

# ENVIRONMENTAL LABORATORY APPROVAL PROGRAM CERTIFICATION MANUAL

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Since ELAP no longer certifies for the CLP tier, the CLP tier personnel requirements were removed from this item.

## **Technical Director**

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 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 specified in this item. The direction of an area of analysis may not be shared between two or more technical directors; i.e., each area of analysis may have only one technical director (e.g., one technical director for all chemistry and one technical director for microbiology).

### Responsibilities

A technical director's responsibilities shall include, but not be limited to, development and implementation of a quality system, 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.

An individual may not be the technical director of more than one accredited laboratory without authorization from ELAP. 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.

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 technical director 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.

### Qualifications

1. A technical director approved in chemical analysis shall be 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 appropriate experience in environmental analysis of representative inorganic and organic analytes for which the laboratory is

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- approved or seeking approval. A masters or earned doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.
2. A technical director approved in chemical analysis that is limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned 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 appropriate experience performing such analysis.
  3. A technical director approved in microbiological and/or biological testing shall be a person with at least 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. Those technical directors with post undergraduate degrees shall have at least one (1) year of experience in environmental analysis of representative analytes for which the laboratory is approved or seeking approval.
  4. A technical director approved in microbiological and/or biological testing limited to fecal and total coliform bacteria and standard plate count shall be a person with at least an 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 (1) year of experience in environmental analysis of representative analytes. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree.
  5. A technical director approved in microbiological testing for anthrax shall be 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, of which at least one (1) course has microbiology as a major component, and at least one (1) year of experience in environmental analysis of representative analytes; or 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, of which at least one (1) course has microbiology as a major component, and at least two (2) years of experience in environmental analysis of representative analytes.
  6. A technical director approved in radiochemical analysis shall be a person with a bachelor's degree in chemistry, physics or engineering with twenty-four (24) college semester credit hours of chemistry and at least two (2) years of experience in

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radiochemical analysis of environmental samples. A masters or earned doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

7. 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.
8. Notwithstanding any other provision of this section, a full-time employee of an industrial waste treatment facility with at least one (1) 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.
9. A technical director approved in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:

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 (1) year of experience, under supervision, in use of the instrument. Such experience shall include identification of minerals.

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 (1) year of experience, under supervision, in use of the instrument. Such experience shall include identification of minerals.

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

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coursework in phase contrast microscopy, and one (1) year of experience, under supervision, in use of the instrument.

10. A technical director approved in determination of radon in air shall be a person with at least an associate's degree in the physical sciences, two (2) years of equivalent and successful college education, and one (1) year of experience in radiochemical measurements, including at least six (6) months of experience in measurement of radon and/or radon progeny.

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.

**A person who meets the experience requirements but not the educational and/or credential requirements of Subpart 55-2, 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.**

### **Quality Assurance Officer**

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. For laboratories with limited staffing, ELAP may approve the quality assurance officer as the laboratory's technical director.

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

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

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. However, with laboratories with limited staffing, the quality assurance officer may also be a technical director.

### **Critical Agent Analyst**

Analysts testing for critical biological agents that are microbiological organisms (specifically anthrax) shall have an associates degree or equivalent, with at least twelve (12) college semester credit hours in the biological sciences, and at least one (1) year of experience in analysis of representative analytes. However, a person with at least three (3) years of such experience, in the applicant laboratory, immediately preceding the effective date of departmental regulations addressing critical agent testing shall be deemed to have met the requisite qualifications for performing the analysis.

### **Autonomous Detection System Operator**

An autonomous detection system operator shall function under the direction of a technical director. The technical director may also serve as the operator. The laboratory must ensure that the operator:

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