

Microbiological Laboratory Certification Requirements

Laboratories submitting compliance monitoring data for public water systems in the State of Tennessee must be certified by the Department of Environment and Conservation. The Division of Water Resources (DWR) Laboratory Certification Program (LCP) evaluates and certifies laboratories for compliance monitoring data reporting. The program ensures that laboratories that submit compliance monitoring data meet the criteria established by the U.S. Environmental Protection Agency in *The Manual for the Certification of Laboratories Analyzing Drinking Water*, ([EPA 815-R-05-004](#)), 5th edition, January 2005. The certification manual can be downloaded from EPA's [laboratory certification webpage](#).

New laboratories wishing to become certified should contact the LCP several months prior to the date when the laboratory wishes to begin submitting compliance monitoring data. LCP staff are available to help guide new laboratories through the process. The process for becoming certified consists of:

1. Designating a laboratory space and obtaining the necessary equipment;
2. Staff training;
3. Data generation;
4. Submittal of application for certification, including laboratory QA Manual, PTs, IDOCs and training documentation for staff; and
5. On-site laboratory evaluation.

Laboratory space and equipment

New laboratories seeking certification should review the laboratory space requirements in both the Division *Design Criteria* and *Standard Methods*. Ideally, there should be a separate room for bacteriological analyses. Where a separate room is not available any space with controlled access, adequate bench space, storage, ventilation/climate control, and hot/cold running water may be acceptable.

The laboratory must have all the equipment necessary to run the analysis as specified by the method. In general, laboratories using enzyme substrate test methods require only an incubator, thermometers, UV light, and a pH meter. A more detailed list of equipment and specifications is included in this information packet.

Staff Training

Analysts analyzing drinking water compliance samples must be properly trained in the methods used for analysis. Analysts can obtain training through the Fleming Training Center in Murfreesboro, Tennessee. Training can also be obtained through providers such as Tennessee Association of Utility Districts (TAUD), or other third parties deemed acceptable by the LCP, and by working under the supervision of another certified microbiological laboratory at their facility. At a minimum, analysts should have 30 days on-the-job training in drinking water microbiology before analyzing compliance samples. Laboratories should review the analyst requirements in Section 1.2 of the Certification Manual.

Data Generation

New laboratories just starting up must generate a minimum of three months of routine and quality control data in order to determine their ability to produce reliable results. This provides an opportunity for laboratory staff to practice and become thoroughly familiar with the method and materials used in laboratory analysis. Laboratories must analyze split samples with a certified laboratory for compliance monitoring reporting. Comparative data between the certified lab and the applicant lab must agree within 95% or better.

Application Documentation

Laboratories desiring certification must submit a written application to the LCP. Along with the application the laboratory must submit a copy of its Quality Assurance Plan, an acceptable Proficiency Test (PT), and documentation of Initial Demonstration of Capability (IDOC) for each analyst that runs compliance samples. An application is not deemed complete and certification will not be granted until all documentation is received.

Laboratories must analyze PT samples acceptable to the LCP. The laboratory should arrange for an A2LA or ANAB accredited vendor to send PT samples for evaluation. A microbiology PT consists of a set of ten samples in various combinations of total coliforms, *E. coli*, non-coliforms, and at least one blank. Laboratories must successfully analyze nine of the ten samples with no false negatives. Results must be reported directly to the LCP by the PT provider. The LCP will not accept results submitted by the laboratory itself. An EPA Lab ID# is required when submitting laboratory results to the PT provider.

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Each analyst reporting compliance monitoring data must have an Initial Demonstration of Capability (IDOC) on file. An IDOC is documentation that the analyst has successfully demonstrated their ability to analyze samples using the specified method. Smaller laboratories with only one or two analysts may choose to utilize the PT as documentation of an IDOC. Laboratories with several analysts may find that ordering a PT for each analyst is cost prohibitive. Laboratories can set up their own blind study by having one analyst inoculate known cultures into sterile water and having another analyst who does not know which culture is present analyze the sample.

On-site Evaluation

Once the laboratory has submitted a complete application and all required documentation an on-site evaluation will be conducted by a laboratory certification officer. The evaluation is to determine, in person, the laboratory's fitness to analyze compliance monitoring samples. The facility and equipment will be inspected, and all records associated with laboratory activities relative to the method used to analyze samples will be reviewed.

Following the on-site evaluation, a report detailing the findings of the evaluation will be sent to the laboratory. If the evaluation shows everything to be acceptable certification may be granted and a certificate issued. Any finding determined to be a deviation must be addressed with a written response to the LCP.