Appendix C

10-144

CHAPTER 263

STATE OF MAINE

MAINE COMPREHENSIVE AND LIMITED ENVIRONMENTAL LABORATORY CERTIFICATION RULES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL AND PREVENTION
DIVISION OF ENVIRONMENTAL HEALTH
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AUGUSTA, ME 04333-0011

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Appendix C

SUMMARY STATEMENT

These rules and regulations are promulgated by the Department of Health and Human Services (DHHS) for the certification of laboratories producing compliance data for programs of DHHS and the Department of Environmental Protection.

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SECTION 1: DEFINITIONS

A. Acceptable performance or acceptable results: "Acceptable performance" or "acceptable results" means analytical test results generated by a laboratory using methods as specified in Section 5 that fall within the acceptance range allowed by the approved provider.

B. Approved provider or approved PT provider: "Approved provider" or "approved PT provider" means a provider of proficiency testing samples that the certification officer has determined meets the requirements of Section 8.

C. Base certification: "Base certification" means acknowledgment by the certification officer that a laboratory has the policies, procedures, equipment, and practices to produce reliable data in the analysis of environmental analytes.

D. Batch: "Batch" means 1 to 20 environmental samples of the same matrix that are prepared together with the same process and personnel, using the same lot of reagents, with the maximum time between the start of processing of the first sample and the start of processing of the last sample being 24 hours, unless the method requirements are more stringent.

E. Bias: "Bias" means the systematic or persistent distortion of a measurement system that causes errors in one direction, so that the expected sample measurement is different from the true value.

F. Calibration: "Calibration" means testing an instrument's response by analyzing a series of analyte standards of differing concentrations, which are plotted on a graph that defines the instrument's linearity and dynamic range.

G. Calibration range: "Calibration range" means the concentrations between and including the concentration of the lowest calibration standard at or above the detection limit and the highest concentration at which linearity has been established.

H. Certification: "Certification" means the written acknowledgment of a laboratory's demonstrated capability to perform tests for a specific purpose.

I. Certification Officer: "Certification Officer" means the person designated by the Director of the Maine Center for Disease Control and Prevention to manage the laboratory certification program.

J. Certified test category or test category: "Certified test category" or "test category" means a group of analytes available for certification. The analysis of the analytes is intended to test for compliance with specific environmental programs.

K. CFR: "CFR" is the abbreviation for the Code of Federal Regulations and is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government.

L. Chain-of-custody: "Chain-of-custody" means the procedures and records that document the possession and handling of samples from collection through disposal.

M. Chemical materials: "Chemical materials" means a product or by-product of an industrial process or collection mechanism that results in a matrix not otherwise defined.

N. Corrective action: "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.

O. Corrective action plan: "Corrective action plan" means a report, including specific paragraphs addressed and a specific date of completion, generated by a laboratory in response to deficiencies.

P. Deficiency or deviation: "Deficiency" or "deviation" means a failure of the laboratory to meet any of the requirements in Sections 1 to 20.

Q. Denial: "Denial" means the certification officer's refusal to certify a laboratory after submission of an application.

R. Director: "Director" means the Director of the Maine Center for Disease Control and Prevention or the director's designee.

S. Document: "Document" means any written or pictorial information describing, defining, specifying, reporting, or certifying any activities, requirements, procedures, or results.

T. Drinking water: "Drinking water" means water used or intended for use as potable water.

U. Duplicate: "Duplicate" means replicate.

V. EPA: "EPA" means the United States Environmental Protection Agency.

W. Fees: "Fees" means the fees described in Section 21.

X. Field of testing: "Field of testing" means the combination of analyte, method, matrix, and test categories for which a laboratory has applied or received certification by the certification officer.

Y. Inspection: "Inspection" means an on-site evaluation of laboratory facilities, records, personnel, equipment, methodology, and quality assurance practices by the certification officer for compliance with the applicable provisions of this chapter.

Z. Internal standard: "Internal standard" means a pure analyte or analytes added to a test sample, extract, or standard solution in known amounts and used to measure the relative responses of other method analytes and surrogates that are components of the sample or solution. The analyte or analytes used for the internal standard is not present in the test sample.

AA. Laboratory: "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

BB. Laboratory control sample or LCS: "Laboratory control sample" or "LCS" means a sample of a controlled matrix known to be free of the analyte of interest, to which the laboratory has added a known and verified concentration of analyte and that the laboratory has taken through all preparation and analytical steps in the method.

CC. Laboratory director: "Laboratory director" means an agent or affiliate of the laboratory responsible for ensuring compliance with Sections 1 to 19.

DD. Laboratory fortified blank or LFB: “Laboratory fortified blank” see "Laboratory control sample."

EE. Limited Laboratory Certification: “Limited Laboratory Certification” means the written acknowledgment by the certification officer of a drinking water or wastewater treatment facility laboratory's demonstrated capability to perform tests for a specific purpose. A limited certified laboratory performs no more than five analytes for two fields of testing in the following categories: Wastewater program bacteriology, Drinking water program bacteriology, Wastewater program inorganic chemistry, and Drinking water program inorganic chemistry.

FF. Managing agent: "Managing agent" means a person is legally authorized to direct the activities of a laboratory and commit the appropriate resources to comply with Sections 1 to 19.

GG. Matrix or matrices: "Matrix" or "Matrices" means the predominant material of which the sample to be analyzed is composed. Matrices include, but are not limited to, drinking water, nonpotable water, sewage sludge, and solid and chemical materials.

HH. Matrix spike: "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.

II. Matrix spike duplicate: "Matrix spike duplicate" means a replicate matrix spike that is prepared and analyzed to determine the precision of the approved test method.

JJ. Measurement system: "Measurement system" means any instruments, gauges, tools, devices, equipment, procedures, methods, or aggregates thereof, used to acquire or control sample data generated according to Sections 1 to 19.

KK. Method: "Method" means the published scientific technique recognized by the certification officer for performing a specific measurement. Methods include instructions for sample preparation and sample analysis.

LL. Method blank: "Method blank" means a sample free of the analyte of interest and processed according to the laboratory's standard operating procedures manual according to Section 6.

MM. Method detection limit or MDL: "Method detection limit" or "MDL" means the minimum concentration of a substance that can be measured and reported with 99 % confidence that the analyte concentration is greater than zero and is determined from the analysis of a sample in a given matrix type containing the analyte. Unless specified in the approved test method, the method detection limit is determined, using the procedures specified in the applicable permit, program, or rule.

NN. Mobile laboratory: “Mobile Laboratory” means (i) a portable enclosed structure within which testing or analysis of environmental samples occurs. (ii) Examples include trailers, vans and skid-mounted structures configured to house environmental testing equipment and personnel.

OO. Nonconformance or noncompliance: "Nonconformance" or "noncompliance" means deficiency of a laboratory to meet any requirement in Sections 1 to 19.

PP. Owner: "Owner" means a person who:

a) is a sole proprietor of a laboratory;
b) holds a partnership interest in a laboratory; or
c) owns five percent or more of the shares in a corporation that owns a laboratory.

QQ. Parameter: "Parameter" means an analyte.

RR. Precision: "Precision" means the measure of mutual agreement among individual measurements of a sample, usually under prescribed similar conditions, usually expressed as the standards deviation, variance, or range, in either absolute or relative terms.

SS. Proficiency testing sample or PT sample: "Proficiency testing sample" or "PT sample" means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis.

TT. Program: "Program" means the laboratory certification program of the Maine Center for Disease Control and Prevention at the Department of Health and Human Services.

UU. Quality control: "Quality control" means the overall system of technical activities, the purpose of which is to measure and control the quality of a product or service so that it meets the needs of users.

VV. Quality control data: "Quality control data" means data generated to assess the accuracy and precision of test data. Quality control data includes data on calibration standards, proficiency testing samples, known standards, duplicate samples, blanks, spiked samples, and limits for quality-control spiked samples, reference standards, duplicates, and detection levels.

WW. Quality system or quality assurance: "Quality system" or "quality assurance" means the actions planned and taken that involve activities including control, assessment, reporting, and improvement in a laboratory's processes to ensure that a product or service meets the requirements of Sections 1 to 19.

XX. Quantitate: "Quantitate" means the arithmetic process of determining the amount of analyte in a sample.

YY. Reagent Water: “Regent Water” for chemical analysis is water with no detectable concentration of the analyte to be analyzed at the detection limit of the analysis.

ZZ. Replicate: "Replicate" means two or more substantially equal aliquots analyzed independently for the same parameter.

AAA. Reporting limit: "Reporting limit" means the lowest level of an analyte that can be accurately recovered from the matrix of interest, (for example, the level of quantitation).

BBB. Revocation: "Revocation" means a determination by the certification officer to invalidate in part, or in total, a laboratory's certification.

CCC. Sample or environmental sample: "Sample" or "environmental sample" means a substance derived from a non-human source and collected for the purpose of analysis.

DDD. Scope of certification: "Scope of certification" means the sum of all fields of testing for which a laboratory has been granted certification by the certification officer.

EEE. Second source: "Second source" means a different vendor or manufacturer, or different lots from the same vendor or manufacturer, usually in reference to standards.

FFF. Solid: "Solid" means: (a) soils; (b) sediments; (c) solid waste; and (d) biosolids.

GGG. Standard: "Standard" means: (a) the certified reference materials produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method; or (b) the dilutions made from these certified reference materials for the purposes of calibration or determining accuracy of a test method.

HHH. Successor in interest: "Successor in interest" means a laboratory that is owned or controlled by a majority of persons owning or controlling a laboratory certified under a previously issued certificate.

III. Surrogate: "Surrogate" means a compound that is similar to the analytes of interest in chemical composition and behavior in the analytical process, but that is not normally found in environmental samples.

JJJ. Suspension: "Suspension" means the temporary invalidation in part or in total of a laboratory's certification for a defined period of time according to Section 4, Sub-Section I, to allow a laboratory time to correct deficiencies or areas of noncompliance to comply with Sections 1 to 19.

KKK. Target or target analyte: "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 certification from the certification officer to test as part of a field of testing.

LLL. Verification: "Verification" means 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 Sections 1 to 19.

SECTION 2 : AUTHORITY

22 MRSA Chapter 157-A authorizes the Director of the Maine Center for Disease Control and Prevention of the Department of Health and Human Services to establish a program for laboratories that must be State-certified or accredited in order to generate data pursuant to specific statutory requirements for programs of the Department of

Environmental Protection and the Department of Health and Human Services. These rules for Maine Comprehensive and Limited Environmental Laboratory Certification are hereby promulgated to implement portions of 22 MRSA Chapter 157-A.

The Director of the Maine Center for Disease Control and Prevention of the Department of Health and Human Services is responsible for implementation of these certification rules. The Director shall designate a Certification Officer to manage the certification program.

SECTION 3: PURPOSE AND SCOPE

The purpose of the Laboratory Certification Program rules is to establish quality guidelines for laboratory data received by the Department of Health and Human Services and the Department of Environmental Protection. The rule establishes procedures for certifying laboratories by creating minimum criteria for laboratory operations, performance, and administration. The program is intended for the certification of all laboratories, including industrial, commercial, college, university and governmental, laboratories, which analyze water, soil, solid or hazardous waste, or radiological samples for the use of programs of the Department of Health and Human Services or the Department of Environmental Protection. This program will certify the following matrices: drinking water, wastewater, and Resource Conservation and Recovery Act aqueous, and solid and chemical materials.

Drinking water laboratories of treatment plants involved in limited analysis required for system/treatment surveillance but deemed by EPA and the Department as analytes not required for analysis by a certified laboratory under 10-144 CMR 231, Section (7), do not need to be certified.

Laboratories operated by waste discharge facilities licensed pursuant to 38 M.R.S.A. § 413 may analyze waste discharges for total suspended solids, total dissolved solids, settleable solids, biological or biochemical oxygen demand, chemical oxygen demand, carbonaceous BOD, pH, chlorine residual, fecal coliform, E. coli, conductivity, color, temperature, turbidity, and dissolved oxygen without being certified under these rules.

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 waste treatment plants for up to 60 days of analysis per year.

This rule does not address the management of waste streams or the use of hazardous or toxic substances. Laboratories should consult with the Department of Environmental Protection regarding any such rules that may apply to their facility or operations.

SECTION 4: CERTIFICATION PROCESS

A. Base certification requirements.

These requirements apply to all laboratories applying for certification, including those applying to limited certification.

(1) A laboratory may request to be certified by the certification officer for the use of methods to test the analytes eligible for certification according to Section 5.

(2) A laboratory must specify the fields of testing for which it seeks certification. No certification shall be awarded for any field of testing without the laboratory meeting base certification requirements. No laboratory may receive base certification without approval of at least one field of testing.

(3) A laboratory must apply on a form that is provided by the certification officer. The laboratory must supply the following information:

(a) the name of the laboratory;

(b) the physical location, postal mailing address, and electronic mailing address of the laboratory;

(c) the owner of the laboratory;

(d) the names and telephone numbers of a designated contact person and the laboratory director;

(e) the names of at least one managing agent with signature, and

(f) the names of supervisory professional staff responsible for the analyses.

(4) An application for certification must include:

(a) the form required under Sub-Section (3) above;

(b) the applicable fees, including a nonrefundable base certification fee and fees for each test method in which the laboratory seeks certification;

(c) a quality assurance manual meeting the standards of Section 9;

(d) a laboratory procedures manual meeting the standards of Section 6;

(e) if the application is an initial request for certification, the most recent proficiency testing result for each field of testing for which the laboratory seeks certification. The proficiency testing samples must be from an approved provider and be analyzed within one year prior to the date that the application is received by the certification officer; and

(f) a list of the laboratory's detection limits and reporting limits for each field of testing for which the laboratory is requesting certification.

(5) Except as provided for mobile laboratories in Sub-Section B below, a laboratory that owns or manages laboratory facilities at different locations must submit a separate application for each laboratory location.

(6) Applications for renewal of certification must be received no later than 90 days before the expiration of certification. The application must meet the criteria of this Sub-Section. If a laboratory fails to submit a renewal application within 90 days before the expiration of certification, the certification officer must notify the regulatory authorities that receive data that the laboratory did not apply to renew its certification. The laboratory must not report results as certified after its certification expires.

B. Requirements for mobile laboratories.

(1) A mobile laboratory is considered a separate laboratory and is subject to all requirements, including application requirements, of Sections 1 to 19.

(2) In addition to the requirements under sub-section 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 Sub-Section A above. The operator of a mobile laboratory must maintain a record or log, documenting places to where the lab is sent, where the actual location is at any given time, which is known by the overall lab manager or business manager.

C. Notice of availability of analytes for certification.

(1) The certification officer will maintain and publish a list of sources for analytes eligible for certification.

(2) The list of analytes must be made available to the public through direct mailing from the certification officer.

(3) The list of analytes must be reviewed at least once every 6 months.

D. Changes in scope of certification.

(1) The certification 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 meets the criteria in Sections 1 to 19 and submits the applicable fees. Fees are required with the addition of fields of testing for each test method. The notification to the certification officer must contain an indication of the changes to the list of analytes.

(2) Requests to add fields of testing for analytes in response to a notice of availability do not require payment of additional fees, if the laboratory holds a certification for that test method and applies for a new analyte within the same test method. Applications for fields of testing for new analytes in response to a notice of availability must meet the requirements of Section 4 (A) and must be received by the certification officer no later than 180 days after the notice of availability is posted.

(3) Requests for the addition of fields of testing received more than 180 days after the notice of availability is posted are subject to fees according to Section 21.

E. Review of application.
After receiving the application and information required in Section 4(A), the certification officer must:

(1) notify the laboratory in writing of any omission or error in the application;

(2) deny certification for an initial application or revoke certification for a renewal application if the laboratory does not submit the required information to the certification officer within 15 days after receiving an error notice under Section 4 (E)(1);

(3) award certification according to sub-Section G if the laboratory's application meets the applicable standards of Sections 1 to 19; or

(4) notify the laboratory that its current certification for fields of testing must be continued until the certification officer fully reviews all documentation for compliance with Sections 1 to 19.

F. Laboratory inspection.

(1) The certification officer may conduct inspections of certified laboratories or laboratories applying for certification. The certification officer must conduct a comprehensive on-site inspection of each laboratory, prior to granting certification. In addition, an on-site inspection of each certified laboratory must be completed at least every two years.

(2) The certification 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 Sections 1 to 19. When the certification officer provides notification, the notification may be written or oral.

(3) When the certification officer determines after inspection that a certified laboratory does not comply with applicable provisions of Sections 1 to 19, the certification officer must notify the laboratory of the deficiencies in writing within 30 days of inspection for in-state laboratories, and after out-of-state laboratories pay fees associated with the inspection.

(4) Additional on-site inspections, announced 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, 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 certification is made.

(5) A laboratory must remedy any deficiencies and provide documentation of the correction to the certification officer.

(a) Within 30 days of receiving the report of deficiencies, the laboratory must submit documentation of corrective actions planned. If the laboratory does not provide corrective action plans within 30 days, the certification officer must notify the laboratory that its certification may be suspended in total or in part according to Section 4(I). If the laboratory does not provide any documentation of deficiency corrections within 30 days, the certification officer will notify the laboratory that its certification is revoked in total, according to Section 4(J).

(b) Within 60 days of receiving the report of deficiencies, the laboratory must submit initial documentation of corrective actions. If the laboratory does not provide initial documentation of corrective actions within 60 days, the certification officer will notify the laboratory that its certification may be suspended in total or in part according to Section 4(I). If the laboratory does not provide any documentation of deficiency corrections within 60 days, the certification officer will notify the laboratory that its certification is revoked in total, according to Section 4(J).

(i) When the certification officer determines after review of initial documentation of corrective actions, the corrective actions do not comply with applicable provisions of Sections 1 to 19, the certification officer will notify the laboratory of the deficiencies of corrective action in writing within 30 days of the inspection.

(ii) Within 30 days of receiving the report of deficiencies of corrective action, the laboratory must submit documentation of corrective actions. If the laboratory does not provide acceptable documentation of corrective actions within 30 days, the certification officer will notify the laboratory that its certification may be suspended in total or in part, according to Section 4(I). If the laboratory does not provide any documentation of deficiency corrections of corrective action within 30 days, the certification officer will notify the laboratory that its certification is revoked in total, according to Section 4(J).

(6) A laboratory may not reapply for certification after suspension or revocation until it has corrected all deficiencies. After all deficiencies are corrected, the laboratory may apply for certification according to Section 4(A). With its new application, the laboratory must submit written documentation of the steps employed to correct the deficiencies.

(7) If a laboratory located in another state is not scheduled for inspection by the certifying or accrediting authority of that state prior to the period specified in that state's rules, this program must be notified 60 days prior to the two-year anniversary of the last complete inspection of the laboratory.

(a) This program will schedule an inspection in accordance with Section 4(F).

(b) The laboratory must pay a fee based on time and travel expenses within 30 days of billing after the onsite visit.

G. Awarding certification.

(1) Documentation of a laboratory's certification must include:

(a) a certificate acknowledging the laboratory's compliance with base certification requirements; and

(b) the scope of certification for the laboratory.

(2) The certificate and scope of certification must include:

(a) the seal of the State of Maine

(b) the name of the laboratory;

(c) the address of the laboratory;

(d) the laboratory identification number; and

(e) the expiration date of the certification.

(3) If a laboratory's scope of certification changes, the certification officer shall issue a new scope of certification.

(4) A laboratory's certification is valid for 2 years from the date of awarding base certification or renewal of base certification, unless conditions warrant suspension or revocation by the certification officer under Sections 4 (I) and (J).

(5) A laboratory must return its scope of certification to the certification officer upon suspension or certificate and scope of certification upon revocation of certification.

(6) A certified laboratory must not misrepresent its certification 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 certification, upon the request of a client, certification authority, or regulatory agency. The laboratory must not supply a copy of its current certificate without the accompanying copy of its scope of certification.

H. Denial.

(1) The certification officer shall deny certification if a laboratory's initial or renewal application does not meet the requirements of Section 5(A).

(2) A laboratory with its request for certification denied may reapply according to Section 4(A). The application and all required documentation must be accompanied by repayment of applicable fees.

(3) The certification officer will not refund a base certification fee if an application is denied.

I. Suspension.

(1) When the certification officer determines that there are grounds for suspension, the certification officer must notify the laboratory in writing. A laboratory's certification 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 certification. If a laboratory takes corrective action before the end of the suspension period, certification for the suspended fields of testing or for the base certification and fields of testing must be restored if the corrective actions satisfactorily address the deficiencies cited in the notice of suspension. The laboratory shall retain certification for the fields of testing for which it continues to meet the requirements of Sections 1 to 19.

(2) Grounds for suspension of certification are:

(a) failure to produce acceptable results in 2 consecutive proficiency testing studies for the same field of testing;

(b) failure to use an approved method or to follow the method in sample analysis;

(c) failure to submit an acceptable corrective action report in response to an inspection or unacceptable proficiency testing results;

(d) failure to notify the certification officer of any changes according to Section 4(N);

(e) failure of the laboratory to maintain records that demonstrate the capability of laboratory staff, as required by Section 5(H)(1)(a); or

(f) for laboratories certified through equivalency, failure to notify the certification officer within 30 days after any enforcement action is administered by the primary certifying or accrediting authority.

(3) The effective date of suspension is the date that the laboratory receives the suspension notice from the certification officer. Upon receiving the notice, the laboratory must return to the client, or subcontract to another certified laboratory, samples for the field of testing of the suspension. 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 certification has been suspended. The notification from the laboratory must be in writing. The laboratory must retain an electronic copy of each notification sent to the client for the review of the certification officer. 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 certification officer at the time the notification is sent to the client.

(4) A laboratory that has had its certification suspended may reapply according to Section 4(A). Repayment of fees is not required for reinstatement if the laboratory corrects the deficiencies within the time-frame required by the certification officer, not to exceed 180 days or the expiration date of the current certification, whichever is sooner. If the laboratory fails to correct the causes of suspension within the specified time frame, the certification officer will revoke in total, or in part, the laboratory's certification, according to Section 4(J)(1).

(5) A laboratory with a suspended certification, due to unacceptable proficiency testing results must submit acceptable proficiency testing results for the fields of testing from 2 successive studies, within 1 year of the suspension, to restore certification.

J. Revocation.

(1) When the certification officer determines that there are grounds for partial or total revocation of a laboratory certification, the certification officer must notify the laboratory in writing. The laboratory must retain certification for the fields of testing for which it continues to meet the requirements of Sections 1 to 19.

(2) Grounds for partial or total revocation of certification are:

(a) failure to respond to deficiencies according to Section 4(F);

(b) failure to correct the deficiencies cited in a notice of suspension within the time frame specified by the certification officer;

(c) failure to implement corrective action related to any deficiencies found during a laboratory inspection;

(d) failure to implement corrective action in response to an unacceptable proficiency testing result;

(e) failure to complete proficiency testing studies and maintain a history of successful proficiency testing studies at the frequency specified in Section 7;

(f) revocation of certification or accreditation by a certifying authority with which the certification officer has deemed equivalent; or

(g) failure to comply with applicable standards of Sections 1 to 19.

(3) Grounds for total revocation of a laboratory's certification are:

(a) failure to respond with a report of corrective actions or corrective action plans for deficiencies identified during an on-site inspection within 30 days of receiving the inspection notice of deficiencies;

(b) submittal of proficiency test sample results generated by another laboratory as its own;

(c) reporting sample results without qualification or notation for fields of testing for which the laboratory's certification has been suspended or for which the laboratory has not requested or received certification;

(d) misrepresentation of any material fact pertinent to receiving and maintaining certification;

(e) denial of entry during normal business hours for an inspection as required under Section 4(F), unless circumstances endangering safety or welfare prohibit entry;

(f) failure to send written notification of revocation or suspension to clients within the time frame specified in this Sub-Section;

(g) for laboratories certified through agreement, failure to notify the certification officer within 30 days after any enforcement action is taken by the reciprocal certifying authority; or

(h) for out-of-state laboratories requiring an on-site inspection, failure to pay the assessment fee.

(4) The effective date of revocation is the date that the laboratory receives the revocation notice from the certification officer via certified mail, return receipt requested. Upon receiving the notice, the laboratory must return to the client, or subcontract to another certified laboratory, samples for the field of testing of the revocation. Notification to the client is required for all fields of testing for which the laboratory's certification has been revoked. The notification from the laboratory must be in writing. The laboratory must submit a list of clients who received the notification, and one ~~a~~ copy of the form letter used for the notification to the certification officer at the time that the notification is sent to the client.

(5) A laboratory that has had its certification revoked must not advertise itself as certified and, when possible, must remove or replace any advertisements that indicate that the laboratory is certified.

(6) A laboratory with a revoked certification may not reapply for certification until it has corrected all deficiencies. The laboratory may reapply according to Section 4(A) and, with the application, must provide documentation of the steps implemented to correct the deficiencies.

K. Successor in interest; recertification.

A successor in interest of a laboratory with a revoked or suspended certification may not apply for re-certification until the end of the term for which the certification was suspended or until all conditions for reapplication after revocation are met.

L. Equivalency and laboratories in other states.

(1) A laboratory in another state may request certification in Maine. This request is performed through equivalency determination of the program of the state in which the laboratory is located or through equivalency determination of the federal agency which certified the laboratory. A laboratory in another state must submit the resident state's or federal agency's certification program requirements for review prior to the certification request.

(a) If the resident state does not offer the specific program for which the laboratory is requesting certification, the certification officer may consider equivalency through another certification or accreditation which the laboratory holds. This certification or accreditation program must be a state or federal entity.

(2) The certification officer shall determine if the certifying authorities of federal agencies and agencies of other states or portions of programs are substantially equivalent. Equivalency will be based on a comparison between this rule and the laboratory's resident state's or federal agency's certification program requirements. For a program to be determined equivalent, the following criteria must be at least as stringent as stated in this rule:

(a) the requirements of these rules,

(b) inspection and corrective action requirements of these rules; and

(c) proficiency testing requirements of the rules.

(3) A certification or accreditation program is not considered equivalent if:

(a) inspections of certified laboratories are performed at intervals exceeding 2 years;

(b) the certifying agency does not require an acceptable corrective action response with support documentation from the laboratory as required under Section 4(F); or

(c) the certifying agency is not the primary authority for necessary enforcement actions, such as suspension or revocation of the laboratory's certification.

(4) When a program is deemed equivalent, the certification officer will certify an out-of-state laboratory that:

(a) submits an application meeting the requirements of Section 4(A);

(b) submits the appropriate fees, not to include an on-site inspection fee for out-of-state laboratories;

(c) provides a copy of current certification from the resident state or federal agency;

(d) provides a copy of the certifying authority's most recent inspection report and complete responses; and

(e) fulfills PT requirements of Section 7.

(5) When a program is not deemed equivalent, the certification officer will certify an out-of-state laboratory that meets the requirements of Sections 1 to 19 as determined by:

(a) review of an application meeting the requirements of Section 4(A);

(b) submission of the appropriate fees, including an on-site inspection fee for out-of-state laboratories;

(c) is inspected under the requirements of Section 4(F); and

(d) fulfills PT requirements of Section 7.

(6) A laboratory certified under this sub-section must notify the certification officer within 14 days after any enforcement action is assessed by the equivalent certifying authority.

(7) A laboratory certified under this sub-section must notify the certification officer within 14 days after any adverse change in certification status is assessed by the equivalent certifying authority. The notification from the laboratory must contain an indication of the changes to the list of analytes.

(8) Laboratories certified under equivalency must comply with the applicable requirements of Sections 1 to 20. Only fixed-base laboratories located within the boundaries of the state represented by the certifying authority may apply for equivalency.

M. Voluntary withdrawal of certification.

(1) If a laboratory chooses to withdraw its application for certification or its current certification in total, or in part, the laboratory must notify the certification officer in writing and specify the effective date of withdrawal.

(2) The certification officer will consider that a laboratory has chosen to voluntarily withdraw its certification, if the laboratory has not submitted a complete renewal application within 90 days before the expiration date of its current certification. In this situation, the effective date is the expiration date of the laboratory's current certification.

(3) By the effective date of the withdrawal of certification, in total or in part, the laboratory must notify current clients and regulatory agencies of its intent to withdraw its certification 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 certification. The notification from the laboratory must be in writing. The laboratory must submit a copy of each notification to the certification officer at the time that the notification is sent to the client.

(4) The certification officer will not refund fees if a current certification is voluntarily withdrawn by the laboratory.

N. Duty to notify.

(1) A laboratory must notify the certification officer in writing within 30 days of a change associated with the following:

(a) the name of the laboratory;

(b) the physical location, postal mailing address, and electronic mailing address of the laboratory;

(c) the owner of the laboratory;

(d) the names and telephone numbers of a designated contact person and the laboratory director;

(e) the name of at least one managing agent with signature;

(f) the names of supervisory professional staff responsible for the analyses; and

(g) major analytical equipment.

(2) With the notification, a laboratory must provide results of proficiency testing samples, or a demonstration of capability, analyzed in the new laboratory location or analyzed under the change in laboratory owner, or instrumentation.

O. Payment of fees.

(1) All applications or requests to change the scope of certification submitted to the certification officer for approval must be accompanied by the fee specified in Section 21.

(2) When a laboratory requests certification for additional fields of testing at any time other than the time of initial or renewal application, the laboratory must submit fees for each test method requested. The fee also applies to the addition of methods or analytes for reinstatement after revocation or denial of certification. This fee also applies to methods modified by the laboratory. 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(D), or for the addition of analytes to a test method which the laboratory maintains certification.

(3) When a laboratory in another state requests certification in Maine, the laboratory must submit all applicable fees with its application, to include an out-of-state inspection fee, unless program equivalency has been determined by the certification officer and for the state in which the fixed-base laboratory is located.

(4) Payment of fees must be in the form of a check, money order, or credit card.

(5) All checks must be payable to ‘‘Treasurer - State of Maine.’’

P. Appeal of administrative decision.

(1) The certification officer will notify a laboratory in writing of the reasons for a decision to suspend or revoke a certification.

(2) A laboratory has 30 days from the date of receiving the decision to appeal the decision. A request to appeal the decision must:

(a) be in writing;

(b) indicate the facts that the laboratory disputes;

(c) be signed by the laboratory director; and

(d) be sent to the Director of the Division of Environmental Health of the Maine Center for Disease Control and Prevention.

(3) Upon receipt of an appeal request, the certification officer will initiate the procedure for conducting the administrative hearing, as set forth in the Administrative Hearing Manual, the rules of the Office of Administrative Hearings.

SECTION 5: METHODS REQUIRED FOR CERTIFICATION

A. Scope.

(1) The laboratory must use appropriate methods and procedures for all environmental 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 environmental 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 where the absence of such instructions could jeopardize the results of environmental tests. 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. Deviation from environmental test methods may occur only if the deviation has been documented, technically justified, authorized, accepted by the client and allowed by regulation.

(3) Laboratories must observe appropriate methodologies for conducting analyses.

B. Wastewater Program.

(1) Methods for the Wastewater Program test category are as provided under the following sections: 40 CFR 136.3, Tables IC, IB and ID; 40 CFR 136.4; 40 CFR 136.5; 40 CFR 136, Appendices A, B, and C; Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act: Analysis and Sampling Procedures (also known as the “Methods Update Rule”), 72 Federal Register 47, March 12, 2007, 40 CFR 136 and Guidelines Establishing Test Procedures for the Analysis of Pollutants, Analytical Methods for Biological Pollutants in Wastewater and Sewage Sludge, 72 FR 57, March 26, 2007, 40 CFR 136 and 40 CFR 503, July 2007.

(2) In the absence of an applicable federal regulation, alternative methods may be used for state-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 receiving approval.

(3) The laboratory must submit a copy of the approval for alternative methods to the certification officer, along with an application, as required under Section 4, (A), and fees as required under Section 21.

(a) The laboratory must validate standard methods used outside its published scope amplifications and modifications of standard

methods to confirm that the methods are fit for the intended use. This confirmation may be accomplished through a Demonstration of Capability.

(b) Modifications are allowed, only if the modified method produces equivalent performance for the analyte(s) of interest, as determined by the certification officer, and the equivalent performance is documented.

C. Drinking Water Program.

(1) Methods for the Drinking Water Program test category are as provided under the following sections: 40 CFR §§ 141.23(k), 141.24(e), 141.24(f)(20), 141.27, 141.40(n)(11),143.4(b); Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act: National Primary Drinking Water Regulations: Analysis and Sampling Procedures (also known as the “Methods Update Rule”), 72 FR 47, March 12, 2007, 40 CFR §141 “Expedited Approval of Alternative Test Procedures of the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures”; 72 FR 107, June 3, 2008, 40 CFR §141; and “Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures”, 74 FR 147, August 3, 2009.

(2) In the absence of an applicable federal regulation, alternative methods may be used for state-specific testing, if the 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 approval.

D. Resource Conservation Recovery Program

(1) Methods for the Resource Conservation Recovery Program test category are as provided under 40 CFR 261, and “Test Methods for Evaluation Solid Waste: Physical/Chemical Methods,” Publication SW-846, as updated and published as final, EPA. The test methods are available on the internet at http://www.epa.gov/epaoswer/hazwaste/teat/main.htm.

(2) In the absence of an applicable federal regulation, alternative methods may be used for state-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 approval.

(3) The laboratory must submit a copy of the approval of alternate methods to the certification officer, along with an application, as required under Section 4 (A) and fees as required under Section 21.

(a) The laboratory must validate standard methods used outside their published scope amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. This validation may be performed through a Demonstration of Capability.

(b) Modifications are allowed only if the modified method produces equivalent performance for the analyte(s) of interest, as determined by the certification officer, and the equivalent performance is documented.

E. Oil Program or Leaking Underground Storage Tanks [LUST] Program.

(1) In addition to meeting the criteria below, the laboratory must be certified under these rules for either Wastewater Program Organic or Resource Conservation and Recovery Program organic compounds analysis.

(2) In the absence of an applicable federal regulation, alternative methods may be used for state-specific testing, if the 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 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 Environmental Lead Laboratory Accreditation Program (NLLAP).

(2) In the absence of an applicable federal regulation, alternative methods may be used for state-specific testing, if the 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 approval.

G. Other Required Methods.

(1) The analytical methods and verification of preservation procedures used for samples required to be analyzed under a permit, program, or rule administered by a state agency must meet the requirements specified by the permit, program, or rule.

(2) The analytical methods and verification preservation procedures used to analyze samples for programs required by a federal agency must meet the requirements specified in the relevant parts of the Code of Federal Regulations.

H. Demonstration of Capability

The laboratory must confirm that it can properly operate all methods before introducing the environmental tests. If there are any changes to the method, the confirmation must be repeated.

(1) Prior to acceptance and institution of any method, satisfactory demonstration of method capability ("DOC") is required. In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean quality system matrix sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., drinking water. In addition, for analytes which do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples.

(a) All demonstrations must be documented. All data applicable to the demonstration must be retained and available.

(b) When an analyte that is not currently found on the laboratory's list of certified analytes is then added to an existing certified test method, an initial evaluation must be performed for that analyte.

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

(2) Procedure for Demonstration of Capability

(a) A quality control sample must be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

(b) The analyte(s) must be diluted in a volume of clean quality system matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration of one to four times the reporting limit.

(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 standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory must assess performance against established and documented criteria.

(3) Thereafter, the laboratory is required to continue demonstrating method performance through the quality control requirements (such as laboratory control samples).

(4) In cases where a laboratory analyzes samples using a method in use by the laboratory before the effective date of this rule, and no significant changes in instrument type, personnel or method has occurred, then the continuing demonstration of method performance and the analyst's documentation of continued proficiency will be acceptable. The laboratory must have records on file to demonstrate that a demonstration of capability is not required.

(5) An initial demonstration of capability must be completed each time there is a change in instrument type, personnel, or method.

SECTION 6: STANDARD OPERATING PROCEDURES

A. Written Procedures Required.

A laboratory must possess a written manual of standard operating procedures 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.

B. Quality control.

Actual practice must conform to the written procedures. A laboratory must ensure that the applicable requirements in Sections 9 to 20 are incorporated into each procedure. All quality control measures must be assessed and evaluated on an ongoing basis. Quality control acceptance criteria in the laboratory's quality assurance manual must be used to determine the validity of the data.

C. Manual requirements.

A standard operating procedures manual must contain the following:

(1) a table of contents;

(2) a unique identification of the manual, 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;

(3) the laboratory's name. When several separate procedures are included in the manual, the name must appear on each procedure;

(4) a revision number; and

(5) a date indicating when the revision became effective.

D. 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.

E. Availability.

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

F. Required Use.

An analyst must use the laboratory's standard operating procedure beginning on the effective date for all laboratory activities for the analysis of samples for which certification is required.

G. Copy to certification officer.

A laboratory must submit an electronic copy of its laboratory standard operating procedures manual to the certification officer at the time of application and within 30 days after the effective date of the revision. All changes to the standard operating procedures must be documented. The changes must be incorporated into the manual at least annually. All updated standard operating procedures must include the signature of the managing agent upon revision. The revised procedure manual must be forwarded to the certification officer in its entirety no later than 30 days after its effective date of revision.

H. Procedure descriptions.

(1) The description of each test procedure must include Sections describing:

(a) the sample type used for the analysis, such as drinking water, groundwater, or solid and chemical materials;

(b) reagents, supplies, materials, and equipment used;

(c) calibration procedures, including type and frequency;

(d) step-by-step analysis procedures sufficient to ensure reproducibility between analysts;

(e) verification of quality control;

(f) methods of calculation;

(g) detection and reporting limits;

(h) safety precautions;

(i) limitations of the procedure; and

(j) method reference.

SECTION 7: PROFICIENCY TESTING REQUIREMENTS

A. Use of approved providers.

(1) A laboratory must obtain proficiency testing samples from an approved provider meeting the requirements under Section 8.

B. Certification requirements.

(1) At the time a laboratory applies for certification, the laboratory must provide an appropriate PT sample result for all fields of testing for which it seeks to obtain or maintain certification by the certification officer.

(2) If the laboratory is certified by this program through equivalency, and maintains certification or accreditation by another certification or accreditation body, proficiency testing sample results for all analytes and programs must be sent only at the request of the certification officer.

C. Frequency.

(1) To be certified initially and to maintain certification, a laboratory must participate in at least one proficiency testing study per calendar year, where available, for each field of testing for which it seeks to obtain or maintain certification.

(2) To maintain certification, a laboratory must complete the annual study, and any corrective action study as required by Section 7(A)(9), by a study close date of October 31st of the calendar year.

D. Laboratory testing of PT study samples.

(1) A laboratory's management and all analysts must ensure that all PT samples are managed, analyzed, reported, and otherwise handled in the same manner as routine samples, including utilizing the same staff, procedures, equipment, facilities, and frequency of analysis as used for routine analysis for that field of testing.

(2) When analyzing a PT sample, a laboratory must employ the same calibration, quality control, acceptance criteria, sequence of analytical steps, number of replicates, and other standard operating procedures as used when analyzing routine samples. The laboratory must follow sample preparation steps for the PT sample as instructed by the approved PT provider for which the PT sample was obtained.

(3) Laboratories under the same ownership are not to participate in the same study by the same approved PT provider for same fields of testing, except when a study is not again available for that field of testing by any approved PT provider within the calendar year.

(4) A laboratory may not send any PT sample or any portion of a PT sample to another laboratory for any analysis.

E. Reporting results.

(1) A laboratory must ensure that results of all proficiency testing samples are received by the certification officer no later than 21 days after the study close.

(2) A laboratory must supply results by authorizing the approved PT provider to release all certification and corrective action results to the certification officer or by an electronic format specified by the certification officer.

(3) A laboratory may use on PT sample to analyze and report results for multiple methods by different technologies.

(4) For programs other than drinking water, a laboratory may use one PT 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 quality control requirements are fulfilled.

(5) A laboratory may not request from the PT provider a revised report when the revisions to the report are due to any error on the part of the laboratory.

F. Restrictions on exchanging information.

(1) A laboratory must comply with the following restrictions on the transfer of PT samples and communication of PT sample results, prior to the time that the results of the study are released;

(2) Laboratory management or staff must not communicate PT sample results with any individual at another laboratory, including intercompany communication; and

(3) Laboratory management or staff must not attempt to obtain the assigned value of any PT sample from an approved provider.

G. Evaluation of results.

(1) All study data released from the PT provider will be scored for compliance with these rules.

(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 certification, the certification officer shall deem unacceptable any reported results not meeting the criteria under this Sub-Section.

(4) Proficiency testing samples analyzed or reported after the study closing date are not valid for compliance with the proficiency testing requirements under this Section.

H. PT samples to obtain or maintain certification.

(1) A laboratory seeking to obtain certification must successfully complete at least one proficiency testing sample, except where

noted above, for each requested field of testing, no more than 6 months before the date the laboratory submits its application.

(2) When a laboratory is granted certification 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 PT sample results submitted to the PT provider.

(3) When a laboratory has attained certification and requests to add a field of testing to its scope of certification, 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.

I. Corrective actions for unacceptable results.

(1) When an approved provider notifies a laboratory that a PT sample result for any reported field of testing is unacceptable, the laboratory must perform the following tasks:

(a) within 30 days after receiving the notification of unacceptable results from the approved provider, submit written documentation to the certification officer that indicates corrective actions planned and implemented;

(b) within 30 days after receiving the notification of unacceptable results from the approved provider, submit written documentation to the certification officer, indicating the laboratory's request to purchase a PT sample from an approved provider; and

(c) within 21 days after the study close of the corrective action study, a laboratory must ensure that results of all proficiency testing samples are received by the certification officer. These results are to be submitted directly by the PT provider.

J. Availability of PT samples.

(1) The certification officer must determine that a PT sample for a particular field of testing is not available if:

(a) none of the approved providers list the PT sample through published catalogs, web sites, or other widely distributed literature; or

(b) none of the approved providers make the PT sample available in a form similar to routine samples. For example, PT 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 PT sample is not considered pretreatment.

(2) If the certification officer determines that no approved provider has PT samples for a field of testing, the certification officer must request written documentation from the laboratory of quality control data, meeting the minimum requirements under Sections 1 to 20 to evaluate the capability of the laboratory to perform testing.

K. Additional samples for compliance.

The certification officer may require certified laboratories to test additional PT samples at any time to determine compliance with Sections 1 to 19.

SECTION 8: APPROVED PROVIDERS OF PT SAMPLES

A. Provider availability.

The certification officer will make available a list of approved PT providers.

B. Criteria for approval.

The certification officer must approve a PT provider, if the PT provider:

(1) is compliant with a national or international standard and is a recognized PT provider acceptable for use by the EPA;

(2) defines the scope of each PT study;

(3) evaluates results from all proficiency testing studies using the acceptance criteria described in national or international standards or those specified by the certification officer;

(4) scores each result as either "acceptable," "not acceptable," "no evaluation," or "not reported";

(5) provides to participant laboratories reports that include:

(a) the provider name, in the header;

(b) the laboratory name, laboratory address (physical location), and 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;

(c) the study number and study type in the header;

(d) the shipment date and closing date of the study in the header;

(e) the date of any amended report, if applicable, in the header; and

(f) the following report information:

(i) analyte name for each analyte included in the sample;

(ii) method description;

(iii) laboratory value as reported;

(iv) assigned values and acceptance values reported to three significant figures, with the exception of tests requiring reports of presence or absence of the analyte;

(v) the acceptable/not acceptable status;

(vi) a "no evaluation" score for reported values containing alpha characters;

(vii) an indication of the amended results, for amended reports, including a brief description of the reason for the amendment; and

(viii) 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.

(6) sends reports of results no later than 21 calendar days after the study closing date;

(7) maintains the overall effectiveness of the provider's quality system to indicate that samples provided for testing are verifiable, homogeneous, and stable;

(8) makes available to the certification 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;

(9) makes available to the certification officer, upon request, a report listing the total number of participating laboratories and the number of laboratories scoring "not acceptable" for each analyte;

(10) supplies reports to the certification officer in an electronic format acceptable to the certification officer; and

(11) supplies the laboratory with a PT sample formulated from a lot that has not been previously sent to the laboratory. If the lot was previously used in a proficiency testing sample or its assigned values sent to any laboratory, the original PT sample tracking ID must be obliterated and the new sample tracking ID must be unique.

C. Questionable PT samples.

Upon notice from a laboratory and verification by the approved provider that a PT sample did not meet the requirements in this Section, the certification officer may:

(1) determine that the affected laboratory must analyze another PT sample for that field of testing; or

(2) review quality control data produced by the laboratory to determine compliance with Sections 1 to 19.

SECTION 9: QUALITY ASSURANCE MANUAL

A. A laboratory must possess and follow a written manual of quality assurance.

B. The manual may include several separate procedures or incorporate documents by reference.

C. The manual or its separate procedures must contain the following:

(1) 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;

(2) the laboratory's name;

(3) a revision number; and

(4) a date indicating when the revision became effective.

D. The manual must be reviewed periodically and updated when necessary. Documentation of the review process must include the scope of the review, identification of the reviewer, and the date the review was completed.

E. At the time of application, a laboratory must submit a copy of the manual, including documents incorporated by reference, if these documents are not generally available to the certification officer. Each subsequent revision of the manual or any of its separate procedures must be submitted to the certification officer in its entirety no later than 30 days after the effective date of the revision.

F. Unless a laboratory justifies why any paragraph is not applicable, the manual must incorporate the quality assurance practices described in Sections 6 through 19, including but not limited to policies and procedures used to:

(1) determine continual compliance with Sections 1 to 19;

(2) collect and transport samples, including containers and preservatives according to Section 10 (A);

(3) track samples from the time the laboratory receives them through the time the samples are disposed, including chain-of-custody procedures for samples requested to be processed for possible legal action, according to Section 10 (B) and (C);

(4) track the purity and acceptability of laboratory standards and reagents, including the laboratory's source of reagent grade water according to Section 11;

(5) maintain functional equipment, including routine maintenance performed and scheduled according to Section 12(B) and 13(B);

(6) determine data accuracy and precision for each certified method and analyte within each test category; for example, establishing control limits, preparing control charts, and performing calculations, according to the applicable provisions of Sections 17 to 19;

(7) validate data conversion, transcription, and reporting according to Section 14;

(8) accept or reject samples according to Section 10 (C);

(9) correct unacceptable proficiency testing results according to Section 7 (I), or perform quality-control checks according to the applicable provisions of Sections 17 to 19;

(10) record changes in training and education of laboratory personnel, including on-the-job training relevant to analysis and reporting of results according to Section 16;

(11) subcontract testing; and

(12) address client complaints.

G. A laboratory must routinely evaluate and document the effectiveness of its quality system to ensure that requirements for certification in Sections 1 to 19 are met.

SECTION 10: SAMPLE HANDLING, RECEIPT, AND ACCEPTANCE

A. Handling samples.

(1) A laboratory must have procedures for the 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.

(2) 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.

(3) Upon receipt of samples, the condition, including any abnormalities or departures from specified conditions as described in the laboratory's quality assurance 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, 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.

(4) When an insufficient amount of sample is received, a laboratory may choose to analyze a lesser amount of sample, if this action would not cause loss of sample integrity. Information concerning the insufficient amount of sample and any decision to analyze must be indicated with the test results.

(5) A laboratory must have procedures and appropriate facilities for avoiding deterioration, contamination, loss, or damage to the sample during storage, handling, preparation, and testing.

(6) 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 or portions concerned.

(7) 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 to prevent contamination between samples.

B. Sample receipt protocols.

The following paragraphs must be verified and the results documented:

(1) 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, unless the time between sample collection and sample acceptance does not permit these conditions;

(2) 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;

(3) 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:

(a) the client and project name, if applicable;

(b) the date and time of laboratory receipt;

(c) a unique laboratory-assigned identification code;

(d) the signature, initials, or equivalent electronic identification of the person making the entries;

(e) the field identification code, which identifies each container, linked to the laboratory-assigned identification code in the sample receipt log;

(f) the date and time of sample collection, linked to the sample container and to the date and time of receipt in the laboratory;

(g) the requested field of testing, linked to the laboratory-assigned identification code; and

(h) any comments resulting from inspection for sample rejection, linked to the laboratory-assigned identification code.

C. Sample acceptance policy.

(1) 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.

(2) A laboratory's sample acceptance policy must be made available to sample collection personnel and must address, at a minimum:

(a) documentation, including sample identification; location, date, and time of collection; collector's name; preservation type; sample type; and any special remarks concerning the sample;

(b) 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;

(c) use of appropriate sample containers;

(d) adherence to specified holding times;

(e) adequate sample volume to perform the requested tests and relevant quality control determinations; and

(f) procedures to be used when samples show signs of damage, contamination, inadequate preservation, or loss of integrity.

(3) If the sample does not meet the sample receipt acceptance criteria listed in the laboratory's quality assurance 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. 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, transmittal form, or the laboratory receipt documents in addition to appropriately qualifying the analysis data on the final report.

SECTION 11: STANDARDS, REAGENTS, AND BACTERIOLOGICAL MEDIA

A. 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.

B. A laboratory must retain records for all standards, reagents, and bacteriological media. The records must include:

(1) identification of the manufacturer or vendor;

(2) certificate of analysis or purity, if supplied;

(3) lot number;

(4) date of receipt or preparation;

(5) preparer’s initials, if applicable;

(6) method of preparation, when prepared in the laboratory;

(7) recommended storage conditions; and

(8) expiration date after which the material must not be used unless its reliability is verified by the laboratory.

C. All containers of reagents, standards, and bacteriological media must be assigned a unique identification linked to records containing the documentation required in this Section.

D. All reagents, standards, and bacteriological media must be laboratory verified before use.

(1) reagents are to be analyzed by use of a method blank before use;

(2) standards are to be verified against a lot number previously determined fit for use by the laboratory; and

(3) bacteriological media must be verified by positive and negative controls before use.

E. All water must be appropriate for use.

(1) Reagent water for chemical analysis:

(a) may be ASTM Type I, Type II or Type III based on the appropriateness for the analysis; or

(b) may be Standard Methods for the Examination of Water and Wastewater, American Water Works Association, 21st Edition, 2005 medium-quality or high-quality water based on the appropriateness for the analysis.

(2) Results of these analyses must meet the specifications of the required method and records of analyses must be maintained for five years.

(3) Reagent water used for bacteriological analysis must meet the following requirements:

Test	Monitoring Frequency	Maximum Acceptable Limit
Chemical Tests:		
Conductivity	Continuously or with each use	>0.5 megohms resistance or <2 umhos/cm at 25°C
pH	With each use	5.5-7.5 S.U.
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
Ammonia/organic nitrogen	Monthly	<0.10 mg/L
Total chlorine residual	Monthly or with each use	<0.01 mg/L
Bacteriological Tests:		
Heterotrophic plate count	Monthly	<1,000 CFU/mL

* Or more frequently if there is a problem.

(a) Results of these analyses must meet the specifications of the required method, and records of analyses must be maintained for five years.

SECTION 12: REQUIREMENTS FOR CALIBRATION OF SUPPORT EQUIPMENT

A. 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, 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.

B. Requirements.

(1) 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.

(2) 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.

(3) Records must be maintained for each major component of equipment, including software. The records must include the following:

(a) the identity of the component of equipment, including software;

(b) the manufacturer's name, type identification, and serial number or other unique identification;

(c) documentation that equipment complies with the manufacturer's specification;

(d) the current location within the laboratory;

(e) the manufacturer's instructions, if available;

(f) dates, results, and copies of reports and certificates of all calibrations, adjustments, and acceptance criteria and the due date of the next calibration;

(g) the maintenance plan and maintenance carried out to date, documentation on all routine and non-routine maintenance activities, and reference material verifications;

(h) any damage, malfunction, modification, or repair to the equipment;

(i) date received and date placed in service, or the date on which its first use or repair was recorded; and

(j) if available, condition when received, such as new, used, or reconditioned.

C. Frequency of calibration.

(1) All support equipment described in Section 12(A) 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, International System of Units.

(2) On each working day, balances, ovens, refrigerators, freezers, and water baths must be checked in the expected use range with standards from an accredited third party or a National Metrology Institute (e.g. NIST) which are traceable to the SI, International System of Units, when available.

(3) 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.

(4) 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.

(5) Volumetric equipment must be calibrated as follows:

(a) equipment with movable parts, such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes, must be calibrated quarterly;

(b) equipment such as filter funnels, bottles, non-Class A glassware, and other marked containers must be calibrated once per lot prior to first use; and

(c) 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.

(6) Dial thermometers must be checked on a quarterly basis. All measurements must be recorded. All thermometers must be calibrated on an annual basis against a thermometer from an accredited third party or a National Metrology Institute (e.g. NIST) which is traceable to the SI, International System of Units.

D. Acceptance Criteria.

(1) The results of calibrations must be within the specifications required of the application for which the equipment is used.

(2) 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.

(3) When the results of calibration of support equipment are not within the required specifications, the laboratory must remove the equipment from service until repaired.

(4) Records must be retained to document equipment performance.

SECTION 13: REQUIREMENTS FOR INSTRUMENT CALIBRATION

A. Scope.

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

B. Requirements.

(1) 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.

(2) 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.

(3) Records must be maintained for each major component of equipment, including software. The records must include the following:

(a) the identity of the component of equipment, including software;

(b) the manufacturer's name, type identification, and serial number or other unique identification;

(c) documentation that equipment complies with the manufacturer's specification;

(d) the current location within the laboratory;

(e) the manufacturer's instructions, if available;

(f) dates, results, and copies of reports and certificates of all calibrations, adjustments, and acceptance criteria and the due date of the next calibration;

(g) the maintenance plan and maintenance carried out to date, documentation on all routine and non-routine maintenance activities, and reference material verifications;

(h) any damage, malfunction, modification, or repair to the equipment;

(i) date received and date placed in service or the date on which its first use or repair was recorded; and

(j) if available, condition when received, such as new, used, or reconditioned.

C. Initial calibration.

(1) 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.

(2) Sample results must be quantitated from the most recent instrument calibration and may not be quantitated from any instrument calibration verification.

(3) All instrument calibrations must be verified with a standard obtained from a second source. Traceability must be to a national standard, when available.

(4) 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 standard operating procedure.

(5) 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.

(6) The following must occur for methods employing standardization with a zero point and a single point calibration standard:

(a) 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;

(b) a zero point and a single point calibration standard must be analyzed with each analytical batch;

(c) a standard corresponding to the reporting limit must be analyzed with each analytical batch and must meet established acceptance criteria as specified under Section 17(H);

(d) the linearity must be verified at a frequency established by the method or the manufacturer; and

(e) if allowed in the permit, program, or rule, a sample result within an analytical batch above its associated single point standard, then:

(i) 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;

(ii) the sample must be diluted such that the result falls below the single point calibration concentration; or

(iii) the data must be reported with an appropriate data qualifier or an explanation in the test report.

(7) 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.

(8) Calibration standards must include concentrations at or below the limit specified in the permit, program, or rule.

(9) If an approved method does not specify the number of calibration standards, the minimum number is three, one of which must be at the reporting limit, 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 document in its standard operating procedures how it determines the number of points required for the instrument calibration employed, and the acceptance criteria for calibration.

D. Calibration verification.

(1) 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.

(2) If calibration verification is not described in the approved method, a calibration verification must be repeated at the beginning of each batch, every tenth sample, excluding quality control samples, and end of each batch.

(3) 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.

(4) Criteria for the acceptance of calibration verifications must be established and evaluated using the same technique used to evaluate the instrument calibration.

(5) 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 with two consecutive successful calibration verifications or perform a new instrument calibration. If the laboratory has not demonstrated acceptable performance, sample analyses must not occur until a new

instrument calibration is established and verified. However, 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:

(a) when the acceptance criteria for the calibration verification are exceeded high (high bias) and all associated samples contain analytes below the reporting limit, then those sample results may be reported; and

(b) 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.

(6) 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.

(7) Test equipment, including both hardware and software, must be safeguarded from adjustments that would invalidate the test results.

SECTION 14: REPORTING

A. Analytical results must be reported accurately, legibly, objectively, and according to any specific instructions in the laboratory's standard operating procedure or quality assurance manual.

B. Laboratories that are operated by a facility with a sole function to provide data to the facility management for compliance purposes must have all applicable information specified in Sub-Section (C) below readily available for review by the state agency administering the permit, program, or rule. Formal reports detailing the information are not required if:

(1) the laboratory is itself responsible for preparing the regulatory reports; or

(2) the laboratory provides information to another individual within the organization for preparation of regulatory reports.

C. The test report must include the following:

(1) a title, such as "Test Report" or "Laboratory Results;"

(2) the name, address, and program designated identification number of the laboratory;

(3) the telephone number and name of a contact person;

(4) the information in Paragraph (2) above for the subcontracted laboratory and the phrase "This report contains data that were produced by a subcontracted laboratory certified for the fields of testing performed," if data were produced by a laboratory other than the laboratory reporting the results;

(5) 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;

(6) the name of the client and project name, if applicable;

(7) identification of the approved method used;

(8) a description of, the condition of, and unambiguous identification of the sample, including the client's identification code;

(9) date and time of sample collection;

(10) the date of receipt of the sample when critical to the validity and application of the results;

(11) time of sample preparation and time of sample analysis when critical to the validity of the sample result;

(12) date of analysis of the environmental test;

(13) the test results with, when appropriate, the units of measurement; whether data are calculated on a dry weight or an "as received" basis; the reporting or detection limit for each sample with appropriate units of measurement; and the counting error for each radiochemistry sample;

(14) the name, function, and signature or equivalent electronic identification of the person authorizing the test report and the date of issue;

(15) a statement to the effect that the results relate only to the samples;

(16) a statement that the report must not be reproduced, except in full, without the written approval of the laboratory;

(17) deviations from the standard operating procedure, such as failed quality control, 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; and

(18) test results that do not meet the requirement, or for which the laboratory is not certified, must be documented with the reason why the result does not meet the requirements and justification as to why the result was reported.

D. When the laboratory analyzes samples by a procedure other than as written, the laboratory records and reports must include:

(1) the sample identification traceable to client;

(2) the modification to the procedure;

(3) the reason for the modification; and

(4) the client's authorization or acknowledgment of the modification.

E. Electronic Reporting of Data to Regulatory Programs

(1) If electronic reporting is required by the Program or these Rules, sample results must be reported in the electronic format acceptable to the Program.

SECTION 15: DOCUMENTS AND RECORDS

A. Document Approval and Issue

(1) 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 issue. 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.

(2) The procedure(s) adopted must ensure that:

(a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

(b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

(c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; and

(d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

(3) Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority (ies).

B. Document Changes

(1) Changes to documents must be reviewed and approved by the same function that performed the original review, unless specifically designated otherwise. The designated personnel must have access to pertinent background information upon which to base their review and approval.

(2) Where practicable, the altered or new text must be identified in the document or the appropriate attachments.

(3) If the laboratory's documentation control system allows for the amendment of documents by hand, pending the re-issue of the documents, the procedures and authorities for such amendments must be defined. Amendments must be clearly marked, initialed and dated. A revised document must be formally reissued as soon as practicable.

(4) Procedures must be established to describe how changes in documents maintained in computerized systems are made and controlled.

(5) The record-keeping system must allow historical reconstruction of all laboratory activities that produced the analytical data. This requirement also applies to inter-laboratory transfers of samples or extracts and the data resulting from the analysis of the samples or extracts.

(6) Unless otherwise required by permit, program, or rule, all records must be retained for a minimum of five years after generation of the last entry in the record. All information required for the historical reconstruction of the data must be maintained by the laboratory. If records are retained only in electronic form, the hardware and software required for the retrieval of electronic records must be retained for the same time period as the records to be retrieved.

(7) The records must include the identity of personnel designated by the laboratory as responsible for the task performed, as described in the person's job description. The laboratory must retain records of the signatures and initials of designated personnel.

(8) All information relating to the laboratory facilities, equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, must be documented.

(9) The record-keeping system must allow the retrieval of all working files and archived records for inspection and verification purposes, including, but not limited to, the systematic naming of electronic files.

(10) 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.

(11) 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.

(12) 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.

(13) A laboratory must maintain a record-keeping system that includes procedures for protecting the integrity and security of the data.

(14) A laboratory must supply any documentation or data listed in Sections 1 to 19 within 7 calendar days of the date that the certification officer requests the information.

SECTION 16: ORGANIZATION AND PERSONNEL

A. Organization.

Each laboratory must:

(1) have managerial staff with the authority and resources needed to discharge their duties;

(2) have procedures in place to ensure that its personnel are free from any commercial, financial or other undue pressures, which adversely affect the quality of their work;

(3) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

(4) specify and document the responsibility, authority, and interrelationship of all personnel who manage, perform or verify work affecting the quality of calibrations and tests. Such documentation must include:

(a) job descriptions; and

(b) a description of the lines of responsibility in the laboratory so that proportioned and adequate supervision is ensured.

(5) maintain a current table of organization showing relationships between all job classifications and responsible lines of authority associated with the procurement, analysis, reporting, and disposal of samples.

B. Laboratory Technical Director.

Each laboratory must appoint a laboratory technical director. The laboratory technical director is responsible for the technical and scientific oversight of all laboratory activities. The laboratory technical director must certify that personnel with appropriate education and technical background perform all tests for which the laboratory is certified. Each laboratory will be certified only after presentation of documentation to the department regarding education and work experience.

(1) Qualifications for laboratory technical director of a chemistry laboratory is as follows:

(a) A bachelor's degree in chemistry, environmental science, biological sciences, physical sciences or engineering, with a minimum of two years of experience in environmental analysis.

(b) For laboratories engaged in inorganic analysis only, excluding metals analysis, the laboratory technical director may be a person with an associate's degree in chemistry or environmental science or equivalent with a minimum of 2 years of experience performing inorganic environmental analysis.

(2) Qualifications for laboratory technical director of a bacteriology laboratory is as follows:

(a) A bachelor's degree in microbiology, biology, chemistry, or environmental science, with a minimum of 2 years of experience in environmental analysis.

(b) For laboratories engaged in microbiological analysis limited to coliform and heterotrophic plate count testing, the laboratory technical director may be a person with an associate degree in science or the equivalent, with at least 4 semester credit hours in microbiology and 1 year of experience in environmental analysis.

(3) Qualifications for laboratory technical director of a radiochemistry laboratory is as follows:

(a) A bachelor's degree in chemistry or physics with two years of experience, 1 year in the supervision of environmental radiochemistry;

(4) A valid treatment plant operator's certificate/license can 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/license must be at least the classification for the drinking water or wastewater treatment facility where the laboratory is located.

(5) When the laboratory engages in more than one analytical category (chemistry, bacteriology, and 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 certified laboratory without authorization from the Department. Circumstances to be considered for authorization include~~s~~, 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.

C. Quality Assurance Officer (QAO).

Each laboratory must appoint a QAO. The QAO is the person responsible for the laboratory's quality assurance program and its implementation.

(1) The QAO must review laboratory quality control data, conduct annual internal laboratory audits, and notify 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. The QAO must have documented training and/or experience in quality assurance/quality control procedures and must have knowledge of the approved analytical methods and quality system requirements. The QAO must maintain the laboratory's quality assurance documents up to date.

(2) The QAO duties and responsibilities may also be carried out by the laboratory technical director when staffing is limited.

(3) The QAO must have direct access to laboratory management.

(4) The QAO should (when possible) have functions independent from laboratory operations for which they have quality assurance oversight.

D. Responsibilities of laboratory management.

The laboratory management must have the authority and resources needed to discharge the following duties:

(1) The laboratory management must be responsible for supervising all personnel employed by the laboratory, all analytical and operational activities, and for documenting the quality of all data reported.

(2) Laboratory management must define the minimum level of qualifications, experience, and basic laboratory skills necessary for all positions in the laboratory.

(3) The laboratory management must ensure all technical laboratory staff has demonstrated capability in the activities for which they are responsible.

(4) The laboratory management must ensure that the training of the laboratory personnel is kept up to date (on-going) by the following:

(a) documentation that the employee has read, understands and uses the latest version of the laboratory's quality documents;

(b) training documentation on equipment, techniques, or procedures;

(c) training in ethical and legal responsibilities;

(d) documentation of analyst(s) continued performance at least once per year by one of the following:

(i) acceptable performance of a blind sample;

(ii) another demonstration of capability;

(iii) successful analysis of a blind performance sample on a similar method using the same technology;

(iv) analysis of at least 4 consecutive laboratory control samples with acceptable levels of precision and accuracy;

(v) or, 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.

(5) The laboratory management must ensure all sample acceptance criteria are verified and samples are logged into the sample tracking system and properly labeled and stored.

(6) The laboratory management must nominate 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 department in writing when the absence of the laboratory technical director exceeds 65 consecutive days.

(7) The laboratory management must develop a proactive program for prevention and detection of improper, unethical, or illegal actions.

(8) The laboratory management must ensure the competence of all who operate specific equipment, perform environmental tests, evaluate results, and sign test reports. When using staff who are undergoing training, appropriate supervision must be provided. Personnel performing specific tasks must be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

(9) The laboratory must have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

(10) The laboratory management must ensure that all personnel are responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test

methods, quality assurance/quality control procedures and records management.

(11) The management of the laboratory must formulate the goals with respect to the education, training and 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.

(12) The laboratory must 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.

(13) The laboratory must maintain current job descriptions for all personnel who manage, perform, or verify work affecting the quality of the environmental tests.

(14) The management must authorize specific personnel to perform particular types of sampling, environmental testing, to issue test reports, to give opinions and interpretations and to operate particular types of equipment. The laboratory must maintain records of the relevant authorization(s), competence, 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.

(15) Records of relevant qualifications, training, skills and experience of the technical personnel must be maintained by the laboratory, including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined for chemical testing.

(16) Data integrity training must be provided as a formal part of new employee orientation and must also be provided on an annual basis for all current employees. Topics covered must be documented in writing and provided to all trainees. Key topics covered during training must include organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping.

(a) Training must include discussion regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring and data integrity procedure documentation.

(b) Employees are required to understand that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences, including immediate termination, debarment or civil/criminal prosecution.

(c) The initial data integrity training and the annual refresher training must have a signature attendance sheet or other form of documentation that demonstrates that all staff have participated and understand their obligations related to data integrity.

(d) Senior managers acknowledge their support of these procedures by upholding the spirit and intent of the organization's data integrity procedures and effectively implementing the specific requirements of the procedures.

(e) Specific examples of breaches of ethical behavior should be discussed, including improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

(f) Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. The data integrity procedures may also include written ethics agreements, examples of improper practices, and examples of improper chromatographic manipulations, requirements for external ethics program training, and any external resources available to employees.

(17) The laboratory must maintain initials and signatures of anyone analyzing or reviewing data so that the records can be traced back to an individual approving the data.

SECTION 17: QUALITY CONTROL CRITERIA FOR CHEMISTRY EXCEPT RADIOCHEMISTRY

A. Scope.

(1) This Section applies to laboratories performing testing under the inorganic chemistry, metals, volatile organic compounds, and other organic compounds test categories unless otherwise indicated.

(2) 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 manual must be followed.

(3) 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.

B. Method blanks.

(1) The method blank must be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure.

(2) 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:

(a) the concentration of a targeted 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

(b) the blank contamination otherwise affects the sample results according to test method requirements or the individual project data quality objectives.

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 reported with appropriate data qualifying codes.

(3) The method blank must be analyzed at a minimum of 1 per batch.

C. Laboratory control sample.

(1) A laboratory control sample (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 reported with appropriate data qualifying codes.

(2) A laboratory control sample must be analyzed at a minimum of one per preparation batch, except:

(a) analytes for which no spiking solutions are available; or

(b) in instances for which no separate preparation method is used, such as volatiles in water, the batch must be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

(3) 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:

(a) 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; and

(b) 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:

(i) for methods that include 1 to 10 analytes, spike all components;

(ii) for methods that include 11 to 20 analytes, spike at least ten components or 80 percent of the analytes, whichever is greater; and

(iii) for methods with more than 20 analytes, spike at least 16 components.

(4) The results of the analytes included in the LCS are calculated in percent recovery or 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. 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.

(5) A laboratory control sample 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 reported with appropriate data qualifying codes.

D. Matrix spike and matrix spike duplicates.

(1) 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. Where no requirement is stated, the laboratory must prepare and analyze at least one matrix spike and one matrix spike duplicate with each batch. The matrix spikes must be prepared from samples contained in the batch.

(2) For a matrix spike, the components to be spiked must be as specified by the approved method or permit, program, or rule requirement. In the absence of specified spiking components, the laboratory may follow client instructions and then must document its criteria for quality control. In the absence of client instruction, the laboratory must spike as follows:

(a) 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; and

(b) 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:

(i) for methods that include 1 to 10 analytes, spike all components;

(ii) for methods that include 11 to 20 analytes, spike at least 10, or 80 percent, of the analytes, whichever is greater; and

(iii) for methods with more than 20 analytes, spike at least 16 components.

(3) The results from matrix spikes and matrix spike duplicates must be expressed as percent recovery, relative percent difference, absolute difference, or other measure. Results of matrix spikes and matrix spike duplicates 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.

E. Surrogate spikes.

(1) This sub-Section applies to the analysis of organic compounds.

(2) Except when the matrix precludes their use, or when not available, surrogate compounds must be added to all samples, standards, and blanks for all appropriate test methods before sample preparation or extraction.

(3) Surrogate compounds must be chosen to represent the various chemistries of the analytes in the method. When specified, the surrogates mandated in the method must be used.

(4) The results from surrogate spikes must be expressed as percent recovery. Results of surrogate spikes 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 method used to establish the limits or utilize client-specified assessment criteria within a permit, program, or rule requirement.

F. Internal standards.

(1) 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 quality control samples before analysis.

(2) 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.

(3) A laboratory must monitor and document the results from analysis of internal standards.

(4) 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.

G. Detection limits.

(1) A laboratory must utilize a test method that provides a detection limit that is appropriate and relevant for the intended use of the data. The detection limit, such as method detection limit (MDL), must be determined by the protocol in the approved method or applicable regulation. If the protocol for determining detection limits is not specified, the selection of the procedure must reflect instrument limitations and the intended application of the test method.

(2) The certification officer must not require a detection limit study for any component for which spiking solutions or quality control samples are not available.

(3) A laboratory must initially determine the detection limit for the compounds of interest in each test method in a matrix in which there are not target analytes or interferences at a concentration that would impact the results, or the laboratory must determine the detection limit in the matrix of interest.

(4) A laboratory must determine the detection limits each time there is a change in the test method that may affect how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

(5) A laboratory must include all sample processing steps of the analytical method in the determination of the detection limit.

(6) A laboratory must document all procedures used to determine the detection limit, including the matrix type of the sample and all supporting data.

H. Reporting limits.

(1) A laboratory must document all procedures used to determine the reporting limit.

(2) A laboratory must establish reporting limits for each field of testing. The reporting limits must be greater than detection limits.

(3) A laboratory must verify the reporting limit each time the instrument is calibrated, or monthly at a minimum. The laboratory must analyze a verification standard with a concentration at or below the reporting limit. The percent recovery of the standard must fall within plus or minus 40 percent of the true value.

(4) If the percent recovery of the reporting limit verification standard is outside the acceptance criteria, a laboratory must elevate the reporting limit for the associated samples to the concentration of the lowest point, above the zero blank, that meets the acceptance criteria defined in Section 17 (C). The laboratory must report all samples analyzed after the failed reporting limit check using the elevated reporting limit until a new calibration curve and reporting limit verification standard meet the acceptance criteria.

I. Selectivity.

(1) This sub-Section applies to volatile organic compounds and other organic compounds.

(2) Absolute retention time and relative retention time aid in identifying components in chromatographic analyses and evaluating the effectiveness of a chromatographic medium to separate constituents. A laboratory must develop and document acceptance criteria for retention time windows if the acceptance criteria are not specified in the approved method.

(3) A confirmation must be performed to verify the compound identification when positive results are detected on drinking water. 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 Fourier transform infrared spectrometer (FTIR). All confirmations must be documented.

(4) A confirmation must be performed to verify the compound identification when positive results are detected on 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 Fourier transform infrared spectrometer. A confirmation is not required on positive results for samples analyzed for diesel range organics and gasoline range organics under the underground storage tank program. All confirmations must be documented.

(5) 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.

J. Manual integrations.

If the integrations are not calculated 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.

K. Constant and consistent test conditions.

(1) A laboratory must ensure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

(2) 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 standard operating procedures manual.

SECTION 18: QUALITY CONTROL CRITERIA FOR BACTERIOLOGY

A. 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 quality control requirements specified by the laboratory's standard operating procedures manual 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.

B. Sterility checks and blanks.

(1) A blank must be analyzed for each lot of pre-prepared, ready-to-use media, including chromofluorogenic reagent, and for each lot of media prepared in the laboratory. The analysis must be done before first use of each lot of media.

(2) For filtration technique, a laboratory must conduct one beginning and one ending sterility check for each laboratory-sterilized 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. For pre-sterilized single-use funnels purchased, a sterility check must be performed on 1 funnel per lot. The filtration series is considered ended when more than 30 minutes elapse between successive filtrations. During a filtration series, filter funnels must be rinsed with three 20 to 30 milliliter portions of sterile rinse water after each sample filtration. In addition, laboratories must insert a sterility blank after every 10 samples per filtration unit or sanitize filtration units by ultraviolet light after each sample filtration.

(3) For pour-plate technique, sterility blanks 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. The analysis must be done before first use of each lot of media.

(4) Sterility checks on sample containers 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. The analysis must be done before first use.

(5) 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.

(6) At least one filter from each new lot of membrane filters must be checked for sterility using nonselective growth media. The analysis must be done before first use.

C. 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.

D. 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, (i.e. 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.

E. Test variability.

For test methods that specify colony counts, such as methods using membrane filters or plated media, duplicate counts must be performed 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 5-percent difference between the counts.

F. 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.

G. Test performance.

To ensure that analytical results are accurate, a laboratory must confirm a target organism specified in the method quarterly.

H. Quality of standards, reagents, and media.

(1) 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 standard operating procedures manual or quality assurance manual.

(2) 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 quality assurance manual.

(3) Distilled water, deionized water, 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 11 (E)(2).

(4) 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 date of preparation, preparer's initials, type and amount of media prepared, manufacturer and lot number, final pH of the media, and expiration date.

(5) Documentation for media purchased pre-prepared and ready-to-use must include the manufacturer, lot number, type and amount of media received, date of receipt, expiration date of the media, and the verification pH of the liquid.

I. Selectivity.

(1) To ensure identity and traceability, reference cultures used for positive and negative controls must be obtained from a recognized national organization.

(2) Microorganisms may be single-use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.

(3) 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.

(4) Working stocks must not be cultured sequentially more than five times and must not be sub-cultured to replace reference stocks.

J. Temperature measuring devices.

(1) 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.

(2) 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 using 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.

K. Autoclaves.

(1) The performance of each autoclave must be evaluated initially by establishing its functional properties and performance, for example 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.

(2) 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.

(3) 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.

(4) Autoclave maintenance, either internally or by service contract, must be performed annually and must include a pressure check and calibration of the temperature device. Records of the maintenance must be maintained in equipment logs.

(5) The autoclave's mechanical timing device must be checked quarterly against a stopwatch and the actual time elapsed must be documented.

L. Ultraviolet instruments.

(1) 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.

(2) 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.

M. Incubators, water baths, ovens.

(1) 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. Temperature of incubators and water baths must be documented twice daily, at least four hours apart, on each day of use.

(2) 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.

N. Labware; glassware and plasticware.

(1) A laboratory must have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use must be used.

(2) Glassware must be made of borosilicate or other noncorrosive material, free of chips and cracks, and have readable measurement marks.

(3) 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.

(4) At least one piece of washed labware must be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with a suitable pH indicator such as bromothymol blue. Records of tests must be maintained.

SECTION 19: QUALITY CONTROL CRITERIA FOR RADIOCHEMISTRY

A. Scope.

(1) This Section applies to laboratories performing radiochemistry testing on environmental samples. All requirements in this Section must be incorporated into the laboratory's standard operating procedures unless otherwise directed by the approved method.

(2) The quality control requirements specified by the laboratory's standard operating procedures manual 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.

B. Method blanks.

(1) 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 manual.

(2) 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.

(3) In the case of gamma spectrometry, where the sample matrix is simply aliquoted into a calibrated counting geometry, the method blank must be of similar counting geometry that is empty or filled to similar volume with ASTM Type II water to partially simulate gamma attenuation due to the sample matrix.

(4) A laboratory must not subtract results of method blank analysis from the sample results in the associated batch, unless permitted by the approved method. This requirement does not preclude the application of any correction factor, such as instrument background, analyte presence in tracer, reagent impurities, peak overlap, or calibration blank, to all analyzed samples, both program- or project-submitted and internal quality control samples. However, the correction factors must not depend on the required method blank result in the associated analytical batch.

(5) The method blank sample must be prepared with similar aliquot size to that of the routine samples for analysis whenever possible.

C. Laboratory control sample.

(1) Laboratory control samples must be performed at a frequency of one per batch. The results of the analysis must be one of the quality control measures to be used to assess the batch.

(2) The laboratory control sample result must be assessed against the specific acceptance criteria specified in the laboratory standard operating procedures manual. When the specified laboratory control sample acceptance criteria are not met, the specified corrective action and contingencies must be followed.

(3) The occurrence of a failed laboratory control sample acceptance criterion and the actions taken must be noted in the laboratory report.

(4) The activity of the laboratory control sample must:

(a) be 2 to 10 times the detection limit; or

(b) at a level comparable to that of routine samples, if the sample activities are expected to exceed ten times the detection limit.

(5) The laboratory standards used to prepare the laboratory control sample must be from a source independent of the laboratory standards used for instrument calibration, if available.

(6) The laboratory control sample 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 need be included in the laboratory control sample. When more than one analyte isotope is added to the laboratory control sample, each isotope must be assessed against the specified acceptance criteria.

D. Matrix spikes.

(1) 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.

(2) The exceptions are gross alpha, gross beta, and tritium, which require matrix spikes for aqueous samples. The results of the analysis must be one of the quality control measures to be used to assess the sample results acceptance. The matrix spike result must be assessed against the specific acceptance criteria specified in the laboratory standard operating procedures manual.

(3) When the specified matrix spike acceptance criterion is not met, the corrective actions specified in the laboratory's standard operating procedures 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 be noted in the laboratory report.

(4) The activity of the analytes in the matrix spike must be greater than ten times the detection limit.

(5) 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.

(6) 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 need 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.

(7) 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.

(8) The matrix spike sample must be prepared with similar aliquot size to that of the routine samples of analyses.

E. Tracer.

(1) For those approved methods that allow or require the use of a tracer, (i.e. 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 quality control measures used to assess the associated sample result acceptance.

(2) The tracer recovery must be assessed against the specific acceptance criteria specified in the laboratory standard operating procedures manual. When the specified tracer recovery acceptance criteria are not met, corrective actions specified in the laboratory's standard operating procedures must be followed. The occurrence of a failed tracer recovery and the corrective actions taken must be noted in the laboratory report.

F. Carrier.

(1) For those approved methods that allow or require the use of a carrier, each sample must have an associated carrier recovery calculated and reported. The carrier recovery for each sample must be one of the quality control measures used to assess the associated sample result acceptance.

(2) The carrier recovery must be assessed against the specific acceptance criteria specified in the laboratory standard operating procedures manual. When the specified carrier recovery acceptance criteria are not met, the corrective actions specified in the laboratory's quality assurance

manual must be followed. The occurrence of failed carrier recovery acceptance criteria and the actions taken must be noted in the laboratory report.

G. Analytical variability; reproducibility for radiochemistry testing.

(1) A laboratory must analyze replicate samples at least once per batch when there is sufficient sample to do so. The results of the analysis must be one of the quality control measures used to assess sample results acceptance. The replicate result must be assessed against the specific acceptance criteria specified in the laboratory's standard operating procedures manual.

(2) When the specified replicate acceptance criteria are not met, the corrective actions specified in the laboratory's standard operating procedures manual must be followed. The occurrence of failed replicate acceptance criteria and the actions taken must be noted in the laboratory test results.

(3) If sample concentrations are expected to contain analytes of interest below three times the detection limit, a laboratory may substitute replicate laboratory control samples or replicate matrix spiked samples for replicate samples in Section (G) (1) above. The replicate result must be assessed against the specific acceptance criteria specified in the laboratory's standard operating procedures manual. When the specified replicate acceptance criteria are not met, the corrective actions specified in the laboratory's standard operating procedures manual must be followed. The occurrence of failed replicate acceptance criteria and the actions taken must be noted in the laboratory test results.

H. Instrument calibration.

(1) Radiochemistry analytical instruments must be calibrated prior to first use in sample analysis.

(2) Calibration must be verified when:

(a) the instrument is serviced;

(b) the instrument is moved; and

(c) the instrument settings have been changed.

(3) The standards used for calibration must have the same general characteristics, (geometry, homogeneity, and density), as the associated samples.

(4) The calibration must be described in the laboratory's standard operating procedures manual.

I. Continuing calibration verification.

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) For gas-proportional and scintillation counters, the calibration verification check for counting efficiency must be performed each day of use.

J. Background radiation measurement.

(1) 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.

(2) Background radiation measurement values must be subtracted from the total measured activity in the determination of the sample activity.

(3) For gamma spectroscopy systems, background radiation measurements must be performed at least monthly.

(4) For alpha spectroscopy systems, background radiation measurements must be performed at least monthly.

(5) For gas-proportional counters, background radiation measurements must be performed at least weekly.

(6) For scintillation counters, background radiation measurements must be performed each day of use.

K. Instrument contamination monitoring.

(1) 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.

L. Detection Limits.

(1) Detection limits must be determined before sample analysis and must be redetermined each time there is a significant change in the test method or instrument type.

(2) The procedures employed must be documented and consistent with published references.

M. Quality of standards and reagents.

(1) The quality assurance manual must describe the procurement, use, and storage of radioisotope standards.

(2) 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.

(3) 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.

(4) 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.

(5) All reagents used must be analytical reagent grade or better.

SECTION 20: WASTE MANAGEMENT

A. All waste must be managed according to the following requirements:

(1) Solid waste, as defined in 38 M.R.S.A. §1303-C(29), must be managed in accordance with the Maine Department of Environmental Protection Solid Waste Management Rules, 06-096 CMR 400-409, 420, 424 and 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 400, et seq. of the Maine Department of Environmental Protection Solid Waste Management Rules. Incinerator ash which meets hazardous waste characteristics, as defined in 06-096 CMR 850 of the Maine Department of Environmental Protection Hazardous Waste Management Rules, must be managed as a hazardous waste.

(3) Hazardous wastes, as defined by 38 M.R.S.A. §1303-C(15), (with the exception of infectious and pathogenic wastes), and in 06-096 CMR 850 (Maine Identification of Hazardous Waste Rules), 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 850, 851, 853 – 857).

i. Some cytotoxic (antineoplastic) drugs are identified as hazardous waste in Maine's Identification of Hazardous Waste Rules, 06-096 CMR 850.

(4) Radioactive material, as defined by the Radiation Protection Act at 22 M.R.S.A. §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 220).

(5) Biomedical waste, as defined by 38 M.R.S.A. § 1303-C (1-A), must be managed in accordance with the State of Maine Biomedical Waste Management Rules at 06-096 CMR 900.

(6) If there is a conflict between another applicable rule or regulation and these Rules, the more restrictive requirement applies.

SECTION 21: FEES

A. The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation, or addition of fields of accreditation.

(1) The total annual certification fee includes the base fee, the test methods fees, and, when applicable, the on-site inspection fee.

(2) The annual certification fees include the following:

(a) base certification fee, $1,250; and

(b) test category certification fees:

TEST METHOD CATEGORIES	CERTIFICATION FEE
Bacteriology Methods	$50 per method
Inorganic Chemistry Methods	$50 per method
Metals Methods	$100 per method
Organic Compounds Methods	$125 per method
Radiochemistry Methods	$125 per method

(3) The total biennial certification fee includes the base fee, the sample preparation technique fees, the test method fees, and, when applicable, the on-site inspection fee.

(4) The biennial certification fees include the following:

a) base certification fee of $1,250; and

b) test category certification fees

TEST METHOD CATEGORIES	CERTIFICATION FEE
Bacteriology Methods	$100 per method
Inorganic Chemistry Methods	$100 per method
Metals Methods	$200 per method
Organic Compounds Methods	$250 per method
Radiochemistry Methods	$250 per method

(5) The limited laboratory certification fee is $650 for biennial certification.

(6) The environmental lead program fee is $600 for biennial certification.

(7) The Department will assess a fee for an on-site inspection to out-of-state laboratories. This fee will be based on the established hourly rate of the laboratory certification officer inclusive of preparation time, travel time and inspection time, as well as the travel expenses (travel, meals, lodging and other associated travel expenses) incurred. The minimum fee assessed will be $1,500 and the maximum fee will be $3,750.

(8) A change fee will be assessed if a laboratory requests additional methods at any time other than when applying for or renewing its certification.

(9) Refunds or credits will not be made for analytes or methods requested, but not approved.

(10) Certification of a laboratory will not be awarded until all fees are paid.

STATUTORY AUTHORITY: 22 MRSA Chapter 157-A Section 567

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NON-SUBSTANTIVE CORRECTIONS:
December 12, 1997 - removal of extra period in Section F (1)(a)(2) and extra underline in TEMP INTERVAL heading under G(1)(d), Temperature monitoring; removed strikeout characters in G(1)(c), Color standards; changed “weight” to “weights” in G(1)(e), Balance, general purpose; inserted missing period at the end of G(3)(b).

AMENDED:
February 13, 2000

NON-SUBSTANTIVE CORRECTIONS:
March 15, 2000 - missing words restored in Section G (2)(b)(1)