

SUBPART 55-2

APPROVAL OF LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

(Statutory Authority: Public Health Law, Section 502)

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EFFECTIVE DATES

Sections 55-2.1 through 55-2.9, 55.2.11 and 55-2.12 effective November 17, 2004

Sections 55-2.10, 55-2.13 and 55-2.14 effective June 16, 2010

Section 55-2.1 Definitions.

For purposes of this Subpart, unless the context indicates otherwise, the following terms shall have the following meanings:

(a) Environmental laboratory means any facility that examines, or is available for the examination of samples or specimens, including, but not limited to: air, stack emissions, water, wastewater, surface water, ground water, recreational waters, swimming pools, leachate, land runoff, solid waste, hazardous waste, soil, sediments and vegetation, as well as any substance that could contribute to the pollution of or that could be contaminated by material contained in such samples or specimens. Such examinations shall be limited to qualitative or quantitative determinations of the biological, chemical, radiochemical or physical characteristics of such samples or specimens for the purposes of public or personal health protection, or the protection of the environment or natural resources. Environmental laboratories shall not include facilities or entities that perform non-laboratory chemical testing associated with residential water softeners and residential swimming pools. Environmental laboratories shall include mobile laboratories, as defined in subdivision (c) of this section.

(b) Approved laboratory means an environmental laboratory that has demonstrated to the New York State Commissioner of Health that it has met the on-site assessment, technical direction and proficiency testing requirements of this Subpart, and therefore has been issued a certificate of approval. For purposes of this Subpart, accredited shall have the same meaning as approved.

(c) Mobile laboratory means a separate, self-contained mobile facility for the examination of environmental samples or specimens as described in subdivision (a) of this section. A mobile laboratory shall have a fixed address, provided to the department with each application for approval, to which proficiency test samples and other correspondence may be sent, and shall be managed by a responsible person authorized to receive service of process.

(d) Technical director means an individual responsible for the technical and scientific operation of an environmental laboratory, and who meets the minimum qualifications in section 55-2.10 of this Subpart. If an environmental laboratory employs more than one technical director, the laboratory owner(s) shall designate one such individual as the lead technical director.

(e) Approved method means an analytical method, including sample preparation, of

proven reliability, which has been approved, or given similar recognition by the United States Environmental Protection Agency (EPA) or a New York State regulatory program in environmental or public health protection, for the specific purpose for which the method is to be used. Methods approved by the department pursuant to section 55-2.5 of this Subpart shall be deemed approved methods. The department shall make available a list of approved methods to approved laboratories.

(f) Quality system means a structured laboratory management system that meets the standards for a quality system as set forth in the department's Environmental Laboratory Approval Program Quality System Standards 2002, July 1, 2002 revision, which is hereby incorporated by reference, with the same force and effect as if fully set forth herein. These standards are available for public inspection and copying at the New York State Department of Health, Records Access Office, Corning Tower, Empire State Plaza, Albany, New York 12237.

(g) Analyte means a chemical and/or physical property, element, compound, group of compounds, organism or group of organisms, to be determined in samples examined. Sample and specimen are synonymous terms, and are used interchangeably in this Subpart.

(h) Statistical mean means the arithmetic average of a data set after outlier rejection, or, if transformation is used, the central point of data set distribution after outlier rejection.

(i) Method detection limit means the minimum concentration of an analyte that can be measured and reported with 99-percent confidence that the analyte concentration is greater than zero, as defined or stated in the least sensitive approved method.

(j) Assigned value means the nominal concentration of an analyte, based on sample preparation.

(k) Relative standard deviation means the standard deviation of a data set divided by the statistical mean, expressed as a percentage. Predictive standard deviation means the standard deviation derived from a linear regression equation based on historical data.

(l) Synthetic blank means an artificial sample with contents of known purity and without added analytes.

(m) Natural blank means a sample derived from the environment, for which the concentration of a given analyte or analytes, after repeated analyses, has been determined to be below the method detection limit.

(n) Spiked sample means a sample to which a known amount of an analyte has been

added.

(o) Natural sample means a sample collected from the environment, to which no analytes have been added.

(p) Contract laboratory protocol (CLP) means a protocol, issued by the New York State Department of Environmental Conservation, for performance of environmental analyses in accordance with specifications describing: the types of samples to be analyzed (such as soil or water); internal sample-handling procedures (such as chain-of-custody or holding times); instrumentation and method of analysis to be used for each analyte; calibration procedures to be implemented (such as numbers of standards, their concentrations and acceptance criteria); quality control samples to be analyzed and the frequency of such analysis; and organization and content of reports to be issued on analytical results obtained.

(q) CLP data package means a collection of documentation whose organization and content are specified by CLPs. A CLP data package shall consist of analytical reports, including, but not limited to, a narrative description of how the analysis was performed, any problems encountered, analytical results for all samples, results for all quality control samples analyzed, copies of instrument printouts, and all logbook pages and laboratory bench sheets.

(r) Department means the New York State Department of Health.

(s) Denial means the department's refusal to approve, in total or in part, an environmental laboratory's application for approval, including resubmission of an initial or renewal application.

(t) Suspension means the department's temporary removal, in total or in part, of an environmental laboratory's approval for a defined period of time not exceeding six (6) months, to allow such laboratory time to correct deficiencies or areas of non-compliance.

(u) Revocation means the department's withdrawal, in total or in part, of an environmental laboratory's approval.

Section 55-2.2 Certificates of approval.

(a) Certificates of approval shall be issued to environmental laboratories in one or more categories, including, but not limited to:

(1) examination of potable water, including, but not limited to, the analytes listed in Part 5 of the New York State Sanitary Code;

(2) examination of nonpotable water, such as wastewater and samples for water quality

monitoring of lakes, streams and rivers;

(3) examination of solid waste, soil and sediment, including, but not limited to, hazardous wastes (see New York State Environmental Conservation Law article 27);

(4) examination of air; and

(5) examination of any sample, specimen or substance listed or otherwise described in section 502 of the Public Health Law.

Certificates of approval shall limit approval to specific analytes within one or more of the above categories.

(b) A certificate of approval issued to an environmental laboratory shall set forth:

(1) the nature of the approval (interim or full);

(2) the approved categories and analytes;

(3) the name of the laboratory lead technical director as defined in section 55-2.1 of this Subpart; and

(4) the expiration date of the approval, which date shall be no later than one year from the date the certificate of approval is issued, unless an earlier date is set forth on the certificate.

(c) All examinations conducted by an environmental laboratory shall employ approved methods, and shall be within the categories listed on the laboratory's current certificate of approval or on any appendices thereof. A laboratory shall employ only approved methods for which a demonstration of capability has been conducted at the same site where the method is employed.

(d) Current certificates of approval and any appendices shall be posted conspicuously in the environmental laboratory, and a copy shall, upon request, be provided by the laboratory to any person or entity requesting the services of the laboratory.

Section 55-2.3 Application for approval.

(a) (1) An application for a certificate of approval shall be submitted to the department by the owner(s) and technical director(s) of an environmental laboratory on a form prescribed by the department. No certificate of approval shall be granted to any laboratory failing to supply all the information requested on the application form.

(2) For each category for which approval is sought, the application for approval shall specify the analytes to be determined, the types of sample(s) to be analyzed (such as soil or

water), and the approved methods to be employed for each analyte/sample type.

(3) The department may require additional information regarding the laboratory, including, but not limited to, its ownership, organization, quality system, testing program, premises, qualifications of personnel, equipment, method of reporting results of analyses, and number of analyses performed each calendar year.

(b) Upon receipt of such application, the department shall review the laboratory's performance in required proficiency testing, quality system documentation, technical director(s) credentials, previous performance in on-site assessments, if applicable, and any additional materials and/or information requested, and shall determine whether the applicant laboratory qualifies for a certificate of approval, the analytes by category for which approval is to be issued, and the approval fee to be paid. Prior to issuance or renewal of a certificate of approval, the approval fee shall be paid, unless otherwise expressly authorized by the department pursuant to Subpart 55-3 of this Part.

(c) For purposes of the application and approval process, testing facilities housed in separate buildings shall be considered separate environmental laboratories, unless such facilities obtain a waiver for this requisite from the department. The requirements of this subdivision shall not be waived unless the department determines that:

(1) effective supervision of the operation of all such facilities can be exercised by the same technical director(s);

(2) the facilities do not duplicate each other's analytical, reporting and/or record keeping activities; and

(3) the facilities are owned by the same legal entity.

Section 55-2.4 Approval criteria.

(a) In such form as may be prescribed by the department, the environmental laboratory owner(s) and technical director(s) shall attest to the following:

(1) the laboratory will be operated in accordance with section 502 of the Public Health Law, the provisions of this Title and/or section 3-0119 of the New York State Environmental Conservation Law;

(2) the laboratory will employ approved methods and will document information pertinent to the approval, demonstration of capability, and use of each method;

(3) records will be maintained for not fewer than five (5) years and shall identify precisely the samples collected, accepted and examined; and procedures used and personnel involved; and shall document test conditions, observations and results of analyses, except that records of chemical analyses related to potable water supplies shall be maintained for not fewer than 10 (ten) years and records of analyses related to critical agents shall be maintained as required in section 55-2.13 of this Subpart;

(4) the technical director(s) will develop, implement and document a quality system as defined in this Subpart; and

(5) the owner shall notify the department if the laboratory is found to be in violation of any federal, state or local law related to the provision of environmental laboratory services or reimbursement for such services, by the federal, state or local agency enforcing that law.

(b) Approval shall be granted to an environmental laboratory for the analytes by categories sought in the application for approval, provided:

(1) the laboratory submits a complete application, including the attestation specified in subdivision (a) above and any additional information required by the department to support the application, and remits to the department the approval fee pursuant to Subpart 55-3 of this Part, unless otherwise expressly authorized by the department;

(2) each proposed technical director submits documentation of his or her qualifications for evaluation by the department, and the department finds such individual(s) qualified pursuant to section 55-2.10 of this Subpart;

(3) the laboratory provides documentation of a quality system in compliance with this Subpart;

(4) pursuant to section 55-2.8, the laboratory participates and performs satisfactorily in proficiency testing for the analytes for which it seeks approval;

(5) except as provided in subdivision (c) of this section, the laboratory undergoes an on-site assessment conducted by the department or by a state regulatory program recognized by the department pursuant to section 55-2.9; the findings of the on-site assessment(s) confirm compliance with the staffing, methodological and other requirements of this Subpart; and the laboratory demonstrates effective implementation of its quality system for planning and assessing the work performed by the laboratory, and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test

results;

(6) the laboratory provides entry to representatives of the department and/or of a state regulatory program recognized by the department, for on-site assessments during normal business hours; and

(7) the department finds the owner(s) and technical director(s) to be of good character and competence after evaluation of factors including, but not limited to:

(i) prior sustained charges of administrative violations of state or federal laws, rules and regulations related to the provision of environmental laboratory services or reimbursement for such services, against the owner or a technical director listed on the application, individually or jointly, or against any laboratory owned or directed by an owner or a technical director listed on the application, or findings by a municipality that a laboratory owned or directed by an owner or technical director listed on the application has violated a local ordinance relating either to collection and analysis of samples, or to reporting of results for the examination of said samples;

(ii) conviction of any crime, including, but not limited to, any offense related to furnishing of, or billing for, environmental laboratory services, which is considered an offense involving theft or fraud;

(iii) consideration of whether any environmental laboratory directed by a technical director listed on the application has demonstrated a pattern of repetitive unsatisfactory performance in required proficiency testing in one or more proficiency testing categories, excluding an unsatisfactory score for administrative reasons such as late result submission;

(iv) consideration of whether any laboratory owned or directed by an owner or a technical director listed on the application has misrepresented any material fact pertinent to obtaining or retaining approval including, but not limited to, falsification of any report on or related to laboratory analysis, or submission of any reports on laboratory work, including work both on samples and proficiency testing, actually performed in another laboratory, without disclosing the fact that the examinations or procedures were performed in another laboratory;

(v) evidence of aiding and/or abetting in the violation of any of the provision of this Subpart; and

(vi) any other factor having a direct bearing on the ability of the owner(s) and technical director(s) listed on the application to provide, direct or supervise the provision of high quality environmental laboratory services, or to ensure compliance with applicable statutory and

regulatory requirements.

(c) Interim approval. (1) A laboratory that has not undergone an on-site assessment may be granted interim approval, for a period not to exceed twelve (12) months, provided all other requirements for approval in subdivision (b) above are met.

(2) A laboratory with interim approval shall be granted full approval in the categories and analytes for which it seeks approval provided the findings of on-site assessment(s) as described in section 55-2.7 of this Subpart confirm compliance with the staffing, methodological and other requirements of this Subpart, and the laboratory demonstrates effective implementation of its quality system for planning and assessing work performed by the laboratory, and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results.

Section 55- 2.5 Department approval of methods.

(a) A laboratory shall obtain department approval prior to performing a laboratory-developed method, or other method not otherwise approved or given similar recognition as described in section 55-2.1(e) of this Subpart. The department may approve such a method, provided the laboratory submits data and other information as required supporting the technical merit of the method, and demonstrating that that the method's precision and accuracy are equivalent or superior to that of an approved method. Such data and information shall include, but not be limited to:

(1) a description of the method, including analyte, sample type, working range, reagents and their preparation, equipment specifications, analytical procedures, precision, accuracy, related calculations, intended purpose and pertinent literature citations;

(2) the anticipated date of method implementation;

(3) comparative data, including: sample source(s), dates and times collected, and matrix; whether the sample was spiked, and, if so, the spiking procedure; the approved method used; and analytical results for both the approved method and the method submitted for approval;

(4) data from inter-laboratory comparisons, demonstrating the method's reproducibility;

(5) demonstration of capability data; and

(6) any other information pertinent to the department's determination of the method's technical merit.

(b) Provided all other requirements of subdivision (a) above are met, the department may approve a method for which reproducibility has not been demonstrated by inter-laboratory comparisons if the laboratory demonstrates that its performance of the method is technically acceptable for the intended sample types and analytical purpose. Such approval shall be limited to the laboratory which applied for such approval.

(c) In addition to the requirements of subdivisions (a) and (b) above, the department may require successful completion of on-site demonstration analysis on samples designed to challenge the procedure.

(d) The department shall respond to a laboratory's request for method approval, notifying the laboratory of method approval, method approval contingent upon approval by the EPA, proposed denial of the request, or the need for further information.

(e) If the department proposes to deny a request for method approval, it shall advise the laboratory of such proposed denial and the reasons for the denial. A proposed denial shall become final thirty (30) calendar days from the date of notice of proposed denial, unless the laboratory submits, within thirty (30) calendar days of the date of such notice, a written request for reconsideration, including all documentation and rationale in support of such request. Within thirty (30) calendar days of the date the department receives a request for reconsideration, the department shall issue a final determination concerning the request for reconsideration.

(f) Notwithstanding the provisions of this Subpart, the department may conduct an independent review of any approved method to substantiate or refute its technical merit. If the method's technical merit is found to be lacking, the department shall notify the affected laboratory(ies) of its proposed determination that the method may not be performed under a New York State environmental laboratory certificate of approval, giving the reasons for such determination. Such proposed determination shall become final thirty (30) calendar days from the date of the notice of proposed determination, unless the laboratory(ies) offering such method submits, within thirty (30) calendar days of the date of the notice, a written request for reconsideration, including all documentation and rationale in support of such request. Within thirty (30) calendar days of the date of department receipt of a request for reconsideration, the department shall issue a final decision regarding the request for reconsideration.

(g) All information and data pertinent to method approval shall be documented, and be made available for department review upon on-site assessment or upon request for a minimum of

two (2) years after the date of the method's discontinuation.

Section 55-2.6 Denial, suspension and revocation of department approval.

(a) The department may deny an environmental laboratory's application for a certificate of approval for the following reasons:

(1) except as provided in section 55-2.4(c), failure to undergo an on-site assessment conducted by the department or by a state program recognized by the department pursuant to section 55-2.9 of this Subpart or failure to demonstrate, during any on-site assessment so conducted: compliance with the staffing, methodological and other requirements of this Subpart; and effective implementation of a quality system for planning and assessing work performed by the laboratory and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results;

(2) failure to participate or perform satisfactorily in proficiency testing pursuant to section 55-2.8 of this Subpart for the analytes for which the laboratory seeks approval;

(3) failure of the laboratory technical director(s) to meet the required qualifications in section 55-2.10 of this Subpart;

(4) misrepresentation of any material fact pertinent to obtaining or retaining approval for any laboratory owned or directed by an owner or technical director listed on the application including, but not limited to, falsification of any report on or related to a laboratory analysis or submission of proficiency test results which were, in fact, generated by a laboratory other than the laboratory to which the samples were distributed;

(5) failure to submit a complete approval application, including the attestation required in section 55-2.4(a) of this Subpart, or failure to provide documentation of a quality system as defined in this Subpart or any additional information required by the department to support the application;

(6) failure to remit the required fees;

(7) the owner(s) and/or technical director(s) listed on the application are determined by the department to lack the character and competence necessary to ensure compliance with the applicable laws, rules and regulations after consideration of factors including but not limited to:

(i) evidence of aiding and/or abetting in violation of any of the provisions of this Subpart;

(ii) prior sustained charges of administrative violations of state or federal laws, rules and regulations related to the provision of environmental laboratory services or reimbursement for such services, against the owner or a technical director, individually or jointly, or against any laboratory owned or directed by an owner or technical director listed on the application, or a finding by a municipality that a laboratory has violated a local ordinance related to collection and analysis of samples or specimens, or to reporting of results for examination of said samples or specimens;

(iii) conviction of any crime, including, but not limited to, any offense related to furnishing of, or billing for, environmental laboratory services, which is considered an offense involving theft or fraud;

(iv) consideration of whether any environmental laboratory directed by a technical director listed on the application has demonstrated a pattern of repetitive unsatisfactory performance in required proficiency testing in one or more proficiency testing categories, excluding an unsatisfactory score for administrative reasons such as late result submission; and/or

(v) any other factor having a direct bearing on the ability of the owner(s) and technical director(s) listed on the application to provide, direct or supervise the provision of high quality environmental laboratory services, or to ensure compliance with applicable statutory and regulatory requirements;

(8) failure to respond to an on-site assessment report with a corrective action plan within the required thirty (30) calendar days after receipt of the report;

(9) failure to respond to an on-site assessment report with an acceptable corrective action plan within the specified timeframe;

(10) failure to implement the responsive actions detailed in the corrective action plan within the specified timeframe; and/or

(11) denial of entry to representatives of the department or of a state program recognized by the department pursuant to section 55-2.9 of this Subpart, for on-site assessment during normal business hours.

(b) (1) If the department proposes to deny an environmental laboratory's application for a certificate of approval, the laboratory shall be given written notice of the proposed denial, stating the reason or reasons for such proposed denial. Such notice shall be sent by certified mail and

shall be a final determination to be effective thirty (30) days from the date of the notice, unless reconsideration is requested;

(2) if the department gives notice of proposed denial, the laboratory may request reconsideration of the proposed denial by submitting a written request for reconsideration to the department within thirty (30) days of the date of the notice of proposed denial. Submission of a request for reconsideration within thirty (30) days shall stay any action to deny a laboratory's application for a certificate of approval, pending the department's decision regarding such request for reconsideration;

(3) the written request for reconsideration shall be signed by the owner(s) and technical director(s), and shall include all information the owner(s) and technical director(s) wish to be considered, including any written documentation that would controvert the reason(s) for the denial or disclose that the denial was based upon a mistake of fact;

(4) if the laboratory properly seeks reconsideration of the proposed denial, the department shall review its proposed denial and shall issue a written determination after reconsideration. The determination after reconsideration may affirm, revoke or modify the proposed denial, allow issuance of a certificate of approval conditional on maintenance of corrective action, or require that the laboratory take corrective action. Such determination shall be the final decision of the department.

(c)(1) An environmental laboratory's certificate of approval shall be suspended automatically upon a change in laboratory ownership, technical direction, or location. However, provided re-application has been made in writing to the department within thirty (30) calendar days of the change, the department may extend an environmental laboratory's certificate of approval for a period not to exceed ninety (90) calendar days after any change in laboratory ownership, technical direction or location, in order to permit the department to evaluate, as applicable, the character and competence of the new technical director(s) and/or new owner(s) considering requirements in section 55-2.4(b) of this Subpart; the qualifications of the new technical director(s); and/or the effect of the change in location on the environmental laboratory's ability to produce accurate and reliable analytical data.

(2) An environmental laboratory's certificate of approval shall be suspended automatically upon failure to remit at least the quarterly payment of the annual approval fee pursuant to Subpart 55-3 of this Part, unless otherwise expressly authorized by the department.

(3) An environmental laboratory's certificate of approval shall be suspended automatically, in affected analytes and/or categories, for failure to maintain a record of at least two (2) satisfactory proficiency testing (PT) events within the three (3) most recent PT events.

(4) (i) The department may suspend an environmental laboratory's certificate of approval, in affected analytes and/or categories, for reasons including:

(a) a pattern of deficiencies on on-site assessment or other demonstration that the laboratory lacks an effective quality system for planning and assessing work performed by the laboratory, and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results; and

(b) failure to notify the department of any change in major analytical instrumentation within thirty (30) calendar days of the change;

(ii) if the department proposes to suspend a laboratory's certificate of approval, the laboratory shall be given written notice of the proposed suspension, stating the reason or reasons for such proposed suspension. Such notice shall be sent by certified mail and shall be a final determination to be effective ten (10) days from the date of the notice, unless reconsideration is requested. A laboratory may request reconsideration of the proposed suspension by submitting a written request for reconsideration to the department within ten (10) days of the date of the notice of proposed suspension. Submission of a request for reconsideration within ten (10) days shall stay any action to suspend department approval, pending the department's decision regarding such request for reconsideration. The written request for reconsideration shall be signed by the owner(s) and the technical director(s) designated responsible for the affected category(ies), and shall include all information the owner(s) and technical director(s) wish to be considered, including any written documentation that would controvert the reason(s) for the suspension or disclose that the suspension was based upon a mistake of fact. The department shall review its proposal to suspend approval and shall issue a written determination after reconsideration. The determination after reconsideration may affirm, revoke or modify the proposed suspension, allow retention of the certificate of approval conditional on maintenance of corrective action, or require that the laboratory take corrective action. Such determination shall be the final decision of the department.

(5) An environmental laboratory whose certificate of approval is suspended pursuant to paragraphs (3) or (4) above shall retain approval for the analytes and/or categories for which it

continues to meet department requirements. A laboratory so suspended shall discontinue analysis of samples for the analytes and/or categories affected by the suspension, as of the date of the suspension.

(6) The department shall change a laboratory's certification status from suspended to approved upon receipt of sufficient documentation to permit the department to determine that the conditions meriting suspension no longer exist, and the laboratory meets the criteria for a certificate of approval in section 55-2.4 of this Subpart.

(7) Notwithstanding any of the provisions of this subdivision, the Commissioner of Health may suspend a laboratory's certificate of approval pursuant to the summary action provisions of Public Health Law section 16.

(d) (1) The department may revoke an environmental laboratory's certificate of approval in affected analytes and/or categories for reasons including:

(i) failure to respond to an on-site assessment report with an acceptable corrective action plan within the specified timeframe;

(ii) a pattern of deficiencies on on-site assessment, or other demonstration that the laboratory lacks an effective quality system for planning and assessing work performed by the laboratory, and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results;

(iii) failure to implement the responsive actions detailed in the corrective action plan within the specified timeframe;

(iv) failure to correct the deficiencies meriting suspension within six (6) months of the effective date of the suspension; or

(v) for an environmental laboratory suspended pursuant to section 55-2.6(c)(3) of this Subpart, unsatisfactory performance in the next PT event results in three (3) consecutive failed PT events.

(2) An environmental laboratory whose certificate of approval is revoked pursuant to paragraph (1) above shall retain approval for the analytes and/or categories for which it continues to meet department requirements, and may reapply for approval once the deficiencies meriting revocation have been corrected.

(3) The department may revoke an environmental laboratory's certificate of approval, in total, for reasons including:

(i) failure to respond to an on-site assessment report with a corrective action plan within the required thirty (30) calendar days after receipt of the report;

(ii) failure to participate in a PT program acceptable to the department;

(iii) falsification of any report on or related to a laboratory analysis, including, but not limited to, submission of proficiency test results which were, in fact, generated by a laboratory other than the laboratory to which the samples were distributed;

(iv) misrepresentation of any material fact pertinent to obtaining or maintaining approval;

(v) denial of laboratory entry to representatives of the department or of a state program recognized by the department pursuant to section 55-2.9 of this Subpart for on-site assessment during normal business hours;

(vi) sustained charges of administrative violations of state or federal laws, rules and regulations related to the provision of environmental laboratory services, or reimbursement for such services, against the owner(s) or technical director(s), individually or jointly, or against any laboratory owned or directed by such individuals;

(vii) conviction of any crime, including, but not limited to, any offense related to furnishing of, or billing for, environmental laboratory services, which is considered an offense involving theft or fraud;

(viii) failure to remit the annual approval fee, or, for partial fee payments, failure to remit such payments within the timeframes established by the department;

(ix) aiding and/or abetting in the violation of any of the provisions of this Subpart; and/or

(x) a finding by a municipality that the environmental laboratory has violated a local ordinance related either to collection and analysis of samples or specimens, or to reporting of results for examination of such samples or specimens.

(4) If an environmental laboratory's certificate of approval has been revoked pursuant to paragraph (3) above and the department finds that the violation was willful, or due to recklessness or gross negligence, no application shall be accepted, for a period of time to be determined by the Commissioner of Health or his or her designee, from any person who was an owner or technical director of such laboratory on the date of notification of proposed approval revocation.

(e) No environmental laboratory's certificate of approval may be revoked without a hearing or an opportunity for a hearing. The environmental laboratory shall be given written

notice of proposed revocation, stating the reason(s) for the department's proposed action. Such notice shall be sent by certified mail and shall be a final determination, to be effective thirty (30) calendar days from the date of the notice, unless a hearing is requested by the laboratory. The environmental laboratory may request a hearing by submitting a written request for a hearing, signed by both the owner(s) and the technical director(s) designated responsible for the affected category(ies), within ten (10) calendar days of the date of the department's notice of proposed revocation. Approval shall be automatically suspended while any hearing requested is pending, provided the hearing is scheduled to begin within ninety (90) calendar days of the request for such hearing.

(f) An environmental laboratory whose certificate of approval has been revoked shall submit a new application for approval and shall meet all criteria for approval provided in section 55-2.4 of this Subpart to be issued a certificate of approval. The department may conduct an on-site assessment of the environmental laboratory before acting on such application.

Section 55-2.7 Laboratory on-site assessments.

(a) An environmental laboratory seeking or holding a certificate of approval under this Part shall, as a condition of approval, permit on-site assessments to be conducted by the department or by a state program recognized by the department pursuant to section 55-2.9 during the laboratory's normal business hours.

(b) The factors to be considered during on-site assessments shall include, but not be limited to, the competence and qualifications of staff, adequacy of facilities and equipment, appropriateness of sampling protocols, use of approved methods, and the laboratory's quality system, including, but not limited to, quality assurance and quality control procedures, and record keeping and reporting practices, as specified in this Subpart.

(c) Each environmental laboratory shall, following each on-site assessment, be furnished with an assessment report which shall set forth the findings of the on-site assessment and any deficiencies to be corrected.

(d) Environmental laboratories located outside of the State of New York shall be assessed the approval fee specified in Subpart 55-3 of this Part, as well as additional expenses incurred by the department in conducting on-site assessments of each laboratory . Such on-site assessments shall not be performed before the department receives payment for such additional

costs.

(e) If deficiencies are found during an on-site assessment, the environmental laboratory may be granted a grace period not to exceed ninety (90) calendar days from the date of notification to correct the deficiencies, provided that, within thirty (30) calendar days of such notification, the laboratory submits to the department or recognized state program performing the assessment a written plan of correction to be implemented within ninety (90) calendar days. If, at the end of the grace period, any of the deficiencies found remain uncorrected, the certificate of approval shall be revoked in affected analytes and/or categories pursuant to section 55-2.6 of this Subpart. If the deficiencies found do not necessarily or immediately affect either the accuracy or reliability of results, and if the environmental laboratory demonstrates in writing that corrections of deficiencies have been delayed for reasons beyond its control, the grace period granted pursuant to this subdivision may be extended further for a period not to exceed ninety (90) calendar days. Such extension may not be renewed further.

Section 55-2.8 Proficiency testing.

(a) Environmental laboratories shall examine proficiency test samples supplied by the department or by a proficiency testing provider recognized by the department pursuant to subdivision (i) of this section. Laboratories shall conduct the specified examinations and submit the results to the proficiency sample provider for all analytes for which the laboratories are approved or are seeking approval, and for which samples have been supplied.

(1) The department shall announce its schedule for mailed proficiency test sample distribution as soon as practicable after the first day of each approval year. Distribution frequency and dates shall be included in this announcement. The department shall specify, in letters distributed with samples, the department's test result scoring criteria. Laboratories participating in the department's proficiency testing program, shall report test results to the department no later than on the dates specified by the department for each manner of result submission (i.e., hardcopy or electronic). No extensions shall be granted. Laboratories whose results are received after the deadline shall be considered to have achieved unsatisfactory performance in the proficiency test event. Laboratories participating in a recognized proficiency testing provider(s)' proficiency testing program, other than the department's program, shall arrange with that provider to have test results forwarded to the department.

(2) To obtain or maintain approval for a given analyte, an environmental laboratory shall attain satisfactory performance in at least two (2) of three (3) consecutive scheduled or unscheduled proficiency test events in which it has participated. Such events shall take place at least thirty (30) calendar days apart.

(3) To obtain or maintain approval for the potable water - total coliforms analyte, for which proficiency testing requires qualitative analysis, an environmental laboratory shall maintain a score of at least ninety (90) percent, without reporting a false negative result for at least two (2) of three (3) consecutive scheduled or unscheduled proficiency test events in which it has participated. Such events shall take place at least thirty (30) calendar days apart.

(4) To obtain or maintain approval in contract laboratory protocol (CLP) analyses, an environmental laboratory shall be evaluated on both proficiency testing performance and conformity to the contract requirements of the CLP data package submitted.

(b) Performance in examining an individual chemical or physical analyte shall be evaluated as follows, for a natural blank test sample:

(1) Satisfactory performance shall be a result, reported with or without the term “less than,” and having a value less than or equal to the detection limit specified by the department, or, if no detection limit is specified, the method detection limit.

(2) Unsatisfactory performance shall be a result, reported with or without the term “less than,” greater than the detection limit specified by the department, or, if no detection limit is specified, the method detection limit.

(c) Performance in examining an individual chemical or physical analyte shall be evaluated as follows, for a synthetic blank test sample:

(1) Satisfactory performance shall be a result reported with the term “less than,” and having a value less than or equal to the detection limit specified by the department, or, if no detection limit is specified, the method detection limit.

(2) Unsatisfactory performance shall be a result reported with or without the term “less than,” and having a value greater than the detection limit specified by the department, or, if no detection limit is specified, the method detection limit.

(d) Performance in examining an individual chemical or physical analyte shall be evaluated as follows, for a spiked or natural test sample:

(1) For data sets examined by the standard statistical procedures described in subdivision

(g) of this section and having a relative standard deviation lower than 34 percent:

(i) Satisfactory performance shall be a result within the 99-percent confidence interval about the statistical mean.

(ii) Unsatisfactory performance shall be a result outside the 99-percent confidence interval about the statistical mean.

(2) For data sets examined by the standard statistical procedures described in subdivision (g) of this section but having a relative standard deviation of 34 percent or higher, the relative standard deviation of the data set used for determining the 99-percent confidence interval shall be set at 34 percent, or a value derived from the scientific literature. Satisfactory and unsatisfactory performance shall be as described in paragraph (1) of this subdivision.

(3) For data sets evaluated by using a reference laboratory panel, the statistical mean and 99-percent confidence interval shall be derived from the reference laboratory data set, after standard statistical analysis. Satisfactory and unsatisfactory performance shall be as described in paragraph (1) of this subdivision.

(4) For data sets evaluated using an interval about the assigned value and defined by a fixed percentage of the assigned value, fixed percentages shall be set based on the department's determination of the reliability, precision and accuracy of the methods used, and:

(i) Satisfactory performance shall be a result within the fixed percentage interval about the assigned value.

(ii) Unsatisfactory performance shall be a result outside the fixed percentage interval about the assigned value.

(5) For data sets evaluated using published linear regression equations to predict the mean and standard deviations:

(i) Satisfactory performance shall be a result within the interval of the predictive mean, plus or minus two (2) predictive standard deviations for potable water analytes, or plus or minus three (3) predictive standard deviations for other matrices.

(ii) Unsatisfactory performance shall be a result outside the interval described in paragraph (i) above.

(e) Performance in examining an individual bacteriological analyte for which quantitation is required shall be evaluated as follows:

(1) For negative coliform and/or standard plate count test samples, including sterile

samples, samples containing bacteria not detectable by the method and samples containing bacteria not producing positive reactions with the required verification procedures, satisfactory performance shall be a result reported as a value lower than the method detection limit.

Unsatisfactory performance shall be any other result.

(2) Performance in examining an individual bacteriological analyte for which quantitation is required shall be evaluated as follows, for a positive inoculated test sample:

(i) Satisfactory performance shall be a result within the 99-percent confidence interval about the statistical mean for Most Probable Number (MPN) and Membrane Filter (MF) coliform data, and within the 95-percent confidence interval about the statistical mean for standard plate count data.

(ii) Unsatisfactory performance shall be a result outside the 99-percent confidence interval about the statistical mean for MPN or MF coliform data, and within the 95-percent confidence interval about the statistical mean for standard plate count data.

(f) The statistical mean and the confidence intervals used to determine satisfactory and unsatisfactory performance for spiked and natural chemical test samples and positive inoculated MF coliform and standard plate count test samples shall be established from statistical analysis of the data set after rejection or weighting of outliers, as described in subdivision (g) of this section. The value assigned to the statistical mean shall be the mean of the resulting data set.

(g) Rejection of outliers in a chemical data set shall be based on the three-standard deviation interval, after eliminating the extreme values in the data set and all values exceeding twice the theoretical value for the test sample. Rejection of outliers in an MF coliform or standard plate count data set shall be based on the three-standard deviation interval, after eliminating the extreme values in the data set. Weighting of outliers, if used in place of rejection of outliers, shall be accomplished using robust analysis. The statistical mean and confidence intervals used to determine satisfactory and unsatisfactory performance for positive inoculated MPN coliform test samples shall be based on the log normal distribution.

(h) Performance in examining potable water bacteriological samples qualitatively shall be evaluated based upon the known presence or absence of total coliform group members of *Escherichia coli* (*E. coli*). Satisfactory performance shall be a result correctly indicating the presence or absence of total coliform bacteria, and correctly identifying *E. coli*, if present. Unsatisfactory performance shall be a result incorrectly identifying the presence or absence of

total coliform bacteria or E. coli.

(i) (1) The department may recognize a proficiency testing provider to offer and score results of proficiency testing samples for purposes of obtaining New York State environmental laboratory accreditation pursuant to this Subpart, provided:

(i) the proficiency testing provider has submitted sufficient documentation to enable the department to determine that the provider adheres to standards for design, production, testing, distribution, data analysis and quality assurance that are at least equivalent to, or more stringent than, the department proficiency testing program's, and applies scoring systems identical to the department's;

(ii) the proficiency testing provider demonstrates it has policies and procedures in place to protect the integrity of its proficiency testing program and prevent fraud in its administration;

(iii) for analytes and sample types with EPA proficiency testing participation standards, the proficiency testing provider possesses a certificate or other documented approval demonstrating compliance with such EPA standards; and

(iv) the proficiency testing provider agrees to supply the department with test scores, and any such other information and documentation requested to resolve any issues concerning compliance with this Subpart.

(2) The recognition granted to a proficiency testing provider pursuant to this subdivision may be withdrawn at any time if the department finds the provider no longer meets the criteria set forth herein, or has failed to provide the department with sufficient information and documentation to permit determination or demonstration of compliance or noncompliance with this Subpart.

Section 55-2.9 Recognition of other state regulatory programs.

(a) An environmental laboratory located in another state may request that the department recognize, for purposes of a New York State certificate of approval, that the requirements of this Subpart for on-site assessment, technical direction, quality systems and/or proficiency testing have been met by the laboratory's participation in another state's environmental laboratory approval program. The department may recognize one or more of such requirements as met by participation in another state's program, provided:

(1) the legal, technical and record keeping requirements of the state regulatory program

in which the laboratory is participating are determined by the department to meet or exceed New York State's requirements;

(2) the laboratory demonstrates good standing in the other state's program, including successful completion of an on-site assessment and satisfactory performance in required proficiency testing, and documents such good standing to the department;

(3) the laboratory submits to the department a completed application for approval;

(4) the laboratory pays all applicable fees required by Subpart 55-3 of this Part;

(5) the laboratory pays any costs incurred by department representatives traveling outside New York State to perform an on-site assessment pursuant to this Subpart; and

(6) the technical director(s) meet(s) the requirements of section 55-2.10 of this Subpart.

(b) The department may enter into agreements with other state agencies or programs to assist the department in assessing an environmental laboratory's performance or in determining whether another state's program meets or exceeds the department's requirements.

(c) Notwithstanding another state program's equivalency to the department's program, the department may require an environmental laboratory to participate in the department's proficiency testing program, on-site assessment, and/or similar evaluations to ensure the laboratory's full compliance with New York State statutes, regulations and standards for laboratories approved pursuant to this Subpart.

Section 55-2.10 Technical director: qualifications and responsibilities.

(a) (1) Each environmental laboratory shall appoint one or more technical directors, who shall be full-time members of the laboratory's staff, and who shall exercise actual day-to-day supervision of laboratory operations, including the reporting of results. The designation of a lead technical director shall be documented; and

(2) each technical director shall have the requisite credentials and experience for an area of analysis, such as microbiology, organic chemistry, inorganic chemistry and radiochemical analysis, and shall supervise only the areas of environmental analysis for which he or she meets the qualifications required by this section.

(b) A technical director's responsibilities shall include, but not be limited to, development and implementation of a quality system as defined in section 55-2.1 of this Subpart, including: monitoring standards of performance in quality control and quality assurance; monitoring the

validity of analyses performed and data generated to ensure reliable data; ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and providing educational direction to laboratory staff.

(c) An individual meeting the requirements of this section may not be the technical director of more than one approved laboratory without authorization from the department. Circumstances to be considered in the department's decision to grant such authorization may include, but not be limited to, the extent to which the operating hours of the laboratories to be directed overlap, adequacy of supervision in each laboratory, and availability of environmental laboratory services in the area served.

(d) A technical director who is absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another full-time staff member meeting the qualifications of this Subpart to assume the responsibilities of technical director temporarily. Whenever the term of such temporary direction exceeds sixty-five (65) consecutive calendar days, the department shall be notified in writing.

(e) A technical director of an approved laboratory engaged in chemical analysis shall be:

(1) a person with an earned doctoral degree in the chemical, environmental, physical or biological sciences, or engineering, with at least twenty-four (24) college semester credit hours in chemistry, and at least one year of experience in environmental analysis of representative inorganic and organic analytes for which the laboratory is approved or seeking approval;

(2) a person with a master's degree in the chemical, environmental, physical or biological sciences, or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least one year of experience in environmental analysis of representative inorganic and organic analytes for which the laboratory is approved or seeking approval; or

(3) a person with a bachelor's degree in the chemical, environmental, physical or biological sciences, or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in environmental analysis of representative inorganic and organic analytes for which the laboratory is approved or seeking approval.

(f) A technical director of a laboratory holding or seeking approval for the contract laboratory protocol tier, in addition to meeting the requirements of subdivision (e) of this section, shall have at least three (3) years of experience, at least one year of which shall be in a supervisory capacity.

(g) A technical director of an approved laboratory engaged in, but limited to, inorganic chemical analysis, other than contract laboratory protocol or metals analysis, shall be a person with at least an associate's degree in the chemical, physical or environmental sciences, or two (2) years of equivalent and successful college education, with at least sixteen (16) college semester credit hours in chemistry. In addition, such a person shall have at least two (2) years of experience performing such analysis.

(h) A technical director of an approved laboratory engaged in microbiological and/or biological testing shall be:

(1) a person with an earned doctoral degree or master's degree in the chemical, environmental, physical or biological sciences, or engineering, with at least sixteen (16) college semester credit hours in the biological sciences, including, for microbiological testing, at least one course having microbiology as a major component, and at least one year of experience in environmental analysis of representative analytes for which the laboratory is approved or seeking approval;

(2) a person with a bachelor's degree in the chemical, environmental, physical or biological sciences, or engineering, with at least sixteen (16) college semester credit hours in the biological sciences, including, for microbiological testing, at least one course having microbiology as a major component, and at least two (2) years of experience in environmental analysis of representative analytes for which the laboratory is approved or seeking approval; or

(3) notwithstanding the requirements of paragraphs (1) and (2) of subdivision (h) above, a person with an earned doctoral, master's, bachelor's, or associate's degree in an appropriate field of the sciences or applied sciences, with at least four (4) college semester hours in general microbiology or a biological science course with a major microbiological component, and one year of experience in environmental analysis of representative analytes, may be a technical director of an approved laboratory, provided the laboratory is engaged in microbiological analysis limited to fecal coliform, total coliform and standard plate counts. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for an associate's degree.

(i) A technical director of an approved laboratory engaged in radiochemical analysis shall be:

(1) a person with an earned doctoral degree in chemistry, physics or engineering, with at

least twenty-four (24) college semester hours in chemistry, and at least one year of experience in radiochemical analysis of environmental samples;

(2) a person with a master's degree in chemistry, physics or engineering, with at least twenty-four (24) college semester hours in chemistry, and at least one year of experience in radiochemical analysis of environmental samples; or

(3) a person with a bachelor's degree in chemistry, physics or engineering, with at least twenty-four (24) college semester credit hours in chemistry, and at least two (2) years of experience in radiochemical analysis of environmental samples.

(j) Notwithstanding any other provision of this section, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements for serving as the technical director of the approved laboratory devoted exclusively to analysis of environmental samples taken within such a facility. Such approval for a water treatment facility shall be limited to determination of total dissolved solids, pH, temperature, alkalinity, acidity, total coliform organisms and standard plate counts. Such approval for a sewage treatment facility shall be limited to determination of biochemical oxygen demand, total solids, suspended solids, pH, temperature, alkalinity, acidity and fecal coliform organisms. However, such approval for a sewage treatment facility shall be extended to include determination of ammonia, total Kjeldahl nitrogen, nitrate or total phosphorus, provided such full-time employee has successfully completed a specialized course of study in the analysis of these substances, generally recognized by leading authorities in the field.

(k) Notwithstanding any other provision of this section, a full-time employee of an industrial waste treatment facility with at least one year of experience in environmental analysis, under supervision, shall be deemed to meet the requirements for serving as the technical director of an approved laboratory devoted exclusively to analysis of environmental samples taken within such a facility for determination of biochemical oxygen demand, total solids, suspended solids, pH, temperature, alkalinity, acidity and fecal coliform organisms.

(l) A technical director of an approved laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:

(1) For procedures requiring use of a transmission electron microscope, a bachelor's degree, successful completion of specialized courses in use of the instrument, and one year of

experience, under supervision, in use of the instrument. Such experience shall include identification of minerals.

(2) For procedures requiring use of a polarized light microscope, an associate's degree or two (2) years of equivalent and successful college study, successful completion of formal coursework in polarized light microscopy, and one year of experience, under supervision, in use of the instrument. Such experience shall include identification of minerals.

(3) For procedures requiring use of a phase contrast microscope, as in determination of airborne fibers, an associate's degree or two (2) years of equivalent and successful college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one year of experience, under supervision, in use of the instrument.

(m) A technical director of an approved laboratory engaged in determination of radon in air shall meet the following requirements:

(1) An associate's degree in the physical sciences, or two (2) years of equivalent and successful college education, and one year of experience in radiochemical measurements, including at least six (6) months of experience in measurement of radon and/or radon progeny.

(2) For radon determinations using a direct continuous monitoring device, as in on-site measurement of residential radon levels, at least a high school diploma or high school equivalency diploma, and certification of successful completion of a training course in operation of the instrument, as well as six (6) months of experience, under supervision, in use of the instrument.

(n) A person who meets the experience requirements but not the educational and/or credential requirements of this Subpart, and is functioning in a technical director's capacity on the date the laboratory becomes subject to these regulations, shall qualify as technical director of that laboratory, or any other laboratory approved by the department and performing similar analyses, provided such person can demonstrate the ability to comply with the proficiency testing and quality system requirements of this Subpart.

Section 55-2.11 Quality assurance officer: qualifications and responsibilities.

(a) Each environmental laboratory shall appoint a quality assurance officer (however named), who shall exercise oversight of the laboratory's quality system. The individual so appointed shall have documented training, and/or experience in quality assurance and quality

control procedures; be knowledgeable in the required quality system; and possess a general knowledge of analytical methods for which he or she performs data review.

(b) The quality assurance officer (and/or his or her designees) shall:

(1) serve as the focal point for the environmental laboratory's quality assurance and quality control, and be responsible for monitoring and/or review of quality control data;

(2) evaluate data objectively and perform independent assessments without outside (e.g., managerial) influence;

(3) arrange for or conduct annual internal audits of the laboratory's entire technical operation; and

(4) notify laboratory management of any deficiencies in the quality system and monitor required corrective actions.

(c) The quality assurance officer shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources, as well as to the technical director(s). The quality assurance officer shall fulfill his or her functions independently from laboratory operations for which he or she maintains quality assurance oversight; provided, however, for laboratories with limited staffing, the quality assurance officer may also be a technical director.

Section 55-2.12 Contract laboratory protocol personnel: qualifications.

(a) To gain or maintain approval for contract laboratory protocol analyses, an environmental laboratory shall employ full-time employees qualified to perform the following functions, as set forth in the protocol:

(1) Laboratory supervisor in the specialties of gas chromatography/mass spectrometry (GC/MS), gas chromatography (GC), and/or inorganics shall be a person with at least a bachelor's degree in chemistry or the physical sciences, and three (3) years of relevant laboratory experience, including one year in a supervisory capacity.

(2) GC/MS operator shall be a person with at least a bachelor's degree in chemistry or the physical sciences, and one year of experience in operating and maintaining a GC/MS data system. Three (3) years of experience in operating and maintaining a GC/MS data system may be substituted for the educational requirement.

(3) Mass spectral interpretation specialist shall be a person with at least a bachelor's

degree in chemistry or the physical sciences, who has successfully completed a specialized training course in mass spectral interpretation and has at least two (2) years of experience in mass spectral interpretation.

(4) Pesticide residue analysis expert shall be a person with at least a bachelor's degree in chemistry or the physical sciences, and two (2) years of experience in operating and maintaining a gas chromatograph, and interpreting gas chromatograms.

(5) Organic sample preparation supervisor shall be a person with at least a bachelor's degree in chemistry or the physical sciences, and at least three (3) years of organic laboratory experience, including at least one year in a supervisory capacity.

(6) Extraction/concentration expert shall be a person with at least a high school diploma, including one course in chemistry and one year of experience in an analytical chemistry laboratory.

(7) Inductively coupled plasma (ICP) spectroscopist shall be a person with at least a bachelor's degree in chemistry or the physical sciences, who has successfully completed specialized training courses in ICP spectroscopy and has two (2) years of applied experience in ICP analysis of environmental samples.

(8) ICP operator shall be a person with at least a bachelor's degree in chemistry or the physical sciences, and one year of experience in the operation and maintenance of ICP instrumentation; or, in lieu of the educational requirement, four (4) years of experience in operating and maintaining ICP instrumentation;

(9) Atomic absorption (AA) operator shall be a person with at least a bachelor's degree in chemistry or the physical sciences, and at least one year of experience in operating and maintaining AA instrumentation for flame, graphite furnace and cold vapor techniques; or, in lieu of the educational requirement, three (3) years of experience in operating and maintaining AA instrumentation as described in this paragraph.

(10) Inorganic sample preparation specialist shall be a person with at least a high school diploma, successful completion of a college-level course in general chemistry or its equivalent, and six (6) months of experience in an analytical laboratory.

(11) Classical techniques analyst shall be a person with at least a bachelor's degree in chemistry or the physical sciences, and six (6) months of experience in classical chemistry laboratory procedures; or, in lieu of the education requirement, two and one-half (2 1/2) years of

experience performing classical chemistry analyses.

(b) Each environmental laboratory seeking approval or wishing to maintain approval for contract laboratory protocol analysis shall have sufficient technical staff to provide continuous coverage, as appropriate, for the functions described in subdivision (a) of this section. The person or persons designated as back-up technical staff shall have at least a bachelor's degree in chemistry or the physical sciences, in addition to the following minimum experience:

(1) for organic chemistry protocols: one year of experience in each of the following areas: GC/MS operation and maintenance, for volatile and semi-volatile analyses; mass spectral interpretation; extraction; and pesticide analyses; or

(2) for inorganic chemistry protocols: one year of experience in each of the following areas: ICP operation and maintenance; AA operation and maintenance; classical chemistry analytical procedures; and sample preparation for inorganic analyses.

Section 55-2.13 Requirements for laboratories engaged in testing for critical agents in environmental samples.

(a) For purposes of this Subpart, *critical agent* shall mean an organism, chemical element or chemical compound, which is recognized as posing a risk to national security and/or requiring special action to protect the public health because the agent: can be disseminated (e.g., in air, water or food) or transmitted person-to-person with ease; causes moderate to high mortality and/or morbidity; and can have a significant public health impact. The term organism includes, but is not limited to, a virus, bacterium, or product or component of an organism (e.g., a toxin). *Critical agents* shall include critical biological and chemical agents, including select agents, specified by the Federal Centers for Disease Control and Prevention (CDC) in published documents, and other such agents as the Commissioner of Health has determined meet the above criteria. The terms chemical element and chemical compound include substances that emit ionizing radiation including alpha, beta, gamma or neutron radiation.

(b) (1) Prior to performing testing for any critical agent in an environmental sample, a laboratory shall submit a request to the department, and receive an initial or revised certificate of approval that includes the specialty of critical agent testing and the approved method(s) the laboratory is authorized to employ as stipulated in sections 55-2.1 and 55-2.5 of this Subpart. The certificate of approval shall also list the specific critical agent(s) included in the approval,

the approved method(s), and the types of samples (e.g., surface swipes, powder, air, fluid and bulk material) the laboratory may accept for testing. No laboratory shall examine an environmental sample for a critical biological agent or critical chemical agent without certification of approval specific to each critical agent for which testing is conducted.

(2) The department may withhold or limit its approval if the department is not satisfied that the laboratory has in place adequate policies, procedures, facilities, equipment, instrumentation and trained personnel to ensure that: collection; labeling; accessioning; preparation; analysis; result reporting or, for an autonomous detection system as defined in section 55-2.14(a) of this Subpart, responding to a signal indicating the presence of a critical agent; storage; transportation; shipping; and disposition of all environmental samples, derivatives and related materials shall be performed in a manner that: ensures consistently correct performance of the approved methods; ensures the protection of the health, safety and welfare of the laboratory's employees and the public; and is consistent with the requirements of this Subpart, and all other applicable laws, rules and regulations. The department shall also consider a laboratory's biosafety level facilities, safety practices, and its capability to assume an appropriate role in the public health and safety response(s) to critical agents, in its determination to approve the laboratory for critical agent testing in environmental samples.

(c) In addition to application and attestation requirements found elsewhere in this Subpart, a laboratory seeking approval to perform critical agent testing in environmental samples shall submit:

(1) a standard operating procedure manual documenting laboratory policies, procedures, facilities, equipment, supplies, instrumentation and personnel for critical agent testing, which are designed to ensure that: collection; labeling; accessioning; preparation; analysis; result reporting or, for an autonomous detection system as defined in section 55-2.14(a) of this Subpart, responding to a signal indicating the presence of a critical agent; storage; transportation; shipping; and disposition of all environmental samples, derivatives and related materials shall be performed in a manner that ensures consistently correct performance of the approved methods; ensures the protection of the health, safety and welfare of the laboratory's employees and the public; and is consistent with the requirements of this Subpart, and all other applicable laws, rules and regulations; and

(2) an attestation signed by the owner(s) and director(s) that the laboratory will accept

only the type(s) of samples (e.g., surface swipes, powder, air, fluid and bulk material) specified on the laboratory's certificate of approval, and that the owner(s) and director(s) will take whatever action is necessary to ensure that such samples are collected, labeled, accessioned, prepared, analyzed, stored, transported, shipped and disposed of, and all results are reported in a manner consistent with the approved method and with all other documentation submitted to the department.

(d) In addition to meeting the preceding requirements of this Subpart, a laboratory engaged in critical agent testing in environmental samples, through its owner(s) and director(s), shall:

(1) establish, maintain, review periodically, and implement written policies and procedures designed to ensure that: collection; labeling; accessioning; preparation; analysis; result reporting or, for an autonomous detection system as defined in section 55-2.14(a) of this Subpart, responding to a signal indicating the presence of a critical agent; storage; transportation; shipping; and disposition of samples shall be performed in a manner that ensures consistently correct performance of the approved methods, ensures the protection of the health, safety and welfare of laboratory personnel, sample collectors and the public to the extent possible, and is consistent with all applicable laws, rules and regulations, as well as recognized standards of practice designed to minimize the risks associated with potential exposure to similar hazardous substances or critical agents. Such policies and procedures shall include specific procedures for containment, secured storage, decontamination, and/or disposal or destruction of the sample(s), derivatives, and related collection materials, supplies and/or equipment, as necessary and/or appropriate for the relevant suspected critical agent;

(2) have written policies and procedures in place to implement a chain-of-custody protocol whenever required by a law enforcement agency. Such policies and procedures shall be developed in consultation with law enforcement officials or other persons with appropriate experience and training in chain-of-custody issues, and shall at a minimum require an intact continuous record of the physical possession, storage, and disposition of the sample and any derivatives, including the signatures of all persons who access the sample and derivatives, the date of such access and other pertinent information;

(3) (i) ensure that all laboratory employees engaged in collecting and/or transporting environmental samples receive sufficient training in hazardous material handling techniques to

ensure they will perform their responsibilities in a safe and reliable manner. Such training shall include, but not be limited to, training in sample collection, packaging, decontamination, transportation, and chain-of-custody policies and procedures established by the laboratory. The laboratory shall maintain documentation of such training for a minimum of three years and take such other action as is necessary to ensure ongoing compliance with such policies and procedures;

(ii) develop and implement sample acceptance criteria designed to protect the health, safety and welfare of laboratory personnel, sample collectors, and the public to the extent feasible. Such criteria shall be consistent with approved methods for sample collection, handling, packaging and decontamination, and shall minimally define conditions under which a sample shall be rejected, and conditions under which a sample shall be tested and results reported with limitations. The laboratory shall make its sample acceptance criteria available to clients;

(4) issue reports of test results in a format and of a content required by the approved method, and necessary for interpretation of the test results or an autonomous detection system signal indicating the presence of a critical agent, including, but not limited to, unambiguous identification of the tested environmental sample, including collection location and time, source and sample type, and limitations of the method. The department may restrict a laboratory's ability to report information concerning a test result whenever confirmatory or supplemental testing is required by the approved method;

(5) report laboratory findings to the department or an authority designated by the department as soon as practicable, but no later than: (i) 24 hours following generation of a test result, via telephone, facsimile and/or electronic transmission, using a number or e-mail address designated by the department or the department's designee; and (ii) as specified in section 55-2.14 of this Subpart for an autonomous detection system, i.e., as soon as practicable but no later than one hour, whenever the findings indicate that an environmental sample contains an organism, its product or component, or a chemical, any of which exhibits characteristics or properties consistent with those of a critical agent. Whenever the department determines that supplemental testing is necessary, the laboratory shall submit all or part of the sample or its derivative(s) to the department or its designee, as directed by the department. For purposes of sections 55-2.13 and 55-2.14 of this Subpart, the term *supplemental testing* shall mean performance of analyses following an initial indication that a critical agent has been detected,

including, but not limited to, confirmatory testing and technical procedures to identify further the characteristics of a critical agent for public health protection and/or law enforcement purposes. The term *confirmatory testing* shall mean supplemental testing that definitively substantiates or refutes the presence of a critical agent;

(6) unless precluded by law enforcement, prosecutorial or homeland security authorities, make available the findings of confirmatory testing conducted in response to an autonomous detection system signal to the approved laboratory operating the autonomous detection system; and

(7) establish and implement a critical agent inventory and tracking system that accounts for all environmental samples and their derivatives suspected or confirmed to contain critical agents. Unless required to demonstrate implementation of chain-of-custody procedures required pursuant to paragraph (2) of this subdivision or required by this paragraph, a laboratory may discontinue inventory and tracking of samples and derivatives, provided laboratory findings have established the absence of a critical agent. Inventory and tracking documentation shall include the identity of all individuals who access such materials and the date and time of access, as well as specific information regarding transfer, disposal or other disposition of the materials. Samples and their derivatives, access records, chain-of-custody records and records of the analyses performed shall be maintained in a secure manner until the statute of limitations for bringing any related criminal or civil action has expired, and the sample and its derivatives are no longer needed for evidence in any pending legal matter or by law enforcement officials. Access records, chain-of-custody records and records of the analyses of confirmed positive samples shall be maintained for 10 years, or as required above if longer.

(e) For critical biological agents, an environmental laboratory's proficiency testing performance shall be evaluated based on the known presence or absence of the critical agent, or, as applicable, its product or component. Satisfactory performance shall be a result correctly indicating the presence or absence of the critical agent, or, as applicable, its product or component. Unsatisfactory performance shall be a result incorrectly indicating the presence or absence of the critical agent, or, as applicable, its product or component.

(f) Personnel requirements for environmental sample testing for critical biological agents that are organisms shall be as follows:

(1) notwithstanding the requirements of section 55-2.10 of this Subpart, the

environmental laboratory shall employ, as director, one of the following:

(i) a person who holds or meets the qualifications for a New York State clinical laboratory director certificate of qualification in the applicable subspecialty of microbiology (such as bacteriology), pursuant to Part 19 of this Title, and, for analyses using technologies other than conventional microbiologic techniques, at least one year of experience in analysis using the specific technology of the device, instrument or system (e.g., nucleic acid detection by the polymerase chain reaction (PCR) technique). For purposes of this subdivision, *conventional microbiologic techniques* shall mean culture, use of differential media, stains and/or biochemical reactions, and morphologic examination of colonies and/or organisms;

(ii) a person with an earned doctoral degree or master's degree in the chemical, environmental, physical or biological sciences or engineering, with at least 16 college semester credit hours in the biological sciences, including: (a) at least one course having microbiology as a major component, and at least one year of experience in analysis using one or more conventional microbiologic techniques for which the laboratory is approved or seeking approval; or (b) at least two years of experience in analysis using the specific technology of the device, instrument or system (e.g., nucleic acid detection by PCR) for which the laboratory is approved or seeking approval; however, one course in the specific technology may be substituted for one year's experience; or

(iii) a person with a bachelor's degree in the chemical, environmental, physical or biological sciences or engineering, with at least 16 college semester credit hours in the biological sciences, including: (a) at least one course having microbiology as a major component, and at least two years of experience in analysis using one or more conventional microbiologic techniques for which the laboratory is approved or seeking approval; or (b) at least three years of experience in analysis using the specific technology of the device, instrument or system (e.g., nucleic acid detection by PCR) for which the laboratory is approved or seeking approval; however, one course in the specific technology may be substituted for one year's experience; and

(iv) with respect to environmental laboratories that limit their critical biological agent testing to toxin analysis, any of the following personnel qualifications may be substituted for qualifications set forth above, as follows: a New York State clinical laboratory director certificate of qualification in toxicology may be substituted for the certification in microbiology requirement specified in subparagraph (i) of this paragraph; and coursework consisting of a

minimum of 16 college semester credit hours in the biological and/or chemical sciences including at least one course in biochemistry may be substituted for the coursework requirements, but not the educational degree requirements specified in clauses (ii)(a) and (iii)(a) of this paragraph; and

(2) with the exception of autonomous detection systems, sample preparation, analysis and related responsibilities shall be performed by an analyst who shall have an associate's degree or equivalent, with at least 12 college semester credit hours in the biological sciences, and at least one year of experience in analysis of representative analytes; however, a person with at least three years' experience in the analysis of representative analytes immediately preceding the effective date of this section shall be deemed to have met the requisite qualifications for performing critical agent analysis in the laboratory in which such experience has been obtained. Analysts with critical biological agent testing responsibilities that are limited to toxin sample preparation, analysis and related responsibilities may meet the semester credit hour qualifications set forth in this paragraph by completing a minimum of 12 college semester credit hours in the biological and/or chemical sciences.

(g) This section shall not apply to bacteriologic testing for total and fecal coliform bacteria (i.e., the common form of *Escherichia coli*) in potable and non-potable water.

Section 55-2.14 Additional requirements for laboratories engaged in testing for critical agents in environmental samples using autonomous detection systems.

(a) For purposes of this Subpart

(1) *autonomous detection system* shall mean a fixed or portable self-contained analytical system that: automatically, continuously or periodically samples the environment; analyzes sample(s); and triggers an alert that a critical agent, as defined in section 55-2.13 of this Subpart, has been detected. For purposes of Subpart 55-2, *signal* and *alert* shall have the same meaning, i.e., a visual and/or audio alert triggered whenever an organism, its product or component, or a chemical, any of which exhibits characteristics or properties consistent with those of a critical agent has been detected by the detection system;

(2) *deploy* and *operate* shall mean to engage the system in real time collection and analysis of environmental samples for purposes of detecting incidental release of a critical agent as defined in section 55-2.13 of this Subpart;

(3) *autonomous detection system* shall not mean a device for environmental sampling and/or analysis of environmental samples deployed for a purpose other than detecting incidental release of a critical agent as defined in section 55-2.13 of this Subpart. Accordingly, the provisions of this Subpart shall not be applicable to;

- (i) carbon monoxide detectors;
- (ii) radon detectors;
- (iii) hand-held detectors, personal dosimeters or Geiger counters designed and intended for use by individuals, or, when used in an academic setting, for instruction or research;
- (iv) detectors deployed within hospitals or other health care facilities;
- (v) detectors deployed by utility companies or in an industrial setting for the purpose of monitoring internal air quality or detecting leakage of hazardous materials;
- (vi) detectors deployed by certified industrial hygienists, labor unions and other individuals or entities responsible for or engaging in testing or monitoring of workplace or environmental safety, including such testing or monitoring in the aftermath of a possible accident or bioterrorism incident involving critical agent(s); and
- (vii) an environmental sampling and/or testing device deployed for a purpose other than detecting the incidental release of a critical agent, and determined by the Commissioner of Health to not require department oversight pursuant to Public Health Law Section 502.

(b) In addition to meeting the requirements stipulated elsewhere in this Subpart, including the department's Quality System Standards as referenced in Section 55-2.1(f), a laboratory engaged in the analysis of environmental samples using an autonomous detection system shall:

- (1) ensure that the system is operated in a secure and safe manner to prevent accidental or deliberate tampering that could compromise the integrity of its operation;
- (2) establish and validate the minimum concentration(s) of specified critical agent(s) that would trigger a signal;
- (3) develop a laboratory response plan acceptable to the department, to be immediately implemented whenever a signal is triggered, that at a minimum includes procedures for: notification of a signal to the client(s) on whose property an autonomous detection system is situated; notification of a signal to state and local public health and emergency preparedness authorities responsible for confirming, responding to and remediating an incident involving critical agent(s); emergency shutdown of any autonomous detection system suspected to be

malfunctioning; communication between the laboratory's technical director and authorities responding to a signal; timely verification that any signal triggered was neither a false positive nor false negative signal, including review of results of any supplemental testing; and remediation for any false signal;

(4) retain documentation that the response plan has been developed in collaboration with:

(i) state public health and emergency preparedness authorities, and comparable local authorities whenever applicable, responsible for confirming, responding to and remediating an incident involving critical agent(s); and includes documentation of approval by state and/or local public health and emergency preparedness authorities. Such documentation shall include a valid permit or certificate authorizing deployment of an autonomous detection system within an area under the authority's jurisdiction; and

(ii) the client(s) on whose property an autonomous detection system is situated and other party(ies) situated at or controlling right of access at that location; and includes an attestation of agreement to follow response plan protocols, signed by the client and any party(ies) situated at or controlling right of access at the location at which the autonomous detection system is deployed;

(5) document, in its standard operating procedures manual:

(i) the laboratory's process for selecting locations in which autonomous detection systems are to be situated, or, if a system is portable, a description of the types of locations in which a system may be deployed;

(ii) procedures to ensure adequate oversight by the technical director of each autonomous detection system deployed by the laboratory, including, but not limited to, review of quality assurance and quality control data and, as available, the results of any postsignal confirmatory testing;

(iii) protocols for monitoring multiple systems or monitoring from a remote location;

(iv) protocols for timely communication between the system's operator and the technical director, and between the client and the laboratory; and

(v) the laboratory's response plan.

(6) for each autonomous detection system in operation: maintain records on its location, including street address, and a description of its exact placement within a building or area; and

(7) whenever the system triggers an alert:

(i) immediately follow procedures prescribed in the laboratory's response plan;

(ii) as soon as practicable, but no later than one hour after a signal has been triggered, notify the department or an authority designated by the department, via telephone using a number designated by the department or the department's designee; and document the date and time of the telephone call, and the name(s) of the responsible person(s) contacted; and

(iii) request for review records of any supplemental testing conducted in response to the triggered signal. Whenever the results of such supplemental testing are inconsistent with the expected reason for a signal, the laboratory shall render inoperable the autonomous detection system that triggered the signal until the cause of the discrepancy is determined and remediated.

(c) The laboratory shall maintain a fixed-base location at which all records required by this Subpart, including but not limited to, calibration, test, quality assurance, quality control, operator training, and client notification protocols and supplemental testing are retained for periods stipulated in this Subpart. The laboratory shall also retain records demonstrating compliance with federal, state, and local rules for registration, use and disposal of any material that meets the definition of a biological or chemical critical agent, including radioactive material, in its possession.

(d) A laboratory may operate one or more autonomous detection systems under the direction of one technical director. Procedures for direct oversight by the technical director of one or more systems and their operator(s) shall be acceptable to the department.

(e) An autonomous detection system, while in operation, shall be continuously monitored by an autonomous detection system operator who functions under the direction of the technical director. The technical director may also serve as the operator. Prior to designating a person as an autonomous detection system operator, the laboratory owner and technical director shall ensure compliance with applicable personnel requirements stipulated in the department's Quality System Standards as referenced in Section 55-2.1(f), as well as ensure that the operator:

(1) receives adequate training specific to the operation of each specific make and model of autonomous detection system in use by the laboratory;

(2) provides written attestation to reading and understanding the general policies and procedures of the laboratory, and those specific to the autonomous detection system(s) in use, including the laboratory's response plan and the operator's responsibilities under that plan; and

(3) undergoes a successful demonstration of capability that includes participation in the mock implementation of each specific response plan for each autonomous detection system

deployed by the laboratory.