On-Site Survey Requirements

The Laboratory Certification Section conducts two types of on-site surveys: announced (scheduled with laboratory) and unannounced (not scheduled with laboratory). The surveys are to confirm the information provided to the Laboratory Certification Section by the laboratory on its application, review and evaluate each analyst and review records maintained by the laboratory.

The following personnel are required to be available during an announced on-site survey:

- All certified personnel seeking renewal or initial certification.
- All personnel seeking initial operational certification.
- A majority of the operationally certified personnel seeking renewal certification.
  - Exemption of operationally certified personnel may not exceed more than one certification cycle.

Surveys are conducted between 8:00 a.m. – 5:00 p.m. Required laboratory records must be located in the laboratory, clearly labeled and easily accessible. Copies of the records must be made available upon request by the certification officer.

It is recommended that at least two people be designated as responsible for allowing access to the laboratory (e.g., city hall employee, plant operator, police officer, etc.). Telephone numbers of the responsible personnel must be posted in a location visible outside the facility to allow access for certification officers.

A. Typical Agenda

During the on-site survey the laboratory must demonstrate acceptable levels of performance including, but not limited to:

- Proficiency in appropriate analytical procedures, methodologies, techniques, and use of equipment by analysts participating in the on-site survey.

- Analysis of proficiency test samples.

- For laboratories seeking initial certification, maintenance of laboratory records for at least thirty (30) days prior to the on-site survey, with the records documenting:
  - All appropriate laboratory equipment and auxiliary equipment is operational within prescribed limits.
  - Sufficient practice analyses have been conducted by each analyst participating in the on-site survey to demonstrate the analyst's proficiency.
  - An acceptable quality assurance plan has been documented and implemented.
  - The analyses, QC procedures and preparation of standards were correctly performed by each analyst participating in the on-site survey, except for analysts to be designated for operational certification.
  - Acceptable method detection limit studies have been completed for each method and instrument.

- Conformance to the laboratory plan as approved by the Director.
• Conformance by the laboratory to the analytical reporting limits identified in rule 3745-89-03 of the OAC.
• Correction of deviations noted in previous survey reports.

B. Review of Survey Findings

At the completion of the on-site survey the certification officer will meet with the appropriate laboratory representatives to review the findings of the survey. A copy of the deviations noted during the survey will be provided within 45 days of the survey.

C. Survey Report

A survey report will be issued to the applicant by the Laboratory Certification Section within forty-five (45) days of an on-site survey. The survey report will indicate the acceptability of the applicant’s performance during the on-site survey and will state deviations required to be corrected prior to certification of the laboratory. If the survey report includes deviations, the Director of Ohio EPA may deny, suspend or revoke certification in accordance with rule 3745-89-06 of the OAC.

In accordance with rule 3745-89-01 of the OAC, a deviation is non-compliance with laboratory certification requirements which cover the physical facility, testing equipment, analytical methods, reporting and all QC requirements whether they are in the method, the laboratory certification manual or the OAC.

Laboratories are generally given 30 days to respond to deviations identified during the survey.