



On-Site Evaluations and the Application Process

Any time a laboratory submits an application for initial accreditation or a revision to its existing accreditations, the Department reserves the right to conduct an on-site evaluation. An evaluation will always be required for new laboratories seeking initial accreditation. For other applications, an audit may be waived. In determining whether or not to waive an on-site evaluation, consideration is given to the time that has elapsed since the last audit, the relative complexity of the technologies or analytes for which accreditation is sought, and overall standing of the laboratory with respect to metrics including PT performance.

Preparing for an On-Site Evaluation

What do you need to do to prepare for an on-site evaluation? Before the Department evaluates your laboratory, you should review your lab's quality manual and SOPs for compliance with:

- [Chapter. NR 149, Wis. Adm. Code,](#)
- [The approved methods of analysis,](#) and
- The "[Manual for the Certification of Laboratories Analyzing Drinking Water, 5th ed.](#)" (January 2005) *for labs performing drinking water testing*

Review ch. NR 149, the Laboratory Certification and Registration Code.

At the time a laboratory signs the application for accreditation, it agrees to comply with the requirements of ch. NR 149 Wis. Admin. Code and to follow quality control procedures specified in it. The auditor is only verifying compliance with the NR 149 Code and the methods of analysis. It is therefore wise to understand the code requirements and the methods. The auditor may also make some suggestions that fall under "good laboratory practices" which are helpful.

Provide the auditor with key facility information prior to the visit.

Department files contain basic information about the laboratory, but it is always useful to familiarize the auditor in advance with particular or unusual aspects of the facilities operation. The more the person knows about the facility, the quicker the evaluation will proceed. Some items that are commonly requested are:

- The facility's quality manual and SOPs
- An updated list of analytical equipment in use at the laboratory
- An organizational chart or personnel roster
- Copies of variances or alternate test procedure approvals obtained by the laboratory
- A schematic layout of the laboratory
- Directions on how to reach the laboratory
- Initial demonstrations of capability (precision and accuracy studies)
- Summary of your lab's quality control acceptance criteria

An auditor may request items in addition to those on the above list. If the laboratory is using methods that are different from those listed on the application, or in its quality manual, it is important to inform the auditor of these changes before the visit so that they can adequately prepare for the evaluation.

Organize the laboratory records.

A key feature of the Laboratory Certification Program is its insistence on "documentation". The auditor will need to see evidence that the laboratory is complying with the various requirements of the Code. A substantial portion of the auditor's time at the laboratory will be spent perusing records. Organize the

laboratory's records to provide maximum availability, accessibility, traceability and clarity. Be prepared to provide the following to the auditor:

- Log of samples received at the laboratory
- Bench sheets or laboratory notebooks
- Quality control records
- Corrective action records
- Maintenance records of laboratory instruments

This is only a list of *some* items that may be requested. The auditor may request any information or document used to confirm compliance with Wisconsin's requirements. It is a common practice during laboratory evaluations to select several samples at random and "track" them through the laboratory's record system. Conduct this paper audit yourself at your laboratory to detect and correct any possible problems or system flaws before the visit.

Organize the laboratory equipment.

The auditor will take a tour of the laboratory and check that the instruments, chemicals and equipment needed to perform the tests for which the laboratory is seeking or currently holds accreditation are available. Purge the laboratory of inoperable equipment and unnecessary chemicals; discard expired stock solutions and make sure that current standards are explicitly labeled and dated.

Be realistic about the efforts to improve the laboratory's operation shortly before an audit. The interval between the auditor's contact and actual evaluation can be efficiently used to do a little "house cleaning", but would not be enough time to devise, revise and implement a full quality system.

Also, please review any previous on-site inspection reports and make sure that any previously noted deficiencies have been corrected!!

Audit Debriefing and the Audit Report

The auditor will hold an informal debriefing at the conclusion of the audit. At this time s/he will identify any deficiencies noted during the evaluation and may also make recommendations for other improvements. A formal report of the on-site evaluation is due to the laboratory within 30 days of the audit. Use the time between the audit and receipt of the final audit report wisely to correct and document resolution of any deficiencies. Please be aware that in reviewing his/her notes in preparing the audit report, it is not unusual for the auditor to discover additional deficiencies not identified during the debrief.

The Audit Response

Any deficiencies identified during the on-site inspection will need to be corrected and must be documented to the Department before the audit can be resolved. Labs are required to submit a formal response to the audit reports within 30 days of receiving the report. Documentation of the corrections should contain how the problem was corrected and actual data proving the implementation of the correction such as photocopies of log book pages, bench sheets, calibration information or raw data. The auditor will offer guidance regarding what is needed in its response. Since the response is historically the most time consuming process of the evaluation, listen to the auditor and read the report carefully. Submitting a complete and acceptable initial response which sequentially addresses issues outlined in the report is the quickest way to become accredited or resolve any enforcement action. It is to the laboratory's advantage to submit exactly what the auditor asks for, which is designed to verify compliance. This may sound simple, but most laboratories submit two or more responses before it is complete and acceptable, which more than doubles the time needed to solve the non-compliance issue. The result of multiple submittals is a longer wait for accreditation, a longer duration for the Notice of Noncompliance or Violation, or a possible escalation in enforcement.