



Laboratory Certification and the Enforcement Process

Enforcement is an unfortunate component of Laboratory Certification. Without the ability to revoke or suspend a laboratory's certification or registration, the quality of data entering the Department (*and used to make environmental decisions*) would be much more difficult to control.

Due process is the foundation upon which the Department's environmental enforcement program is built. Due process is a constitutional guarantee that all legal proceedings will be fair, that adequate notice of any government actions will be provided, and an opportunity to be heard will be provided before the government acts in a manner which might be construed as denying one's life, liberty, or property. Finally, due process provides a constitutional guarantee that a law shall not be unreasonable, arbitrary, or capricious.

Stepped Enforcement Philosophy

The overall Department goal is to obtain voluntary compliance. When there is a violation, however, enforcement occurs in a sequence. Primary enforcement actions, which are informal and coordinated by the program staff, come first. Geared towards solving problems, these actions lay the foundation for succeeding actions when violations are not resolved. Secondary enforcement is more formal and requires the involvement of more Department staff, coordinated by an enforcement specialist.

Each step in the enforcement process represents a separate attempt to resolve the violation. Department staff try to resolve the violation at the lowest possible level. Once the issue at hand is resolved, the violation can be closed out at any time.

The process usually begins with primary enforcement, termed informal enforcement. Department staff make these first steps as a part of routine operations. On occasion, a Notice of Non-compliance can be used to accentuate the need for a regulated facility to address Department concerns. The sequence continues into secondary enforcement. These actions are taken by different Department staff (normally an enforcement specialist) and are formal in nature, including legal actions such as orders or lawsuits.

Some serious violations need faster response. For these, Department staff may choose to skip the entire primary enforcement level and start with a Notice of Violation (NOV). In cases of severe violations or emergencies, a direct action can be taken, such as an emergency order or a direct referral.

Notice of Non-Compliance (NON)

The NON is the first formal written notice to the facility and is generally written by field/program staff. The letter informs the entity of the noncompliance with statutory or code requirements and identifies the specific violation. A response is usually requested within a specific time period from the entity as to how the problem will be solved. The NON can also request remedial measures and set a date at which further enforcement action will be taken if the violator has not returned to compliance.

Typically, if the Notice of Noncompliance arises from an on-site assessment, the assessment report is issued as the NON.

Notice of Violation (NOV)

An NOV represents the first level of what is termed "formal" enforcement. The key distinction between NON and NOV is that an NOV is no longer between (in our case) the auditor (or the LabCert Program) and the facility. An Environmental Enforcement Specialist--from the Regional or Central Office Environmental Enforcement Program-- must be involved. An NOV usually represents the first step towards what could potentially lead to suspension or revocation of certification/registration (if deficiencies remain uncorrected). In many cases, an enforcement conference is scheduled in addition to the NOV.

Objectives of a NOV include:

- alleging existence of specific violations of the law, citing code and statutory authority,
- Indicating detection of the violation and alleging violator responsibility,
- advising of possible prosecution and forfeitures,
- requesting a written response within a specified time period,
- requesting remedial action within a specified time period,
- requesting additional information, including a compliance schedule within a specified time period, and
- scheduling an enforcement conference (if deemed necessary).

Enforcement Conferences and Orders

An enforcement conference is a formal meeting with the facility/laboratory. An enforcement specialist takes the lead role. During the conference, the Department enforcement specialist should guide the discussion to a mutually acceptable resolution of the problems. The following should occur as part of the enforcement conference process. These are similar to the parts of an administrative order.

Gather information about the violation(s).

- *Provide opportunity for the violator to explain the cause of the violation(s).*
- *Explain the Department's intended actions if the violation(s) are not resolved.*
- *Obtain a commitment from the violator(s) to achieve compliance.*
- *When compliance measures are decided upon at the conference, commitments made by the violator should be documented in a letter which establishes the following:*

The facts of the violation(s)

- The legal basis of the Department's action(s)
- The actions which the violator agreed to take in order to correct the violation(s), including a compliance schedule and a final compliance date.

Actions that require more than six months to implement are typically made legally enforceable through an Administrative Order or Court Schedule.

Orders of Suspension

A laboratory's certification is valid until it expires, is *suspended* or revoked. A laboratory's registration is valid until it expires or is revoked. If, after opportunity for a contested case hearing, the department finds that an accredited laboratory materially and consistently failed to comply with the provisions of this chapter, the department may suspend or revoke a laboratory's certification or revoke a laboratory's registration by analyte, group of analytes or test category. Contested case hearings for out of state laboratories regulated by this chapter shall be held in Madison, WI.

An Order of Suspension is typically reserved for those cases in which the deficiencies are associated with a defined, but temporary, situation. A good example of this is a laboratory that can no longer analyze metals because their flame or graphite furnace AA is no longer functional for whatever reason) and the laboratory does not anticipate replacing it for a period of time. An Order of Suspension could be written which effectively removes metals (by GFAA/FLAA) from the laboratory's accreditations until such time as the instrument is replaced and shown to be fully operative. Once the time period or

conditions of the Suspension Order have been fulfilled, the laboratory can continue analyzing metals without the need to re-apply.

Orders of Revocation

An Order of Revocation is used to formally cancel a laboratory's certification, either in whole, or in part. Orders of Revocation usually result from either chronic reference sample failure, or failure --despite the efforts of LabCert Program staff--to resolve deficiencies identified during an on-site evaluation.

Audit-Related Enforcement

During an evaluation, if an accredited laboratory is found to be significantly out of compliance, the first phase of the Department's enforcement strategy may be initiated.

Depending upon the nature, number, and severity of the deficiencies (or the identification of repeat deficiencies), the auditor may issue either a Notice of Noncompliance (NON) or a Notice of Violation (NOV). These notices may be specific to a matrix, technology, or even analyte. This means a laboratory may be doing a fine job in one area (e.g., metals), yet receive a NON in another (e.g., BOD). The notices can be resolved when the laboratory has satisfactorily proven to the auditor that it has come into compliance or when the deficient areas are withdrawn from its accreditation. The first option can be accomplished by the documentation of corrected deficiencies in a written response to the audit report or by a successful follow-up visit by the auditor. If progress in correcting the deficiencies is not made in a timely manner, the enforcement status will escalate to the next step. The second option, to voluntarily withdraw deficient areas, can be done through formal correspondence to the Laboratory Certification & Registration (LabCert) Program stating which accreditation(s) is (are) to be withdrawn.

Tips to Avoid Audit-Related Enforcement

Laboratories need to follow certain practices to produce high quality data.

- Establish and maintain a comprehensive quality system. A strong quality system is founded by documentation and accountability. The system must ensure that all data meet specific data quality objectives or are "flagged" appropriately.
- Ensure traceability of data. Documentation must exist to prove who generated the data, how it was generated, what reagents and standards were used in its generation, and how final results were calculated.
- Follow the method. Laboratories must closely adhere to the approved analytical methodologies in order for the Department to compare results between laboratories.

If a laboratory does not follow the required methodology, disregards quality control results, and its data is biased high or low, the resulting data could lead to incorrect environmental management decisions. Decisions based on faulty data sets cost additional time and money and could lead to greater environmental risk for fish, wildlife or human health