

**ENVIRONMENTAL LABORATORY APPROVAL PROGRAM
CERTIFICATION MANUAL**

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Primary and Secondary Accreditation

Laboratories are granted either Primary or Secondary Accreditation from ELAP. The following laboratories are granted Primary Accreditation:

1. All laboratories located in New York State (NYS) and
2. Out-of-state laboratories that do **not** hold NELAP / TNI accreditation from another NELAP-recognized accreditation body.

Secondary Accreditation is granted to laboratories located outside New York State **and** accredited by a NELAP / TNI-recognized state accreditation body.

All applicants for Primary or Secondary Accreditation must submit a completed “Environmental Laboratory Application for Approval” (Form 107), which includes a Certification of Compliance signed by the laboratory’s Owner (or Owner representative), Lead Technical Director, and Quality Assurance (QA) Officer. In addition, they must submit a categorical application form.

The period of approval lasts one year (April 1 through March 31). Application form 107 must also be submitted whenever there is a change in ownership, laboratory address, or when applying for new technical personnel.

Laboratories applying for Primary Accreditation must submit a Quality Manual, demonstrating that the laboratory has a Quality System meeting the requirements of the program, and must satisfy proficiency testing (PT) requirements, if applicable and as described in Certification Manual Item 300.

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Laboratories applying for Secondary Accreditation are also required to submit a Quality Manual, as well as, their most recent assessment report and corrective action response issued by their Primary Accreditation Body.

An accreditation fee of \$500 will be assessed after the laboratory is full approved.

Personnel

Key personnel must be identified on the application form and documentation of the qualifications and experience of the key personnel must accompany the application. Certification Manual Item 140 describes the personnel requirements. Appropriate documentation is as follows:

- a. For College/University Degrees/Courses, a copy of transcripts showing required course work and degree granted. Exceptions would be for those individuals holding Chemistry and Biology degrees from a U.S. college/university. If the degree is in Chemistry, a copy of the degree indicating the major of chemistry is sufficient. Likewise, if the degree is in Biology, a copy of a college diploma with the major of biology is sufficient.

*** If the degree was granted by a foreign college/university, attach a copy of the evaluation of the transcript performed by an organization such as World Educational Service, Inc. (1 Battery Place, New York, NY 10004; (800) 937-3895, and <http://www.wes.org/>). ***

- b. For Drinking Water or Sewage Treatment Plant Operators, a copy of the license certificate.
- c. For Industrial Waste Facility, a letter from a person in authority documenting the required experience.

Technical directors wishing to direct more than one laboratory must request approval in writing and provide information on the operating hours of the laboratories, adequacy of supervision, including the qualifications of subordinates, arrangements for contacting the director with problems, availability of services in the area, etc.

Fields of Accreditation

The Fields of Accreditation offered by ELAP are listed in Certification Manual Item 180. The approvals are issued for specific Fields of Accreditation, comprising Matrix – Technology/Method – Analyte. Laboratories must submit the appropriate application form, based on matrix type. The application forms are provided on the ELAP website as:

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- a. Form 108 – Drinking Water
- b. Form 109 – Non-potable Water
- c. Form 1977 – Solid & Hazardous Waste
- d. Form 1977CA – Critical Agents
- e. Form 1978 – Air & Emissions
- f. Form 110 – Medical Marijuana**

Laboratories wishing to add or delete fields of accreditation after accreditation has been given must request changes by completing one of the forms listed above. If the laboratory is adding an analyte, place an “A” in the space before the analyte to indicate it is a request to add an analyte. If the laboratory is removing an analyte from its scope, place an “E” in the space before the analyte to indicate it is a request to drop or erase the analyte. In addition, if a prep method is applicable to an analytical method, the laboratory must list it on the application form as either an addition or deletion to its scope.

Interim Accreditation

The current NELAC /TNI standards permit interim accreditation to be granted under the following conditions. If a laboratory completes all of the requirements for accreditation except that of an on-site assessment because ELAP or another Primary Accreditation Body is unable to schedule the assessment, the accreditation body may issue an interim accreditation. Interim accreditation, which may not exceed 12 months, allows a laboratory to perform analyses and report results with the same status as an accredited laboratory until the on-site assessment requirements have been completed. The interim accreditation status is a matter of public record.

In practice, when ELAP grants interim accreditation, it is “NY-ELAP only”, and certificates do not bear the NELAP / TNI logo. Laboratories granted interim accreditation may not claim or advertise to be NELAP / TNI accredited. Following a satisfactory on-site assessment, interim accredited laboratories are granted full NELAP / TNI accreditation for those fields of accreditation that are within the scope of the current NELAC / TNI standards. Since an on-site assessment can usually be conducted in a timely manner, laboratories located in New York will not generally be granted Interim accreditation.

Notification and Reporting Requirements

Laboratories must notify ELAP (or their Primary Accreditation Body) of any changes in key accreditation criteria within 30 calendar days of the change. This written notification includes, but is not limited to, changes in the laboratory ownership, location, key personnel, and major instrumentation. All such updates are public record, and any or all of the information contained therein may be placed in the NELAP /TNI national database.

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Additionally, all requested changes in Fields of Accreditation (Matrix – Technology/Method -- Analyte), including addition or removal of analytes and methods, must be submitted in writing and approved by ELAP before the change can take effect.

Certificates must be returned to ELAP promptly upon request for these two situations:

- (1) if your lab has had administrative action taken against it (e.g., suspension, denial, or revocation), or
- (2) if your lab has had insufficient proficiency tests and/or proficiency test failures.

Expired certificates do not need to be returned to ELAP at renewal time (i.e., April 1st of each year). Furthermore, original certificates do not need to be returned when additions and/or removals of analytes and methods are made to your scope of accreditation.

Corrective Actions for Failed Proficiency Tests

As noted in Certification Manual Item No. 300, each unsatisfactory analytical result requires that the laboratory's management investigate the root cause of the laboratory's performance and establish a corrective action report (or response). The report must be on file and available for review during an on-site assessment.

In addition, if your lab lost accreditation due to two PT failures, you must submit the corrective action response to ELAP for review and approval before accreditation will be reinstated. The four main components of a corrective action that must be submitted include the following: outcome of investigation conducted to identify root cause of the failure, description of root cause, description of process put in to place to prevent reoccurrence, and a comment regarding the potential affect that the root cause issue had on sample data. In addition to the corrective action response, your laboratory will also need to participate in two additional PT studies.

Multiple Test Facilities

When a laboratory has more than one testing facility and these testing facilities are located in separate buildings, a waiver to have all the testing facilities considered one laboratory is to be requested in writing. This application should include the location of each testing facility, name of the laboratory, the technical director who will effectively supervise all the testing facilities, and certification that the individual testing facilities do not duplicate analytical reporting and record keeping activities. After inspection of all these testing facilities and review of the application, a decision will be made.

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Changes in Directorship

Whenever a position of technical director is vacated, the laboratory's approval will be terminated automatically unless the ELAP office is notified in writing within 30 calendar days of the vacancy. Approval may be extended for 90 days to recruit a new technical director and to allow ELAP to evaluate the qualifications of the new proposed technical director. The new proposed technical director must meet the regulation requirements for laboratory technical director. Documentation of proposed technical director qualifications is to be submitted to the central ELAP office as soon as possible.

Change of Ownership and/or Location of Laboratory

Changes in laboratory location and/or ownership must be filed with the ELAP office within 30 calendar days of the change. All records and analyses performed pertaining to accreditation must be kept for a minimum of 5 years and are subject to inspection by ELAP or another Primary Accreditation Body during this period without prior notification to the laboratory. This stipulation is applicable regardless of change in ownership, accountability or liability.

Similarly, a laboratory that is remodeling in which the quality of the analytical data may be affected is to be reported to ELAP. The precise nature of the change is to be described. The ELAP office must be notified 30 calendar days **prior** to the remodeling.

Voluntary Withdrawal

If a laboratory wishes to withdrawal from ELAP, in total or part, it must notify ELAP in writing, and include the effective date of withdrawal. For laboratories withdrawing in part, a revised certificate will be issued to your lab.

For laboratories withdrawing in total, all certificates are to be returned to ELAP, and a written notification must be sent to ELAP as to where laboratory records will be stored. Please refer to Certification Manual Item 176 for retention time of records. Also, please note that outstanding fees may be assessed based upon the laboratory's time of withdrawal.

Complaints and Appeals

If a laboratory wishes to make a complaint (known or anonymous) or appeal an application or accreditation decision, it can contact ELAP through one of these means:

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- (518) 485-5570
- 1-800-682-6056 (Regulatory Affairs, Laboratory Investigative Unit's Hotline)
- elap@health.ny.gov
- P.O. Box 509, Albany, NY 12201-0509

Please include the following information:

- Description of the concern
- Name/address of the laboratory
- Date incident occurred
- Name of individuals involved/affected
- Other agencies to whom the incident was reported
- Estimate of the frequency or pervasiveness of the issue