

# Laboratory Certification Program Summary

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## **History**

The Wisconsin Department of Natural Resources' (WDNR) Laboratory Certification & Registration (LabCert) Program was created in 1986 to help insure that laboratories submit reliable and consistent data to the Department's various environmental programs. The program has grown significantly since its inception and currently certifies or registers more than 380 laboratories in 17 states.

The program currently offers accreditations designed to accommodate the needs of many DNR programs operating under the federal regulatory umbrella including testing under the Clean Water Act, Resource Conservation and Recovery Act and the Safe Drinking Water Act. Two levels of accreditation are offered; certification for large, commercial laboratories or registration for smaller municipal or industrial laboratories required to perform compliance monitoring by their permit.

## **Program Structure**

The program operates under Chapter NR 149 of the Wisconsin Administrative Code, which establishes specific requirements for accredited laboratories. Ch. NR 149 sets the scope of the available fields of accreditation and the fees for each. Available fields of accreditation are defined by Matrix-Technology-Analyte (or Analyte group) for aqueous and solid matrices and Matrix-Method-Analyte (or Analyte group) for the drinking water matrix. This allows a laboratory some flexibility in choosing the analyses and technologies/methods for which they wish to be accredited, thereby limiting their accreditation costs. The fees charged to laboratories participating in the program are considerably lower than similar programs in many other states.

The accreditation period is for one year, running from September 1 of the current year to August 31 of the following year. All labs are billed in May for the upcoming certification period. Each year, laboratories are required to pass the necessary reference samples and pay the appropriate annual fee prior to being renewed. Laboratories which do not meet the criteria for renewal are contacted by program staff, and a resolution is usually quickly achieved.

## **Program Staff**

LabCert Program staff consists of the program section chief, a program chemist, and five audit chemists. While the section chief and program chemist are housed in the Department's Central Office located in Madison, audit chemists maybe located either in the Central Office or in various regional offices throughout the state.

All audit staff have been trained initially through a mentoring program which ensures technical competence and strong auditing skills. Most auditors have also successfully completed the

EMSL- Cincinnati Drinking Water Laboratory Certification Course. Training emphasizes the value of having auditors, in addition to their regulatory compliance role, spend time helping laboratories understand current state and federal regulations and suggest ways to improve their operations.

The program's performance is overseen by an advisory council mandated by state statute. The Certification Standards Review Council consists of statutorily-defined representatives from the laboratory community and other related environmental interests. The Council meets with the LabCert program quarterly, and provides input on program performance and direction.

#### **On-site Evaluations**

On-site evaluations (audits) are the cornerstone of the Laboratory Certification Program. All new laboratories applying for accreditation are required to pass an on-site evaluation before entering the program. Once accredited, routine audits of all facilities occur every three years.

Any laboratory seeking accreditation in Wisconsin is required to establish and maintain a strict quality system which is verified through the on-site evaluation. Through audits, the program emphasizes quality systems, proper method execution and traceability of analytical results. The on-site evaluations consist of intensive surveys that examine laboratory facilities, sample receipt and handling, performance of analytical procedures, quality assurance, records and data reporting.

An audit report detailing any laboratory deficiencies identified and areas for improvement is issued within 30 days after the on-site inspection. These reports may be issued in conjunction with an enforcement action in severe cases of non-compliance.

The audit is an evaluation of a laboratory's systems and performance. Laboratories applying for Safe Drinking Water (SDWA) analyses and Underground Storage Tank (UST) analyses are also required to submit initial demonstrations of capability and method detection limit data. In addition, all labs are required to pass requisite proficiency testing (PT) samples initially and annually thereafter.

## **Technical Strengths**

In addition to the in-depth audit process, LabCert staff participate in a wide variety of activities related to environmental laboratories. These activities range from method development (e.g. the Wisconsin Modified Diesel and Gasoline Range Organics Methods) to data review and validation. The LabCert Program has developed guidance in several areas of analytical interest, including preparing laboratory quality assurance manuals and determining the limit of detection for a specific analyses.

The program's staff are also knowledgeable about a wide range of environmental regulations on both the state and federal level, and are willing to share knowledge will the laboratory community through a variety of forums including conferences, meetings and newsletters.

### Fiscal Responsibility

The LabCert Program is entirely supported by program revenue generated through annual accreditation and application fees. The program operates under a balanced budget; fees charged to laboratories are designed to recover the actual costs of administering the program, and cannot exceed the Department of Administration's approved spending authority allocated through the state's biennial budget process.

#### **Enforcement**

Laboratories found to be deficient either during an on-site evaluation or through the annual performance criteria are given several opportunities to comply with the regulations. The program follows a stepped enforcement process that escalates as deficiencies remain unresolved. The enforcement process can be very time consuming and tedious, going from a Notice of Noncompliance to a Notice of Violation and finally to Suspension or Revocation of certification, but it provides due process and is fair. The stepped enforcement allows laboratories to work with program staff to become a fully compliant, high quality laboratory.