310 CMR 42.00: CERTIFICATION AND OPERATION OF ENVIRONMENTAL ANALYSIS LABORATORIES

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42.01: Purpose and Applicability

(1) 310 CMR 42.00 establishes a program for Department certification of laboratories to conduct analytical measurements for purposes of determining chemical, radiochemical, and microbiological parameters in environmental samples.

(2) A laboratory performing analyses shall be subject to the requirements of 310 CMR 42.00 for those analyses for which it holds Department certification and that it identifies in any issued report as having been conducted in accordance with the Department's certification standards. An analysis for which a laboratory holds Department certification is deemed to be identified in a report as having been conducted in accordance with the Department's certification standards unless the report expressly states that the analysis was not conducted in accordance with the Department's certification standards.

42.02: Authority

310 CMR 42.00 is promulgated by the Commissioner of the Department of Environmental Protection pursuant to authority conferred by M.G.L. c. 21, §§ 26 through 53, M.G.L. c. 21A, § 2(28), M.G.L. c. 21C, § 4, M.G.L. c. 21E, § 3, M.G.L. c. 111, §§ 142A through 142E, 150A and 160.

42.03: Definitions

As used in 310 CMR 42.00, the following terms shall have the meanings stated:

Ambient Water refers to any fresh, marine, or estuarine surface water used for recreation, propagation of fish, shellfish, or wildlife, agriculture, industry, or navigation.

Analyst means a chemist, microbiologist or technician who actually performs a test.

Analytical Batch means a group of up to 20 samples to be analyzed for chemical or radiochemical parameters, or a group of up to ten samples to be analyzed for microbiological parameters, that behave similarly with respect to the testing procedures being employed and that are processed as a unit. For quality control purposes, if the number of samples in a group to be analyzed for chemical or radiochemical parameters is greater than 20, then each group of 20 or fewer samples will be handled as a separate batch. If the number of

samples in a group to be analyzed for microbiology parameters is greater than ten, then each group of ten or fewer samples will be handled as a separate batch.

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Category means an analyte or group of analytes for which certification is offered.

Certification Officer means the person or persons designated by the Department to inspect and evaluate environmental laboratories for compliance with the criteria set forth in 310 CMR 42.00.

Certified Thermometer means a thermometer that has documentation showing that it has been compared against a National Institute of Standards and Technology thermometer for the temperature range in which it is to be used.

Check Standard means a solution of one or more analytes that is used to check laboratory performance. It is prepared from a source of reagents different from those used to prepare the stock standards and primary dilution standard solutions.

Department means the Department of Environmental Protection of the Commonwealth of Massachusetts.

Discipline means a scientific area of expertise for testing (*e.g.*, microbiology, chemistry, radiochemistry).

EPA means the United States Environmental Protection Agency.

Field Reagent Blank means reagent water or analyte-free solvent placed in a sample container in the laboratory, taken to the sampling site and returned to the laboratory unopened. It is treated as a sample in all respects, including exposure to sampling site conditions, storage, preservation and all analytical procedures.

Holding time means the maximum amount of time a sample may be held from collection to analysis or, where applicable, from collection to extraction (sample holding time) or the maximum amount of time a sample extract may be held from extraction to analysis (sample extract holding time).

Instrumentation Analyst means an analyst who operates an instrument including, but not limited to, an atomic absorption spectrophotometer, ion chromatograph (IC), gas chromatograph, liquid chromatograph (LC), gas chromatograph/mass spectrometer (GC/MS), inductively coupled plasma-atomic emission spectrometer (ICP), ICP/MS, or LC/MS.

Laboratory Fortified Blank means an aliquot of reagent water to which known quantities of the method analytes are added in the laboratory. The laboratory fortified blank is analyzed exactly as a sample. Its purpose is to determine whether the methodology is in control, and whether the laboratory is capable of making accurate measurements at the required method detection limit.

Laboratory Fortified Sample Matrix means an aliquot of an environmental sample to which known quantities of the method analytes are added in the laboratory. The laboratory fortified sample matrix is analyzed exactly as a sample. Its purpose is to determine whether the sample matrix contributes bias to the analytical results. The background concentrations of the analytes in the sample matrix must be determined in a separate aliquot and the measured values in the laboratory fortified sample matrix corrected by background concentrations.

Laboratory Reagent Blank means an aliquot of reagent water that is treated exactly as a sample including exposure to all glassware, equipment, solvents, reagents, internal standards, and surrogates that are used with other samples. The laboratory reagent blank is used to determine if method analytes or other interferences are present in the laboratory environment, the reagents, or the apparatus.

Matrix means the substrate of a test sample (*e.g.*, potable water, non-potable water).

Maximum Contaminant Level means the maximum permissible level of a contaminant in water that is delivered to any user of a public water system.

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Maximum Residual Disinfectant Level means a level of a disinfectant added for water treatment that may not be exceeded at the consumer's tap without an unacceptable possibility of adverse health effects pursuant to the Department's Drinking Water Program.

Method Detection Limit means the minimum concentration of substance that can be identified, measured, and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. The method detection limit refers to samples that have been processed through all the steps of an established analytical procedure.

Minimum Reporting Level means the minimum concentration that can be reported as a quantitated value for a target analyte in a sample following analysis.

Person means an individual, corporation, company, association, trust, partnership, the Commonwealth, a municipality, district or other subdivision or body politic of the Commonwealth, and any department, agency or instrumentality of the United States.

Primary Dilution Standard Solution means a solution of several analytes prepared in the laboratory from stock standard solutions and diluted as needed to prepare calibration solutions and other needed analyte solutions.

Proficiency Test (PT) Samples mean samples that contain known amounts of analytes and are obtained from the Department or from a third party acceptable to the Department. The composition of the sample is unknown to the laboratory performing the analysis. The PT sample is used to evaluate the ability of the laboratory and of the individual analyst to produce accurate and precise results within specified acceptance criteria. PT samples may be single blind (*i.e.*, the laboratory/analyst knows that the sample is a PT sample), or double blind (*i.e.*, the PT sample appears to be a routine sample so the laboratory/analyst is unaware that the sample is a PT sample).

Proficiency Testing means a program in which proficiency test samples are used to evaluate the analytical performance of a laboratory.Signature means any mark, such as initials, printed or handwritten name, or equivalent electronic documentation made by a person to signify his or her responsibility for the performance of an action such as a measurement or the authentication of documentation produced internal to the laboratory analytical process. The signature must represent a unique person who can be identified with a specific action in the laboratory.

Source Water means untreated water from streams, rivers, lakes, or underground aquifers that is used to supply private wells and public drinking water.

Stock Standard Solution means a concentrated solution containing a single certified standard that is a method analyte, or a concentrated solution of a single analyte prepared in the laboratory with an assayed reference compound.

Surrogate Analyte means a pure analyte(s), which is extremely unlikely to be found in any sample, and which is added to a sample aliquot in known amount(s) before extraction and is measured with the same procedures used to measure other sample components.

Valid Data means analytical data that are:

(a) technically sound (*i.e.*, generated in accordance with good laboratory practices and meeting the quality control criteria of approved analytical methods) and
(b) legally defensible (*i.e.*, the laboratory's compliance with quality control criteria designed to assure the accuracy of the analysis is completely and accurately documented).

42.04: Application Procedure

(1) Filing. An application for certification in one or more matrices, disciplines, or categories shall be submitted on forms provided by the Department.

(2) Inspection. The applicant must submit to an inspection of the laboratory to enable the Department to determine whether the laboratory satisfies the Department's standards for certification.

(3) Proficiency Testing. The applicant must satisfactorily analyze samples from a proficiency-testing program approved by the Department for the matrices, disciplines, and categories for which certification is sought.

42.05: Certification Matrices, Disciplines and Categories

Qualified applicants may be certified in one or more of the following matrices, disciplines and categories:

(1) Potable Water. Certification in this matrix applies to analyses of drinking water supplies for purposes of, but not limited to, determining compliance with 310 CMR 22.00: *Drinking Water Regulations*. Certification in this matrix may be obtained in any or all of the following disciplines and categories:

(a) Microbiology. Certification in this discipline may be obtained in any or all of the following categories:

1. Total Coliform (Water Treatment and Distribution);
2. *Escherichia coli* (Water Treatment and Distribution);
3. Heterotrophic Plate Count;
4. Total Coliform in Source Water;
5. Fecal Coliform in Source Water;
6. *Escherichia coli* in Source Water;
7. Enterococci in Source Water.

(b) Chemistry. Certification in this discipline may be obtained in any or all of the following categories:

1. Metals:
   a. Antimony;
   b. Arsenic;
   c. Barium;
   d. Beryllium;
   e. Cadmium;
   f. Chromium;
   g. Copper;
   h. Lead;
   i. Mercury;
   j. Nickel;
   k. Selenium;
   l. Silver;
   m. Thallium;
   n. Aluminum;
   o. Iron;
   p. Manganese;
   q. Zinc;
2. Nitrate-N;
3. Nitrite-N;
4. Fluoride;
5. Sodium;
6. Sulfate;
7. Cyanide;
8. Turbidity;
9. Residual Free Chlorine;
10. Calcium;
11. Total Alkalinity;

12. Total Dissolved Solids;
13. pH;
14. Polychlorinated biphenyls;

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15. Herbicides:
    a. 2,4-D;
    b. 2,4,5-TP;
    c. Dalapon;
    d. Dinoseb;
    e. Pentachlorophenol;
    f. Picloram;
16. Pesticides:
    a. Alachlor;
    b. Atrazine;
    c. Chlordane;
    d. Endrin;
    e. Heptachlor;
    f. Heptachlor epoxide;
    g. Hexachlorobenzene;
    h. Hexachlorocyclopentadiene;
    i. Lindane;
    j. Methoxychlor;
    k. Simazine;
    l. Toxaphene;
17. Carbamates:
    a. Aldicarb;
    b. Aldicarb sulfone;
    c. Aldicarb sulfoxide;
    d. Carbofuran;
    e. Vydate;
18. Benzo-a-pyrene;
19. Adipates/Phthalates;
20. Trihalomethanes;
21. Volatile Organic Compounds (including vinyl chloride);
22. 1,2-Dibromo-3-chloropropane (DBCP) and 1,2-Dibromoethane (EDB);
23. Asbestos;
24. Diquat;
25. Endothall;
26. Glyphosate;
27. Haloacetic Acids;
28. Bromate;
29. Chlorite;
30. Perchlorate;
31. 1,4-Dioxane
32. Chloride.

(c) Radiochemistry. Certification in this discipline may be obtained in any or all of the following categories:

1. Gross Alpha;
2. Gross Beta;
3. Strontium-89;
4. Strontium-90;
5. Radium-226;
6. Radium-228;
7. Tritium;
8. Uranium;
9. Iodine-131;
10. Cesium-134;
11. Cesium-137;
12. Cobalt-60;
13. Ruthenium-106.

(2) Non-Potable Water. Certification in this matrix applies to analyses of water conducted in accordance with 40 CFR part 136, *Guidelines Establishing Test Procedures for the Analysis of Pollutants under the Clean Water Act*. Certification in this matrix may be obtained in any or all of the following disciplines and categories:

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(a) Microbiology. Certification in this discipline may be obtained in any or all of the following categories:

1. Ambient Water:
   a. *Escherichia coli*;
   b. Enterococci.
2. Wastewater:
   a. Fecal Coliform;
   b. *Escherichia coli*;
   c. Enterococci.

(b) Chemistry. Certification in this discipline may be obtained in any or all of the following categories:

1. Metals:
   a. Aluminum;
   b. Antimony;
   c. Arsenic;
   d. Beryllium;
   e. Cadmium;
   f. Chromium;
   g. Cobalt;
   h. Copper;
   i. Iron;
   j. Lead;
   k. Manganese;
   l. Mercury;
   m. Molybdenum;
   n. Nickel;
   o. Selenium;
   p. Silver;
   q. Strontium;
   r. Thallium;
   s. Titanium;
   t. Vanadium;
   u. Zinc.
2. Minerals:
   a. pH;
   b. Specific Conductivity;
   c. Total Dissolved Solids;
   d. Total Hardness (as Calcium carbonate);
   e. Calcium;
   f. Magnesium;
   g. Sodium;
   h Potassium;
   i. Total Alkalinity (as Calcium carbonate);
   j. Chloride;
   k. Fluoride;
   l. Sulfate;
3. Nutrients:
   a. Ammonia-N;
   b. Nitrate-N;
   c. Kjeldahl-N;
   d. Orthophosphate;
   e. Total Phosphorus;

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4. Demand:
   a. Chemical Oxygen Demand;
   b. Biochemical Oxygen Demand;
   c. Total Organic Carbon;
5. Total Cyanide;
6. Residue, Non-Filterable (Total Suspended Solids);
7. Total Residual Chlorine;
8. Oil and Grease;
9. Total Phenolics;
10 Volatile Organic Compounds (VOCs):
   a. Volatile Halocarbons;
   b. Volatile Aromatics;
11. Pesticides:
   a. Chlordane
   b. Aldrin;
   c. alpha-BHC (alpha-Hexachlorocyclohexane);
   d. beta-BHC (beta-Hexachlorocyclohexane);
   e. gamma-BHC (gamma-Hexachlorocyclohexane);
   f. delta-BHC (delta-Hexachlorocyclohexane);
   g. Dieldrin;
   h. 4,4'-DDD;
   i. 4,4'-DDE;
   j. 4,4'-DDT;
   k. Endosulfan I;
   l. Endosulfan II;
   m. Endosulfan sulfate;
   n. Endrin;
   o. Endrin aldehyde;
   p. Heptachlor;
   q. Heptachlor epoxide;
   r. Toxaphene;
12. Polychlorinated biphenyls (water);
13. Polychlorinated biphenyls (oil);
14. Perchlorate;
15. Semi-Volatile Organic Compounds (SVOCs):
   a. Acid Extractables;
   b. Base/Neutral Extractables.

42.06: Laboratory Certification Ratings

The Department shall classify a laboratory by matrix, discipline, and category according to the following rating scheme:

(1) Certified - the laboratory meets the Department's minimum requirements for certification and is deemed capable of producing valid data;

(2) Provisionally certified - the Department deems the laboratory capable of producing valid data despite minor deficiencies;

(3) Not certified - the laboratory fails to meet the Department's minimum requirements for certification and is deemed incapable of consistently producing valid data.

42.07: Criteria for Certification

(1) Proficiency Testing. Satisfactory performance in the proficiency-testing program is accomplished when the analytes in a category are correctly identified and acceptably quantified. Criteria for acceptability shall be set by the Department for each analyte in each

discipline and category. Continued unsatisfactory performance in the analysis of an analyte within a category may result in revocation of certification for that analyte.

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(2) Inspections.

(a) The Department may conduct an inspection of each laboratory to determine whether or not the laboratory meets the Department's standards for performing analyses in the matrices, disciplines, and categories for which certification is sought or is obtained.

(b) The Department shall consider the following factors in determining whether to certify or continue certification of a laboratory:

1. Education and experience of laboratory personnel;
2. Adequacy of laboratory facilities and equipment;
3. Adherence to Department-approved methodology and quality assurance/quality control procedures;
4. Adherence to Department-approved methods of handling and reporting data;
5. Adequacy of safety equipment and training; and
6. Any other factors the Department deems relevant to the determination of the ability of a laboratory to operate in a professional manner.

(c) If the Department issues a report of deficiencies found during an inspection of a laboratory, the laboratory shall have 90 days from the date of issuance of the report to take the necessary corrective actions specified in the report and submit documentation of such corrective action to the Department.

42.08: Minimum Standards for Certification

(1) Personnel. Certified laboratories and laboratories seeking certification shall designate a laboratory director and laboratory supervisor(s), and employ a sufficient number of qualified analysts commensurate with the laboratory's workload. The designated laboratory director and laboratory supervisor may be the same individual if he or she possesses the minimum qualifications and fulfills the responsibilities of both positions as set in 310 CMR 42.08(1).

(a) The laboratory director shall have the following responsibilities:

1. Developing policies, programs, and standard operating procedures that will ensure accurate and objective analytical results;
2. Employing and ensuring the training of qualified laboratory personnel;
3. Reporting analytical results to the Department in accordance with 310 CMR 42.13;
4. Interpreting and evaluating reports of analyses submitted by the laboratory upon request of the Department.

(b) A laboratory supervisor shall have the following responsibilities:

1. Performing analyses and/or providing personal and direct supervision and training to laboratory analysts performing analyses in the categories for which the supervisor is qualified;
2. Instruction and general supervision of all other laboratory operations including sample tracking, data validation, quality control, verification, and prompt reporting of results; and
3. Acceptance and nonacceptance of samples submitted to the laboratory for analysis.

(c) Minimum Qualifications of Laboratory Director.

1. Academic Training. The laboratory director shall possess a Bachelor's degree in biology, chemistry, or a closely related field. If chemical analyses are to be performed by the laboratory, the director must have at least 24 college credits in chemistry.
2. Experience. The laboratory director shall have a minimum of three years of experience in an environmental analysis laboratory.

(d) Minimum Qualifications of Laboratory Supervisor for Laboratories Certified in the Discipline of Chemistry or Radiochemistry.

1. Academic Training. The laboratory supervisor shall possess a Bachelor's degree in chemistry, biology, or a closely related field, and have at least 30 college credits in chemistry.
2. Experience.

a. Chemistry. The laboratory supervisor shall have a minimum of two years of laboratory experience in chemical analysis including one year of experience in the specific chemical methods supervised.

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b. Radiochemistry. The laboratory supervisor shall have a minimum of two years of laboratory experience in radiochemical analyses, including one year of experience in the radiochemical methods for which the laboratory is certified.

(e) Minimum Qualifications of Laboratory Supervisor for Laboratories Certified in the Discipline of Microbiology.

1. Academic Training. The laboratory supervisor shall have a minimum of a Bachelor's degree in biology, chemistry, or a closely related field with at least four college credits in microbiology.

2. Experience. The laboratory supervisor shall have a minimum of one year of experience in the microbiological methods for which the laboratory is certified.

(f) Minimum Qualifications of Instrumentation Analyst.

1. Academic Training. An instrumentation analyst shall possess a minimum of a high school diploma or equivalent and eight college credits in chemistry.

2. Experience. An instrumentation analyst shall have a minimum of one year of training or experience in the operation of the appropriate instrumentation.

(g) Minimum Qualifications of Analyst.

1. Academic Training. An analyst shall possess a minimum of a high school diploma or equivalent.

2. Training. An analyst shall receive specialized training in the methods to be performed.

(h) The Department may exempt a laboratory holding certification status on the effective date of 310 CMR 42.00 from one or more of the requirements set forth in 310 CMR 42.08(1), if the Department finds that strict compliance with such requirements would result in an undue hardship and would not serve to further the intent of 310 CMR 42.00. An exemption, when granted, shall be effective for not more than one year unless renewed by the Department.

(2) Facilities. A certified laboratory shall have:

(a) Adequate space in which to perform the analyses and related activities in the disciplines and categories in which it is certified;

(b) A well-lighted laboratory work bench area of ample size that is convenient to a sink, hot and cold running water, gas, suction, and electrical outlets if necessary;

(c) Clear aisles between benches that provide adequate room for passage of personnel and equipment;

(d) Appropriate ventilation including exhaust hoods for the handling of chemicals and samples in order to limit contamination of samples, standards, and other laboratory areas with the performance of each exhaust hood and biological safety cabinet tested by a qualified person annually and determined to be operating satisfactorily;

(e) Appropriate facilities for the storage of volatile, corrosive, and flammable materials;

(f) Controlled laboratory temperature and humidity at the levels required for the proper performance of the analyses and for the optimum operation of instruments that are sensitive to variations in temperature; and

(g) A locked facility for storage of chain-of-custody samples.

(3) Equipment and Materials. Certified laboratories and laboratories seeking certification shall have readily available on the premises all equipment, supplies, reagents, glassware, and instrumentation necessary to perform the analyses for which the laboratory is certified or seeks certification and related quality control activities. Such equipment and materials shall be maintained in good working condition, meet the performance criteria of the analytical method used, and, where appropriate, meet the criteria specified in 310 CMR 42.08(3):

(a) Refrigerator. Aqueous reagents and samples may be stored in a standard household refrigerator. A flammable materials refrigerator shall be used for storage of organics and flammable materials. The internal temperature of a refrigerator shall be maintained at 4°C $\pm$ 2°C. Organics and flammable materials not requiring refrigeration shall be stored in a flammable storage cabinet.

(b) Drying Oven. The drying oven shall have selectable temperature control with a range from room temperature to 180°C ± 2°C or higher.
(c) Source of Distilled or Deionized Water. Distilled or deionized water shall meet the minimum criteria of the methodologies employed.

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(d) Top-loader Balance. The balance pan shall be clean and free of corrosion. The balance must be capable of detecting a weight of 100 mg at a 150 g load or one mg for a load of 10 g or less.
(e) Hot Plate. The hot plate shall have selectable temperature controls for safe heating of laboratory reagents.
(f) Magnetic Stirrer. The magnetic stirrer shall be of variable speed with a stirring bar coated with inert material.
(g) Glassware. Glassware shall be made of borosilicate glass. Volumetric glassware shall be marked "Class A."
(h) Analytical Balance. The analytical balance shall be readable to 0.1 mg. It shall be mounted on a stable shock-proof base and protected from interference due to air currents.
(i) Conductivity Meter. The conductivity meter shall be readable in appropriate units, have a range from 2 ohms to 2 megohms or equivalent micromhos or Siemens, and be capable of measuring conductivity with an error not exceeding ± 1% or 1 μS/cm, whichever is greater..
(j) pH Meter. The pH meter shall be accurate to at least ± 0.05 units and have scale readability to ± 0.01 units.
(k) Thermometer. The thermometer shall have 1°C or finer subdivisions and be calibrated in degrees Celsius for the temperature range in which it will be used. The column shall have no separations. An organic solvent-filled thermometer may be used in a refrigerator. The laboratory may use electronic temperature measurement devices having the appropriate accuracy and readability for their intended use.
(l) Water Baths. Water baths may be electric or steam heated and capable of controlling temperature to 100°C within 5°C.
(m) Incubators. Incubators shall have an internal temperature-monitoring device and be capable of maintaining proper temperature.
(n) Autoclave. The autoclave shall be equipped with an accurate thermometer, a separate pressure gauge, and an operational safety valve. It shall maintain the sterilization temperature throughout the sterilization cycle and depressurize slowly so that no air bubbles form in inverted tubes and medium does not boil over. When being used to sterilize carbohydrate-containing media, the autoclave must be capable of completing an entire cycle (*i.e.*, time when materials are exposed to heat) within 45 minutes when a 12-15 minute sterilization period is used.
(o) Hot-Air Sterilization Oven. Hot-air sterilization ovens shall be capable of maintaining a stable sterilization temperature (170°C - 180°C).
(p) Muffle Furnace. Muffle furnaces shall be capable of heating glassware to 400°C for cleaning.
(q) Reagents, Standards, Media. Consumable supplies such as, but not limited to, reagents, standards, and media must not be used beyond their expiration date.
(r) Stereo Microscope. Stereo microscopes must have a magnification of 10-15x and be equipped with a fluorescent light source.
(s) Colony Counter. When the pour plate technique is used, a dark-field colony counter must be used to count heterotrophic plate count colonies.

(4) Laboratory Safety Measures Affecting Laboratory Analysis Capability. Certified laboratories shall be in compliance with local, state, and federal laws to the extent that required conditions directly affect laboratory capability in providing accurate and reliable analysis and maintaining the integrity of samples and of the analytical process; or are referenced as required for environmental laboratories by the acceptable analytical method(s) employed. These conditions include, but are not limited to, safety protocols involving physical, chemical, radiochemical, and biological hazards; availability and use of fire safety equipment; protective clothing and equipment including respirators; appropriate handling of compressed gas cylinders; and appropriate storage and disposal of materials and wastes.

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(5) Quality Assurance/Quality Control.

(a) General Requirements.

1. Quality Assurance Plan. Certified laboratories shall establish, maintain, and follow a written Quality Assurance (QA) Plan acceptable to the Department. Each laboratory's QA plan shall be made available to all analysts employed by the laboratory. At a minimum, QA plans shall include:

a. QA organization and responsibility;

b. QA objectives for precision and accuracy;

c. Standard operating procedures (SOPs) that accurately reflect all phases of current laboratory activities. The standard operating procedures section of a laboratory's QA plan shall include the following:

i. Sample receipt and handling procedures including sample custody and storage procedures;

ii. Calibration procedures and frequencies;

iii. Analytical procedures, including any modifications to published procedures;

iv. Data reduction, validation and reporting procedures;

v. Internal quality control procedures (type and frequency);

vi. Provision for performance and system audits, both internal and external, and schedules;

vii. Preventive maintenance procedures and schedules;

viii. Specific procedures for assessing data precision and accuracy;

ix. Procedures for taking corrective actions;

x. Quality assurance reporting procedures; and

xi. Laboratory safety plans.

A standard operating procedure for an analytical method or other laboratory procedure may be a separate document. The QA plan must include a list of all such standard operating procedures. Only the laboratory director or supervisor may make changes in standard operating procedures. Such changes shall be effective only when put in writing.

d. Record Maintenance. The record maintenance procedures section of a laboratory's QA plan shall include the procedures for creating, controlling, and maintaining the following records:

i. Raw data (including, but not limited to, laboratory notebooks, instrument printouts, and electronic records);

ii. Chain-of-custody records;

iii. Calculations;

iv. Quality control data; and

v. Reports.

2. Temperature Records.

a. A laboratory shall measure and record the temperature of each drying oven and hot-air sterilizing oven for each day of use. The temperature measurement device must be immersed in sand or other suitable material and placed on one of the shelves. A laboratory may use a temperature-measuring device that can be read from outside the oven without the need to open the door provided that it has verified the accuracy of the device.

b. A laboratory shall measure and record the temperature of each refrigerator and incubator either continuously or each day of use. The thermometers must be immersed in liquid and placed on one of the shelves. A laboratory may use a temperature-measuring device that can be read from outside the refrigerator or incubator without the need to open the door provided that it has verified the accuracy of the device.

3. Laboratory Chemicals and Reagents. Analytical reagent (AR) grade or American Chemical Society (ACS) grade chemicals or better are required for analyses, unless otherwise required by the analytical method. In addition, laboratory chemicals and reagents shall meet the following requirements:

a. All chemicals shall be labeled with the date of receipt by the laboratory to prevent the use of outdated reagents;

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b. Stock and working standard solutions shall be compared with check standards and inspected prior to use for signs of decomposition, such as formation of precipitates, evaporation, and/or discoloration;

c. All reagents and standards shall be labeled with identification of the compound, concentration, solvent, date of preparation, date of expiration, and the name of the analyst who prepared the solution;

d. Preparation of all stock standards and primary dilution standards shall be documented, and the concentration of stock and working calibration standards shall be verified against a primary dilution standard prepared from a source of reagents different from those used to prepare the calibration standards; and

e. The use of the acceptable grade of reagents and compressed gases required by the analytical procedure employed shall be documented.

4. Laboratory Glassware. The laboratory must follow cleaning procedures for glassware and other labware that are specified in the analytical methods. If no specifications are given in a method, then glassware and sample containers must be cleaned prior to use by washing in a warm detergent solution, followed by thorough rinsing with tap water and several additional rinses using deionized or distilled water. The laboratory must use a detergent designed for laboratory use. Commercially prepared glassware and sample containers may be used, provided the laboratory documents the source and cleaning procedures utilized. Certain analytical methods may require additional glassware preparation procedures or the maintenance of a separate dedicated set of glassware.

5. Maintenance of Laboratory Instrumentation and Equipment. Analytical instrumentation and equipment shall be maintained in accordance with the manufacturer's instructions, analytical method requirements, and good laboratory practices. A secure record of maintenance procedures shall be maintained for each instrument and piece of equipment.

6. Instrumentation Calibration Requirements.

a. General Requirements.

i. Unless directed otherwise by the analytical method employed, all instruments shall be calibrated immediately prior to analysis using a minimum of a blank and three calibration standards that bracket the expected concentration range.

ii. Unless directed otherwise by the analytical method employed, all instrument calibrations shall be verified through the analysis of a calibration check sample that has been prepared using a source of reagents different from that used to prepare the calibration standards. Unless directed otherwise by the analytical method employed, the calibration check sample shall be analyzed at the beginning and at the conclusion of the analysis session and after every 20 or fewer samples. If the result does not agree within 20% of the original value, corrective action shall be taken.

iii. For instruments with a calibration curve that has been set by the instrument manufacturer, the laboratory shall verify the calibration curve using a minimum of three calibration check standards that bracket the expected concentration range. The check standards shall represent low, medium, and high concentrations and include a standard at the minimum reporting level (MRL). If the result of the calibration check does not agree within 10% of the assigned value of each check standard, instrument recalibration must be performed.

iv. The laboratory shall keep a secure record of instrument calibration procedures.

b. Analytical Balance. Each analytical balance shall be checked and adjusted annually by a qualified service person. The accuracy of each analytical balance shall be checked each day it is to be used using a minimum of two ASTM Class 1 weights, or equivalent, in ranges appropriate to the laboratory’s weighing needs. The laboratory shall keep a secure record of the results of accuracy checks, the date performed, and the signature of the analyst who performed the check. The

non-reference weights used for this check must be calibrated annually using reference weights and the results recorded. The accuracy of reference weights must be certified every five years. The balance level shall be checked prior to each use and adjusted if necessary.

42.08: continued

c. pH Meters. Each pH meter shall be calibrated daily or prior to each use with pH 7.0 and pH 4.0 or 10.0 buffer standards that bracket the expected value of the sample, medium, or reagent being tested. The buffers used shall be recorded, including the date of calibration and the name of the analyst who performed the calibration.

i. The laboratory must use pH buffer aliquots only once.

ii. The laboratory must date commercial buffer solution containers upon receipt and when opened.

iii. The laboratory must record the pH meter slope monthly after calibration and take corrective action if the slope falls outside the range of 95% to 105%.

d. Conductivity Meters.

i. The conductivity meter must be calibrated at least monthly using a certified and traceable low-level standard. Alternatively, the laboratory must determine the cell constant monthly.

ii. An in-line meter may be used to check reagent-grade water provided that it is calibrated annually.

e. Thermometers. The accuracy of all temperature measurement devices used to monitor temperatures shall be verified by comparing the reading of each device with that of a certified reference thermometer that is graduated in degree increments no larger than those of the device whose accuracy is being verified. The laboratory must discontinue use of a thermometer graduated in 0.5°C increments or less that differs from the certified thermometer by more than 1°C. The accuracy of glass and electronic thermometers must be verified annually; metal thermometers must be verified quarterly; infrared detection devices must be verified every six months; and the certified reference thermometer must be calibrated at least once every five years. The correction factor and date of verification of accuracy must be indicated on the thermometers. The laboratory shall maintain a secure record that includes:

i. The identification number of each thermometer;

ii. The temperatures displayed on both the certified thermometer and the thermometer being verified;

iii. Any applicable correction factor;

iv. The date each check was performed; and

v. The signature of the analyst who performed each check.

f. On-line Monitors and Portable Equipment. Continuous on-line monitors and portable equipment used in obtaining on-site measurements must be calibrated in accordance with the manufacturer's instructions. The calibration must be verified through analysis of an independent check sample or use of an independent monitoring technique. Verification shall be recorded.

g. Spectrophotometer Wavelength Verification. The wavelength setting of the spectrophotometer shall be checked annually by comparing the wavelength setting to that of colored standards or filters, such as didymium glass. The wavelength observed, date of performance, and the name of the analyst or service person that performed the check shall be recorded.

h. Top-Loader Balance. Each top-loader balance must be checked for accuracy monthly in its range of use with ASTM Class 1 weights or equivalent.

7. Sample Collection, Preservation and Handling.

a. Acceptable procedures, as referenced or defined in current federal regulations shall be utilized for sample collection, handling and preservation.

b. The laboratory may reject the sample if it is not assured of the sample identification or of the validity of the sample collection, handling and preservation procedures. The laboratory must have a written policy listing its criteria for rejection of samples. When rejecting a specific sample, the laboratory must document the reason(s) for the rejection.

c. Samples shall be stored in such a way that cross-contamination from other samples, standards or reagents is avoided.

d. The laboratory shall adhere to the sample and extract holding times prescribed in the analytical methods.

42.08: continued

e. Chain-of-custody information must include:

i. Sample number;

ii. Sample description including any preservation (*e.g.*, chemical, thermal, *etc*.) used;

iii. Date and time of sample collection;

iv. Specific location of sample collection;

v. Name of sample collector and intermediate custodians, if any;

vi. Date(s) and time(s) of custody transfer to the laboratory; and

vii. Name(s) and signature(s) of the individual(s) receiving the sample.

f. A chain-of-custody form must accompany all samples including those shipped by mail or courier.

g. The laboratory shall maintain a system of internal sample tracking that documents sample custody from the time of receipt at the laboratory to the time of disposal.

8. Analytical Methodology. The laboratory shall utilize acceptable analytical methods. The acceptable methods shall be those defined or referenced in the current federal regulations for the environmental matrix being tested.

(b) Additional Requirements for Chemical and Radiochemical Laboratories.

1. Quality Control Procedures.

a. Unless directed otherwise by the analytical method or the Department standard employed, the laboratory shall prepare and analyze a laboratory reagent blank, sample duplicate, and laboratory fortified blank for every 20 or fewer samples processed as an analytical batch. Duplicates of radiochemical samples must be prepared and analyzed for every ten or fewer samples. In addition, a laboratory fortified sample matrix shall be run if required by the Department. Corrective action shall be taken if the results of these analyses do not meet acceptance criteria developed within the laboratory according to accepted analytical procedures. The preparation of blanks, laboratory fortified sample matrices, and duplicates and the results of their analyses shall be recorded.

b. Each laboratory must establish acceptance limits for precision and accuracy and maintain and use quality control charts for each of the analytes in the matrices, disciplines, and categories in which the laboratory is certified. These limits may not be less stringent than those defined in approved analytical methods or approved by the Department.

c. Certified laboratories shall utilize surrogate analytes as required by the analytical procedure employed. Acceptance limits for surrogate analyte recoveries shall be established by the laboratory. Quality control charts must be maintained and used for each surrogate.

d. Certified laboratories shall perform and document all quality control procedures in established analytical protocols or the quality control procedures the Department requires and specifies.

e. When integrating chromatography peaks, either automatically or manually, each laboratory must ensure that integrations are performed in a correct and consistent manner for standards and samples, including quality control samples. Each laboratory must maintain documentation of manual integrations that includes the following:

i. The laboratory's written procedure for manual integration;

ii. The original chromatogram and the manually integrated chromatogram;

iii. The analyst's initials, date of manual integration, and the reason(s) for the manual integration.

2. Determination of Method Detection Limit.

a. Each laboratory shall experimentally determine the method detection limit for analysis of each analyte, except pH, for each matrix in which the laboratory is certified.

b. The laboratory must document its procedure for determining the method detection limit. The laboratory must use the procedure for determining the method detection limit that is described in the analytical method being used. If the analytical method does not include a procedure for the determination of method detection limits, then the laboratory must determine the method detection limit using the procedure described in 40 CFR Part 136, Appendix B or other Department- or EPA-approved procedure. For those analytes requiring pattern recognition for identification (e.g., chlordane, toxaphene), the method detection limit is defined as the lowest concentration at which pattern recognition is possible.

c. Calculations and supporting documentation used in determining limits must be available for inspection.

d. Detection limits shall be expressed in appropriate units.

e. The laboratory must achieve the method detection limits required by the applicable regulations.

42.08: continued

f. Sample preparation and analyses for the method detection limit calculation must be made over a period of at least three days.

g. Method detection limits must be determined as part of a laboratory's initial demonstration of capability to perform an analysis, when any change occurs in the laboratory that could affect the method detection limits, and as required by an analytical method.

h. Method detection limits must be determined using analysts and instruments that are representative of those used in the performance of analyses.

i. The laboratory must verify its capability to analyze low level samples on an ongoing basis through the analysis of low level standards or through a method detection limit determination.

j. The laboratory shall determine the minimum reporting level for analysis of each analyte, except pH, for each matrix in which the laboratory is certified. The laboratory shall document the procedure used to determine the minimum reporting level. The laboratory shall verify the minimum reporting level on an ongoing basis.

3. Laboratory Reagent Water. The laboratory must demonstrate that its reagent water meets the specifications required by the analytical methods it uses including that it is free of analytes of interest above their method detection limits. When the method specifies the resistance or conductivity of the source of reagent water, verification of such quality shall be made and documented each day the water is used.

(c) Additional Requirements for Microbiology Laboratories.

1. Autoclaves.

a. For each sterilization cycle, the signature of the analyst, date, sterilization time and temperature, the materials being autoclaved and their total time in the autoclave shall be recorded.

b. A maximum-temperature-registering thermometer, electronic temperature read-out device, or continuous recording device must be used during each autoclave cycle. The temperature must be recorded.

c. Automatic timing mechanisms must be checked quarterly with an accurate timepiece, such as a stopwatch, and the results recorded.

d. The laboratory must check the performance of the autoclave each week during which the autoclave is used with *Geobacillus stearothermophilus* spore strips, suspensions, or capsules and record the results.

e. Biological waste must be autoclaved for at least 30 minutes followed by proper disposal.

2. Hot Air Sterilizing Ovens. The laboratory must check the performance of the hot air sterilizing oven each week during which the oven is used with *Bacillus subtilis* or *Bacillus atrophaeus* spore strips and record the results.

3. Incubators.

a. Incubators, both air-type and water bath, must maintain the temperature specified by the method. On days when the incubator is in use, the temperature of each incubator must be recorded continuously or at least twice per day, with each reading separated by at least four hours and the times of each reading recorded. For air-type incubators, the thermometer shall be immersed in liquid and placed on one of the shelves in use.

b. If an aluminum block incubator is used, culture dishes and tubes must fit snugly.

c. Water bath incubators must be cleaned at least monthly.

d. The laboratory must record the date and time at the beginning and at the end of sample incubation.

4. Germicidal Ultraviolet Lamps. Germicidal ultraviolet lamps shall be tested quarterly by exposing agar spread plates containing 200 to 250 microorganisms to the light for two minutes. If such irradiation does not reduce the count of control plates by 99%, the lamps shall be replaced. Alternatively, the laboratory shall use an ultraviolet light meter to ensure that the lamp emits at least 70% of its initial output. Cleaning of germicidal ultraviolet lamps shall be done at least monthly by disconnecting the unit and cleaning the lamps with a soft cloth moistened with ethanol.

42.08: continued

5. Microscopes. The optics and stage of microscopes shall be cleaned with lens paper prior to each use.

6. Sterility of Rinse/Dilution Water and Sample Bottles.

a. Each batch or lot of dilution/rinse water must be checked for sterility by adding 50 mL of the water to a 50 mL volume of a double strength non-selective broth (*e.g.*, tryptic soy broth, trypticase soy broth, or tryptose broth), which is then incubated at 35°C $\pm$ 0.5°C and checked for turbidity signifying growth at 24 and 48 hours and the results recorded.

b. After sterilization, at least one bottle per batch of sterilized sample bottles or per lot of commercially prepared sample containers shall be checked for sterility by adding approximately 25 mL of sterile non-selective broth medium to each bottle. The bottle shall be capped and rotated so that the broth comes in contact with all surfaces and shall be incubated at 35°C $\pm$ 0.5°C and checked for growth at 24 and 48 hours and the results recorded. Prepared sample bottles from each batch or lot shall not be used unless satisfactory results are obtained from the tested bottle.

7. Residue Testing of Glassware.

a. Inhibitory Residue Test. With the initial use of each lot of a detergent or washing product, the rinsing process using distilled or deionized water shall be demonstrated to provide glassware that is free from toxic material based on the use of the Inhibitory Residue Test, as specified in the most recent edition of *Standard Methods for the Examination of Water and Wastewater*, American Public Health Association, American Water Works Association, Water Environment Federation, Washington D.C. The results of the test must be recorded. Alternatively, the laboratory may obtain written, traceable certification from the product manufacturer that the inhibitory residue test has been performed on the lot of detergent or washing product according to the *Standard Methods* procedure. The actual test results must be included with the certification.

b. Bromthymol Blue Test. Each batch of clean, dry glassware or plasticware shall be tested for residual alkaline or acid residue using bromthymol blue indicator and the results recorded. If the results of the indicator test are not within the desired color range of light green to dark blue, corrective action shall be taken by rerinsing, air drying and retesting.

8. Microbiological Media - Quality Control Measures.

a. The laboratory shall keep records that indicate the kind, amount, date received, lot number, expiration date, and date of opening of bottles of media. Media shall be stored in a desiccator or cool, dry location. If caking or discoloration of media occurs, media shall be discarded.

b. Records shall be available for inspection on all batches of laboratory-prepared media showing lot numbers, date prepared, details of preparation, total volume prepared, sterilization time and temperatures, final pH, and the name of the individual who performed the work.

c. Prior to first use of media, the laboratory shall test each batch of medium prepared in the laboratory and each lot of pre-prepared, ready-to-use medium with at least one pure culture of a known positive reaction.

d. Prior to first use of media, the laboratory shall test each batch of medium prepared in the laboratory and each lot of pre-prepared, ready-to-use medium with one or more negative culture controls, *i.e.*, non-target organisms, as appropriate to the method.

e. Prepared plates shall be refrigerated in sealed containers with a label containing the date of preparation or expiration and the name of the medium. Plates may be kept no more than two weeks following preparation. Broth media in loose-capped test tubes may be kept no more than two weeks following preparation. Broth media in tightly capped tubes may be kept three months from the date of preparation.

42.08: continued

9. Dechlorination Sufficiency. If chlorinated water is to be analyzed, sufficient sodium thiosulfate must be added to the sample bottle before sterilization to neutralize any residual chlorine in the water sample. The laboratory may also use commercially prepared, pre-sterilized bags or bottles containing sodium thiosulfate.

10. Membrane Filter Procedure Quality Control Specifics.

a. Only membrane filters recommended for water analysis by the manufacturer shall be used.

b. Lot numbers of membrane filters and date of receipt shall be recorded.

c. Procedural Contamination. A start and finish membrane filtration control test of rinse water, medium, and supplies shall be conducted for each filtration series. If sterile controls indicate contamination, all data on samples affected shall be rejected and a request made for immediate resampling of those waters affected.

d. Verification of Membrane Filter Colonies on m-Endo medium.

Total Coliform Procedure. All sheen or borderline colonies up to ten on each membrane shall be verified in accordance with the accepted standard procedure contained in the latest edition of *Standard Methods for the Examination of Water and Wastewater* (*Standard Methods*).

11. Quality Control.

a. When quality control samples are available, each analyst shall analyze at least one quality control sample per year for the categories to be certified.

b. During the initial training of an analyst in a method requiring the identification and enumeration of colonies, the new analyst must count plates from at least ten positive samples having varying colony counts within the ideal counting range for the method. The laboratory supervisor must count the same plates. The replicate counts between the analysts must agree within 10%.

c. For methods used for the enumeration of colonies, 10% of routine samples must be analyzed in duplicate and the range of logs determined. Corrective action shall be taken if the results of these analyses do not meet acceptance criteria developed within the laboratory according to accepted analytical procedures.

12. Laboratory Reagent Water. The laboratory shall use satisfactorily tested reagent water from a water purification system (*e.g.*, still, deionization unit, or a reverse-osmosis unit) to prepare media, reagents, and dilution/rinse water for performing microbial analyses.

a. If the source water is chlorinated, the laboratory reagent water must be tested monthly for total chlorine residual and found to contain less than 0.1 mg/L of chlorine residual.

b. The laboratory reagent water must be analyzed annually for the presence of lead, cadmium, chromium, copper, nickel, and zinc. The concentration of each metal must

be no greater than 0.05 mg/L. The concentration of the metals collectively must be no greater than 0.1 mg/L.

c. The conductivity of the laboratory reagent water must be monitored each day that the water is used and found to be less than 2 µS/cm at 25°C or greater than 0.5 megohms-cm resistance at 25°C.

d. A heterotrophic plate count must be performed on the laboratory reagent water monthly. The laboratory may use the reagent water only if the heterotrophic plate count is less than 500 CFU/mL.

e. The test of the bacteriological quality of the laboratory reagent water must be performed annually. The ratio of the growth rate must be between 0.8 and 3.0. The test is described in Section 9020B of the 18th and 19th editions of *Standard Methods for the Examination of Water and Wastewater*. The bacteriological quality test is not required of laboratories that document that their laboratory reagent water meets the criteria for Type II water or better, as defined in *Standard Methods* (18th and 19th editions), Section 1080C or Medium quality water or better as defined in *Standard Methods* (20th edition), Section 1080C.

(6) On an annual basis, certified laboratories and laboratories seeking certification shall require all personnel to participate in a laboratory ethics training program. Training shall include the following topics: proper procedures to ensure data integrity, recognition and prevention of improper laboratory practices, the promotion of objectivity and impartiality in the generation and reporting of analytical data, and procedures for confidential reporting of data integrity concerns to a laboratory supervisor, director, or owner, as appropriate. The laboratory must document the content of the training and the date of participation in the training for each staff member and shall make this documentation and the materials used in the training available for review during an inspection.

42.09: Issuance of Certificate

(1) Upon satisfactory fulfillment of the criteria provided herein, the Department shall issue a certificate indicating the laboratory's certification rating for each matrix, discipline and category, including the acceptable analytical methods used by the laboratory. The certificate, which includes the list of certified analytes and methods, shall be conspicuously displayed at the location stated in the certificate.

(2) Certificates shall be valid for one year unless earlier downgraded or revoked in accordance with 310 CMR 42.12, or surrendered.

(3) Certification status shall apply only to the laboratory located at the address stated in the certificate. Each affiliated or branch laboratory must obtain a separate certificate. Certificates are not transferable or assignable.

42.10: Requirements for Maintaining Certification Status

(1) To maintain certification status, a laboratory shall satisfactorily analyze samples from a proficiency testing program administered or approved by the Department and pass inspections conducted or approved by the Department.

(2) A laboratory must continue to meet the Department's minimum standards for certification set forth in 310 CMR 42.00 to maintain certification status.

(3) A laboratory shall not misrepresent its certification status on any document. On reports of sample analysis, the laboratory must clearly distinguish among analyses for which it is certified, analyses for which it is provisionally certified, and analyses for which it is not certified. The laboratory’s certification status indicated on a report of sample analysis must be accurate as of the date of the analysis. For all other documents, including promotional materials, catalogues, advertising, Internet sites, business solicitation proposals, quotations, or other materials on which the laboratory’s certification status appears, the laboratory, to the extent possible, must correct its certification status appearing on such documents within 30

calendar days of its receipt of a notice of revocation of certification or within 30 calendar days of its voluntary withdrawal from certification.

42.11: Renewal of Certificate

Filing. At least 45 calendar days prior to the expiration date noted on its certificate, a certified or provisionally certified laboratory must file an application for renewal of certification on forms provided by the Department. Timely filing of the application for renewal causes the certification to continue until the Department issues a final written decision regarding the laboratory's certification status. A laboratory that fails to file an application for renewal by the expiration date of the certification loses its certification, may not file an application for renewal, and must submit a new application for certification, including payment of the application fee, if it wishes to secure a new certification.

42.12: Denial, Downgrading, and Revocation of Certification

42.12: continued

(1) Denial. The Department may deny a laboratory's request for certification, including a request for renewed certification, if:
   (a) the application does not meet the requirements of 310 CMR 42.00
   (b) the laboratory's current or prior certification has been downgraded or revoked;
   (c) the laboratory or one of its owners or employees has been or currently is subject to an order issued pursuant to 310 CMR 42.17(1); or
   (d) the laboratory or one of its owners or employees has been or is currently in violation of 310 CMR 42.00.

(2) Provisional Certification. For minor deficiencies not affecting the laboratory's ability to produce valid data, the Department may downgrade a laboratory's certification status to provisional, in total or in part, for a period not to exceed 180 calendar days. If the Department determines that there are grounds for downgrading, the Department shall notify the laboratory in writing by certified mail.
   (a) The following may be grounds for downgrading if the Department determines that the infraction is minor in nature and does not affect the laboratory's ability to produce valid data:
      1. Failure to pass an inspection;
      2. Failure to report compliance data to a public water system, the Department, or other responsible party in a timely manner, or interfering with the reporting of such data produced by other entities;
      3. Careless or inaccurate reporting of analytical measurements and supporting documentation;
      4. Failure to notify the Department in writing within the prescribed timelines listed in 310 CMR 42.13 regarding any change in ownership, laboratory name, laboratory location, personnel, equipment, or any other factor that could impair the analytic, reporting, or operational capability of the laboratory;
      5. Reporting sample results without indicating whether or not the laboratory is certified for that analysis;
      6. Reporting sample results for analyses for which the laboratory is certified without indicating whether or not the analyses were conducted in accordance with Department certification standards;
      7. Failure to use an approved method or to follow the approved method for sample analysis where the report issued for the analysis indicates that the analysis was conducted in accordance with Department certification standards;

8. Handling samples in a manner so as to compromise sample integrity; and
9. Failure to comply with any other requirement of 310 CMR 42.00.

(b) A laboratory that has had its certification downgraded to provisional may request reinstatement within the time period prescribed in the notification of downgrading and in accordance with the requirements of 310 CMR 42.12(4). If the laboratory fails to correct the deficiencies listed in the notice of downgrading and request reinstatement within the time specified by the Department in the notification, the Department may revoke, in total or in part, the laboratory's certification, pursuant to 310 CMR 42.12(3).

(3) Revocation. The Department may revoke a laboratory's certification, in total or in part, if the Department determines that there are grounds for revocation. The Department shall notify the laboratory in writing via certified mail in the event of a revocation.

(a) Grounds for revocation are:

1. Failure to pass an inspection;
2. Failure to report compliance data to a public water system, the Department, or other responsible party in a timely manner or interfering with the reporting of such data produced by other entities:
3. Failure to participate in or analyze proficiency test samples, or to meet the requirements for successful performance of such tests;
4. Operating the laboratory in such a manner so as to endanger public health or safety;
5. Making an intentionally false oral statement or written statement on any document issued by the laboratory or on any document associated with certification;
6. Careless, inaccurate, or falsified reporting of analytical measurements and supporting documentation;
7. Failure to notify the Department in writing within the prescribed timelines pursuant to 310 CMR 42.13 regarding any change in ownership, laboratory name, laboratory location, personnel, equipment, or any other factor that could impair the analytic, reporting, or operational capability of the laboratory;
8. Unethical conduct in the operation of the laboratory;
9. Fraudulent or deceptive practices;
10. Reporting sample results without indicating whether or not the laboratory is certified for that analysis;
11. Failure to use an approved method or to follow the approved method for sample analysis where the report issued for the analysis indicates that the analysis was conducted in accordance with Department certification standards;
12. Reporting sample results for analyses for which the laboratory is certified without indicating whether or not the analyses were conducted in accordance with Department certification standards;
13. Performing, reporting, or failing to report drinking water analyses in a manner so as to threaten public health or welfare;
14. Failure to implement, report, or maintain corrective action related to any deficiencies found during a laboratory inspection or deficiencies otherwise indentified by the Department;
15. Failure to correct the deficiencies cited in a notice of downgrading to provisional certification and apply for reinstatement during the time frame specified by the Department;
16. Handling samples in a manner so as to compromise sample integrity; and
17. Failure to comply with any other requirement of 310 CMR 42.00.

(b) A laboratory that has had its certification revoked must not advertise itself as certified for those matrices, disciplines, or categories for which the laboratory's certification has been revoked and, to the extent possible, must remove or replace any advertisements that indicate that the laboratory is certified within 30 calendar days of the laboratory's receipt of a notice of revocation of its certification.

(c) A laboratory that has had its certification revoked must not perform analyses in those disciplines and categories for which its certification was revoked where the Department or the laboratory's client requires that the analyses be performed by a Massachusetts-certified laboratory and/or that the Department's certification standards of analysis be used.

(d) The Department may impose a waiting period of up to three years in its notice of revocation, during which time the laboratory may not apply for recertification. After the waiting period ends, the laboratory must submit a new application for certification, including payment of the application fee, if it wishes to become recertified.

(e) A laboratory that has had its certification revoked, but no waiting period imposed, may request reinstatement within 180 days of the date of revocation in accordance with the requirements of 310 CMR 42.12(4). A laboratory that fails to request reinstatement within 180 days must submit a new application for certification, including payment of the application fee, if it wishes to become recertified.

(4) Reinstatement.

(a) A laboratory for which certification has been downgraded to provisional may request reinstatement within the time period prescribed in the notification of downgrading and in accordance with the requirements of 310 CMR 42.12(4)(c).

(b) A laboratory for which certification has been revoked and no waiting period imposed may request reinstatement within 180 days of the date of revocation and in accordance with the requirements of 310 CMR 42.12(4)(c).

(c) Laboratories seeking reinstatement shall submit a written report to the Department detailing corrective action that has been taken in regard to the deficiencies that resulted in the downgrading or revocation of the certification. At the same time, the laboratory shall submit a written request for reinstatement review by the Department. The corrective action report and the request for reinstatement must be submitted within the time frame specified in 310 CMR 42.12(4)(a) or (b), as applicable.

(d) The Department may reinstate a certification that has been downgraded or revoked if the laboratory has corrected all the deficiencies identified in the notice of downgrading or revocation to the Department's satisfaction and if the laboratory has applied for reinstatement in accordance with 310 CMR 42.12(4). The reinstatement of a laboratory's certification status following a downgrading or revocation is not effective until the Department has issued its decision in writing to the laboratory.

(e) If a laboratory's request for reinstatement after revocation is denied by the Department, the laboratory shall submit a new application for certification, including payment of the application fee, if it wishes to become recertified.

(f) A laboratory that has had its certification revoked and a waiting period imposed may not request reinstatement.

(5) Successor. The revocation of a laboratory's certification shall operate to prohibit any successor from applying for certification from the Department except in accordance with 310 CMR 42.12(4).

42.13: Reporting Requirements

(1) No certified or provisionally certified laboratory shall report analytical results as a Department-certified laboratory unless:

(a) The laboratory conducted the analytical measurements at the laboratory's address as stated in its current certificate;

(b) The laboratory clearly distinguishes in the report among those analyses for which it is certified, provisionally certified, or not certified by the Department; and,

(c) For those analyses for which it is certified or provisionally certified, the laboratory clearly distinguishes in the report between those analyses that it conducted in accordance with Department certification standards and those that it did not conduct in accordance with Department certification standards.

(2) All reports of analytical measurements conducted by a Department-certified laboratory in accordance with the standards of 310 CMR 42.00 where such standards are required or otherwise specified by the laboratory's client must include the following information:

(a) The Massachusetts Laboratory Certification identification number of each laboratory that performed the analytic measurements;

(b) The results of analysis of samples with the specific analytes measured by each laboratory that performed any of the analyses identified in the report;

(c) The results of analyses of reagent blanks, laboratory fortified blanks, laboratory fortified sample matrices, and duplicates, and surrogate analyte recovery data when requested by the Department;

42.13: continued

(d) The analytical methods used to detect and quantify the analytes of interest. Sample preparation procedures, if not included in the referenced analytical procedures, must also be referenced or described; and

(e) The date of sample extraction, if applicable to the analytical method performed, and the date of sample analysis.

(3) With the exception of reports submitted to the Department in a format approved by the Department, all reports of finished drinking water analyses must indicate the maximum contaminant level and/or the maximum residual disinfectant level for each analyte measured where a maximum contaminant level or maximum residual disinfectant level has been established by the EPA or by the Department. Where a maximum contaminant level or maximum residual disinfectant level has not been established, the laboratory must indicate the drinking water guideline for each analyte as published by the Department's Office of Research and Standards.

(4) The actual format of the data submitted to the Department is left to the discretion of the laboratory unless otherwise specified. The Department encourages the use of summary tables that allow the reader to easily review and compare the data.

(5) A certified laboratory shall be required to have current knowledge of all Federal and Massachusetts standards for all categories in which it has been certified or provisionally certified, and to report analytical results in a timely manner.

(a) Following completion of sample analysis, a certified laboratory shall notify its clients of the results of all samples that exceed any EPA- or Department-established maximum contaminant level (MCL), maximum residual disinfectant level, or reportable concentration or that identify the presence of microbiological organisms in potable water. Notification must clearly indicate that a regulatory limit has been exceeded. The date, time, and manner of notification must be documented and kept on file.

(b) A laboratory that accepts potable water samples for analysis must notify its client public water system of the results of all samples that exceed a regulatory limit. Such notification must be given within 24 hours of the analysis of the sample whether or not the laboratory accepting the sample subcontracted the analysis to another laboratory.

(c) Laboratories must identify, in writing, those samples needing special reports (*e.g.*, MCL exceedance) when the laboratory subcontracts with another laboratory.

(d) Laboratories accepting samples to be analyzed for the purpose of determining regulatory compliance must ensure that analytical data are reported in a timely manner to meet their clients' reporting requirements. A laboratory that has had regulatory compliance samples subcontracted to it by another laboratory must release analytical data to the client laboratory before the client laboratory's reporting deadline.

(e) Laboratories must have written standard operating procedures in place which are designed to ensure that the requirements of 310 CMR 42.13(5)(a)-(d) are met.

(f) Preliminary data and data for which data quality objectives were not achieved must be accompanied by a case narrative describing quality control outliers or any other factors affecting data usability.

(6) A laboratory shall notify the Department in writing upon any change in ownership, laboratory name, laboratory location, personnel, equipment, or any factor that could impair the analytic capability of the laboratory. Personnel changes must be reported within ten calendar days and shall be limited to loss or replacement of the Laboratory Director, Laboratory Supervisor, or any other personnel that results in the unavailability of trained and experienced analysts necessary to perform the analyses for which the laboratory has been certified. Changes affecting the availability of properly operating equipment to perform analyses for which the laboratory is certified must be reported in writing to the Department within seven calendar days of the change.

(7) The present owners of a certified or provisionally certified laboratory shall notify the Department in writing of a sale or change in ownership of the laboratory within ten calendar days of the same.

(8) The owner of a certified or provisionally certified laboratory seeking to maintain its certification status while changing the laboratory location shall notify the Department in writing at least 30 calendar days prior to any such change. The Department may issue an amended certificate for the new location indicating the laboratory's certification rating for each matrix, discipline and category if it finds that the laboratory meets the Department's criteria for certification.

(9) A laboratory that has been certified by EPA or by its resident state shall notify the Department upon receipt of notice from EPA or the resident state that its certification has been downgraded, suspended, or revoked.

(10) A laboratory shall submit to the Department a copy of the following kinds of documents:

(a) within 30 calendar days of receipt by a Department-certified laboratory of a citation, settlement agreement, judgment, order, enforcement notice or report, or inspection report that is issued by any local, state, or federal government agency that cites violations of that laboratory's conditions, equipment, or operations.

(b) a Department-certified laboratory must supply a copy within 30 calendar days of receipt of documents from its director, supervisor, and owner holding greater than 5% equity. The documents include a citation of violations or settlement agreement issued by any local, state, or federal government agency naming the individual and documents evidencing a civil or criminal conviction of that individual involving operations of any other environmental laboratory certified or accredited by EPA or any state. The Department-certified laboratory must ensure that its director, supervisor, and owner are required to submit a copy to it within 30 calendar days of receipt of such documents by the individual.

(c) a laboratory applicant for certification shall provide a copy pursuant to 310 MR 42.13(10)(a) of documents received within the last five years, and pursuant to 310 CMR 42.13(10)(b) of documents received by a current owner, director, and or supervisor within the past five years.

42.14: Maintenance of Records

(1) Certified laboratories shall maintain copies of all analytical reports, logs, charts and records created in accordance with 310 CMR 42.00 for a minimum of ten years or as otherwise specified by the Department. Records related to performance on proficiency tests shall be maintained for a minimum of five years. Records shall include the results and supporting documentation of analyses of samples including proficiency test samples, reagent blanks, laboratory fortified blanks, laboratory fortified sample matrices and duplicates, and surrogate analyte recovery data. Records of analysis of samples shall include documentation of sample preparation procedures, including, but not limited to, pH adjustments, distillations, digestions, extractions, and turbidity measurements.

(2) Certified laboratories shall record observations, data, and calculations at the time they are made. Handwritten records must be made in ink, not pencil. Mistakes in records shall be crossed out with a single line such that the original entry is still legible and the correct value entered. All alterations to records must be signed by the person making the correction. In the case of records stored electronically, equivalent measures must be taken to avoid loss or change of original data.

(3) Certified laboratories shall maintain current records of personnel, including a resume documenting education, training, experience, description of duties and dates of relevant employment for each employee.

(4) Certified laboratories shall maintain all records in accordance with the Department-approved QA plan for the laboratory. The laboratory must ensure that all records, including those stored electronically, are readable throughout the required retention time of the records.

42.15: Right of Entry

Agents and employees of the Department may make such inspections of laboratory property, facilities, or operations as the Department deems necessary to carry out its responsibilities under and ensure compliance with 310 CMR 42.00. The owner or operator of any laboratory subject to 310 CMR 42.00 shall allow such agent(s) or employee(s) free and unrestricted access at reasonable times to examine any property, facility, operation, equipment, or activity for determining compliance with 310 CMR 42.00. Such agent(s) and employee(s) may also inspect, conduct tests, and review books, papers, electronic documentation, data packages, and records relevant to the enforcement of 310 CMR 42.00.

42.16: Reciprocity

Certificates may be issued in a comparable classification without an inspection to any laboratory that holds a certification from the EPA or from its resident state if, in the opinion of the Department, the standards for certification under which such laboratory's certificate was issued are at least as stringent as those set forth in 310 CMR 42.00.

42.17: Orders, Violations, and Penalties

(1) Without limitation, the Department may issue orders or downgrade or revoke a certification as necessary to aid in the implementation and enforcement of M.G.L. c.21, §§ 26-53, M.G.L. c. 21A, § 2(28), M.G.L. c. 21C, § 4, M.G.L. c.21E, § 3, M.G.L. c. 111, §§ 142A-142E, 150A, 160, or 310 CMR 42.00. Such orders may include, but shall not be limited to, orders requiring persons to cease any activity which is in violation of the aforementioned statutes or 310 CMR 42.00 or to carry out activities necessary to bring such persons into compliance. The Department may also require any person to submit such information as the Department may reasonably require to evaluate whether that person is subject to, in compliance with, or in violation of the aforementioned statutes or 310 CMR 42.00.

(2) Violations. Without limitation, it shall be a violation of 310 CMR 42.00 for any person to:
   (a) Fail to comply with any order of the Department;
   (b) Engage in any activity that is contrary to the terms and conditions of 310 CMR 42.00, or of any certificate or order issued pursuant to 310 CMR 42.00;
   (c) Make any false, inaccurate, incomplete, or misleading statement in any application, record, report, plan, file, data package, log, register, or other document submitted to the Department or required to be kept by 310 CMR 42.00 or the terms of a certificate; or
   (d) Make any false, inaccurate, incomplete, or misleading statement in any record, report, plan, file, data package, log, register, or other document issued by or on behalf of a laboratory; or
   (e) Fail to provide any information requested by the Department, in a timeframe the Department specifies, pursuant to 310 CMR 42.00.

(3) Penalties. Any person violating 310 CMR 42.00 shall be subject to the full range of legal actions authorized by M.G.L. c. 21, § 42, M.G.L., c. 21A, § 16, M.G.L. c. 111, §§ 142A and 150A, 310 CMR 5.00, and any other applicable law or regulation including, without limitation, criminal fines, imprisonment, and civil and administrative orders and penalties.

42.18: Right to Appeal

Any person who has been denied certification or whose certification has been revoked may make a written request for an adjudicatory hearing before the Department pursuant to M.G.L. c. 30A and 310 CMR 1.01. The request for a hearing must be sent by certified mail or hand-delivered, and received by the Department within 21 calendar days of the date of receipt of the decision being appealed. The request for hearing shall state specifically, clearly, and concisely the facts which are the grounds for the appeal, the relief sought, and any additional information required by 310 CMR 1.01(6)(b) or other applicable law or regulation. In every proceeding the burden shall be on the applicant for, or the holder of, a certification to demonstrate compliance with 310 CMR 42.00.

42.19: List of Certified Laboratories

The Department shall publish or cause to be published at least annually a list of certified laboratories. This list shall include the name and location of the laboratory, the name of the director, and categories of analysis in which the laboratory has been granted certification.

42.20: Potable Water

(1) To receive certification to conduct analyses for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium, and thallium the laboratory must:

(a) Analyze Proficiency Test samples provided by EPA, the Department, or by a Department-approved third party; and

(b) Achieve quantitative results on the analyses that are within the following acceptance limits:

Contaminant	Acceptance Limit
Antimony	± 30% at ≥ 0.006 mg/L
Arsenic	± 30% at ≥ 0.003 mg/L
Asbestos	2 standard deviations based on study statistics
Barium	± 15% at ≥ 0.15 mg/L
Beryllium	± 15% at ≥ 0.001 mg/L
Cadmium	± 20% at ≥ 0.002 mg/L
Chromium	± 15% at ≥ 0.01 mg/L
Cyanide	± 25% at ≥ 0.1 mg/L
Fluoride	± 10% at 1 to 10 mg/L
Mercury	± 30% at ≥ 0.0005 mg/L
Nickel	± 15% at ≥ 0.01 mg/L
Nitrate	± 10% at ≥ 0.4 mg/L
Nitrite	± 15% at ≥ 0.4 mg/L
Selenium	± 20% at ≥ 0.01 mg/L
Thallium	± 30% at ≥ 0.002 mg/L

(2) To receive certification to conduct analyses for the contaminants in 310 CMR 42.19(2)(b) the laboratory must:

(a) Analyze Proficiency Test samples provided by EPA, the Department, or by a third party with the approval of the Department; and

(b) Achieve quantitative results on the analyses that are within the following acceptance limits:

Contaminant	Acceptance Limit (percent)
1,2-Dibromo-3-chloropropane (DBCP)	± 40
1,2-Dibromoethane (EDB)	± 40
Alachlor	± 45
Atrazine	± 45
Benzo[a]pyrene	2 standard deviations
Carbofuran	± 45
Chlordane	± 45
Dalapon	2 standard deviations
Di(2-ethylhexyl)adipate	2 standard deviations
Di(2-ethylhexyl)phthalate	2 standard deviations
Dinoseb	2 standard deviations
Diquat	2 standard deviations
Endothall	2 standard deviations
Endrin	± 30
Glyphosate	2 standard deviations
Heptachlor	± 45
Heptachlor epoxide	± 45
Hexachlorobenzene	2 standard deviations
Hexachlorocyclopentadiene	2 standard deviations
Lindane	± 45

Methoxychlor	± 45
Oxamyl(Vydate)	2 standard deviations
Polychlorinated biphenyls (as decachlorobiphenyl)	0-200
Picloram	2 standard deviations
Simazine	2 standard deviations
Toxaphene	± 45
Aldicarb	2 standard deviations
Aldicarb sulfoxide	2 standard deviations
Aldicarb sulfone	2 standard deviations

42.20: continued

Pentachlorophenol	± 50
2,4-Dichlorophenoxyacetic acid (2,4-D)	± 50
2-(2,4,5-Trichlorophenoxy)propionic acid (2,4,5-TP) (Silvex)	± 50

(3) To receive certification to conduct analyses for benzene, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethylene, p-dichlorobenzene, 1,1,1-trichloroethane, trichloroethylene, o-dichlorobenzene, cis-1,2-dichloroethylene, trans-1,2-dichloroethylene, 1,2-dichloropropane, ethylbenzene, monochlorobenzene, styrene, tetrachloroethylene, toluene, xylenes (total), dichloromethane, 1,2,4-trichlorobenzene, and 1,1,2-trichloroethane the laboratory must:

(a) Analyze Proficiency Test (PT) samples provided by EPA, the Department, or by a Department-approved third party;

(b) Achieve the quantitative acceptance limits on the analyses performed under 310 CMR 42.19(3)(a) for at least 80% of the regulated organic chemicals listed at 310 CMR 42.19(3);

(c) Achieve quantitative results on the analyses performed under 310 CMR 42.19(3)(a) that are within ± 20% of the actual amount of the substances in the PT sample when the actual amount is greater than or equal to 0.010 mg/L;

(d) Achieve quantitative results on the analyses performed under 310 CMR 42.19(3)(a) that are within ± 40% of the actual amount of the substances in the PT sample when the actual amount is less than 0.010 mg/L; and

(e) Achieve a method detection limit of 0.0005 mg/L according to the procedures in Appendix B of 40 CFR Part 136.

(4) To receive certification for vinyl chloride, the laboratory must:

(a) Analyze Proficiency Test samples provided by EPA, the Department, or by a Department-approved third party;

(b) Achieve quantitative results on the analyses performed under 310 CMR 42.19(4)(a) that are within ± 40% of the actual amount of vinyl chloride in the PT sample;

(c) Achieve a method detection limit of 0.0005 mg/L according to procedures in Appendix B of 40 CFR Part 136; and

(d) Obtain certification for the contaminants listed in 310 CMR 42.20(3).

(5) To receive certification for total trihalomethanes (chloroform, bromodichloromethane, dibromochloromethane, and bromoform), haloacetic acids (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid, known collectively as HAA5), bromate, and chlorite the laboratory must:

(a) Analyze Proficiency Test (PT) samples approved by the Department at least once each calendar year by each method for which the laboratory desires certification;

(b) Achieve quantitative results within the acceptable limit for each analyte included in each PT sample and, for haloacetic acids, on a minimum of 80% of the analytes included in each PT sample. The acceptance limit is defined as ± 20 percent of the true value for each of the trihalomethanes; ± 40 percent of the true value for each of the haloacetic acids; ± 30 percent of the true value for chlorite; and ± 30 percent of the true value for bromated;

(c) Report quantitative data for concentrations at least as low as the regulatory minimum reporting level of 0.0010 mg/L for each of the trihalomethanes, 0.0020 mg/L for monochloroacetic acid, 0.0010 mg/L for dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid, 0.020 mg/L for chlorite, and 0.0050 mg/L for bromate (0.0010 mg/L for laboratories using EPA Methods 317 Revision 2.0, 326.0 or 321.8);

(d) Use calibration curves for the analysis of trihalomethanes, haloacetic acids, bromate, and chlorite that encompass the regulatory minimum reporting level (MRL) concentration. Data may be reported for concentrations lower than the regulatory MRL as long as the precision and accuracy criteria are met by analyzing an MRL check standard at the lowest reporting limit chosen by the laboratory. The laboratory must verify the accuracy of the calibration curve at the MRL concentration by analyzing an MRL check standard with a concentration less than or equal to 110% of the MRL with each batch of samples. The measured concentration for the MRL check standard must be ± 50% of the expected value if any field sample in the batch has a concentration less than 5 times the regulatory MRL. Method requirements to analyze higher concentration check standards and meet tighter acceptance criteria for them must be met in addition to the MRL check standard requirement; and

(e) When adding the individual trihalomethane or haloacetic acid concentrations in order to calculate the total trihalomethane or HAA5 concentrations, respectively, use a zero for any analytical result that is less than the MRL concentration for that particular analyte.

(6) To receive certification to conduct analyses for perchlorate, the laboratory must:

(a) Analyze PT samples approved by the Department;

(b) Achieve quantitative results within the acceptable limit for this analyte in each PT sample. The acceptance limit is defined as the 95% confidence interval calculated around the mean of the PT study data;

(c) Use analytical methods acceptable to the Department; and

(d) Comply with specific Department policies regarding quality assurance/quality control and data reporting procedures for this analyte.

(7) To receive certification to conduct analyses for 1,4-dioxane, the laboratory must:

(a) Analyze PT samples approved by the Department;

(b) Achieve quantitative results within the acceptable limit for this analyte in each PT sample. The acceptance limit is defined as the 95% confidence interval calculated around the mean of the PT study data; and

(c) Use analytical methods, quality assurance/quality control protocols, and data reporting procedures acceptable to the Department.

(42.21: Non-Potable Water. Reserved)

42.22: Severability

If any provision of 310 CMR 42.00, or its application to any person, is held invalid, such invalidity shall not affect other provisions or applications of 310 CMR 42.00 which can be given effect without the invalid provision or application, and to this end the provisions of 310 CMR 42.00 are declared to be severable.

REGULATORY AUTHORITY

310 CMR 42.00: M.G.L. c. 21, §§ 26 through 53; c. 21A, § 2(28); c. 21C, § 4; c. 21E, § 3; c. 111, §§ 142A through 142E, 150A and 160.

NON-TEXT PAGE