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Biennial on-site assessments will be performed on each laboratory which is issued a certificate of approval. Follow-up or non-routine assessments can occur at any time.

Pursuant to NYCRR Subpart 55-3.8 and 55-2.9, the laboratory pays any costs incurred by department representatives traveling outside New York State to perform an on-site assessment. The purpose of the inspection fee is to offset the additional travel costs incurred by the department in sending inspectors out-of-state. Failure to pay the fee for out-of-state inspection shall result in suspension or nonrenewal of the laboratory approval. Such payment must be received by ELAP in advance of the assessment.

All information and data reviewed during an on-site assessment will be considered confidential. Additionally, environmental laboratory consultants (or assessors) are entitled to copy laboratory documents and records in the process of verifying that the conditions for accreditation are met. A laboratory may request information and data to be claimed as "Confidential Business Information", and any release of such information is subject to the state's Freedom of Information Law (FOIL) and Public Officers Law (Article 6).

The general checklist used for on-site assessments will focus on the laboratory's quality system, which means a structured laboratory management system that meets the standards for a quality system set forth by the Program. Currently, the checklist includes items from the National Environmental Laboratory Accreditation Conference (NELAC) 2003 Standards. The checklist also includes references to the 2009 TNI Standard. Depending on the laboratory's scope of accreditation, the assessors may use method specific checklists (e.g., asbestos by PLM, fibers by PCM, and radon by CRM). Checklists utilized by the assessors are available on the Program's website.

Upon arrival to the laboratory, the assessors will hold an opening conference to discuss the following:

- Purpose of the assessment - The assessment may be a comprehensive evaluation of laboratory conformance to the standards, or limited in scope, such as a follow-up assessment where a deficiency was identified by a previous assessment. It is an evaluation of the laboratory to verify it is in conformance to current ELAP & NELAC Standards.
- Identify Standard - The Lead Consultant identifies the standards that will be used to assess the lab.
- Introduction of the Assessment Team - The Lead Consultant is identified and introduces the other members of the team.
- Checklist – The Lead Consultant is to identify the checklist that will be used to assess the lab, and indicate to the lab that all checklists are available on the ELAP website.
- Attendance Sheet – Each lab representative and assessor attending the opening conference signs the attendance list and includes their title.

- Hours – Lead Consultant is to identify the start and stop times, as well as, lunch.
- Pre-Assessment Report (PAR) and Fields of Accreditation (FOAs) – The Lead Consultant is to verify the accuracy of the general information (email, contact information, etc.). He/she also verifies the lab's fields of accreditation. For a routine assessment this includes all FOAs for which ELAP is the laboratory's primary Accrediting Body, or which ELAP has agreed to assess on behalf of another primary Accrediting Body.
- Tentative Closing – The Lead Consultant is to provide a tentative date and time for the closing conference.
- Tour – The Lead Consultant is to request that an escorted tour be given for first visits or to a remodeled facility.
- Appraisal Form (OSA Form 2) – The Lead Consultant is to provide the assessment appraisal form to the responsible lab official.
- Records – The Lead Consultant is to define the records and operation procedures to be examined during the assessment and the names of the individuals responsible for providing the team with the necessary documents. Arrangements shall be made for an area to conduct document review and employee interviews.
- Questions – The Lead Consultant is to discuss any questions that the laboratory may have about the assessment process.
- Key Managers roles and responsibilities – The Lead Consultant is to have the lab identify these key personnel and their duties.
- Organizational Chart - The Lead Consultant is to request a copy of the chart and compare the lab's organizational chart with the "Key Personnel" noted on the PAR.
- Confidential Business Information – Refer to procedures in Section 4.1.5 and 8. The laboratory has the right to claim that information provided during the assessment is CBI (Section 4.1.5 and 8).
- Safety Procedures – The Lead Consultant asks if the lab requests any special safety procedures, but do not sign any type of statement waiving the lab's responsibility for your safety.

During an on-site assessment, the assessors will review various aspects of the laboratory's operation and communicate with technical (e.g., technical director, quality assurance officer, and analysts) and support staff (e.g., sample receiving and purchasing unit). The areas assessed include, but are not limited to, the following:

1. organization and management (i.e., technical directors and QA officers);
2. quality system;
3. document control;
4. review of request, tenders and contracts;
5. subcontracting;
6. services and supplies;
7. service to client;
8. complaints;
9. control of nonconforming work;

10. corrective action;
11. preventive action;
12. records (i.e., record system);
13. internal audits;
14. managerial reviews;
15. data integrity and ethics;
16. personnel's competence, continuing employment, and training records (e.g., demonstration of capability);
17. physical facilities (accommodation and environmental conditions);
18. test methods, SOPs and method validation;
19. equipment and reference materials;
20. measurement traceability and calibration;
21. sampling;
22. sample handling;
23. assuring the quality of test results;
24. reports;
25. detailed chemical, microbiological, radiochemical, asbestos, and/or critical agent method reviews; and
26. any other factors that might affect the quality of laboratory data.

At the conclusion of an on-site assessment, the assessors will discuss any **preliminary** deficiencies found with the laboratory management. **In addition, the assessors will discuss the presence of any repeat deficiencies that may result in a proposal of suspension at the discretion of the Program and answer any questions the lab may have.**

In most cases, the Program will issue a deficiency report to the laboratory within thirty (30) calendar days of the closing date of the on-site assessment. However, at certain times, the Program will issue a "proposal of suspension" letter with the deficiency report. The laboratory must respond to the proposal of suspension letter within ten (10) calendar days.

In either case, the laboratory is to respond to the deficiency report with a corrective action plan within thirty (30) calendar days after receipt of the report. The laboratory director or a designee shall outline in the space marked "Corrective Action" the steps that have been taken to correct the noted deficiency. Evidence of completed corrective actions must be attached. In addition, the laboratory director must sign the report to attest that this plan of correction has been/or will be implemented by the date(s) indicated.

The Program has thirty (30) calendar days to review the laboratory's corrective action responses. In general, if the corrective action responses are acceptable, the assessment will be closed out and a letter issued to the laboratory. If the responses are unsatisfactory, the Program will either issue another deficiency report or take administrative action (e.g., proposal of suspension and suspension).

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If the laboratory receives a second deficiency report, the laboratory will have thirty (30) calendar days to submit a revised corrective action report. Once again, the laboratory director or a designee shall outline in the space marked "Corrective Action" the steps that have been taken to correct the noted deficiency. Evidence of completed corrective actions must be attached. In addition, the laboratory director must sign the report to attest that this plan of correction has been/or will be implemented by the date(s) indicated. If the laboratory receives an administrative action letter with the second deficiency report, the laboratory must take action as indicated in the letter (i.e., respond within ten (10) calendar days).

The Program has thirty (30) calendar days to review the laboratory's corrective action responses to the second deficiency report. In general, if the corrective action responses are acceptable, the assessment will be closed out and a letter issued to the laboratory. If the responses are unsatisfactory, the Program will take administrative action (e.g., proposal of suspension and suspension).

Pursuant to NYCRR Subpart 55-2.6, failure to make a timely response to cited deficiencies may lead to suspension of approval. Furthermore, if, at any time, it becomes apparent that a deficiency (or deficiencies) of such magnitude exists as to impair the quality of analytical data being generated by the laboratory, steps will be taken to immediately suspend the laboratory's certification.