessment of the activity of the reference traceable standard indicates a noticeable deviation from the certified value. The laboratory must not use a value other than the decay-corrected certified value.
- e.** All reagents used must be of analytical reagent grade or better.

SECTION 12: WASTE MANAGEMENT**A. SOPs for waste management**

The laboratory shall have SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products. All waste must be managed according to the following requirements:

- 1.** Solid waste, as defined in the *Maine Hazardous Waste, Septage and Solid Waste Management Act*, 38 MRS § 1303-C(29), must be managed in accordance with the *Solid Waste Management Rules*, 06-096 CMR, Chs. 400 - 425.
- 2.** Incinerator ash, provided it is not hazardous by characteristic, is a special waste. Regulations governing the handling, storage and disposal of incinerator ash are specified in 06-096 CMR, Chs. 400 - 425 of the *Solid Waste Management Rules*. Incinerator ash which meets hazardous waste characteristics, as defined in *Identification of Hazardous Wastes*, 06-096 CMR, Ch. 850, must be managed as a hazardous waste.
- 3.** Hazardous wastes, as defined by 38 MRS § 1303-C(15) (with the exception of infectious and pathogenic wastes) and in 06-096 CMR, Ch. 850 must be managed in accordance with Maine's Standards for Hazardous Waste Facilities, Licensing of Transporters of Hazardous Waste Rules, Standards for Hazardous Waste Facilities Rules, Interim Licenses for Waste Facilities for Hazardous Wastes Rules, Licensing of Hazardous Waste Facilities Rules and Hazardous Waste Manifest Requirements (See 06-096 CMR, Chs. 850 - 857).
- 4.** Radioactive material, as defined by the Radiation Protection Act pursuant to 22 MRS § 673, must be managed in accordance with the rules of the U.S. Nuclear Regulatory Commission and the Maine Rules Relating to Radiation Protection (10-144 CMR, Ch. 220).
- 5.** Biomedical waste, as defined by 38 MRS § 1303-C(1-A), must be managed in accordance with the *Biomedical Waste Management Rules*, 06-096 CMR, Ch. 900.
- 6.** If there is a conflict between another applicable rule or regulation and this rule, the more restrictive requirement applies.

STATUTORY AUTHORITY: 22 MRS § 567

EFFECTIVE DATE: (NEW) December 19, 2018

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