



Obtaining Laboratory Certification

A. Introduction

As authorized by the Safe Drinking Water Act (SDWA), the United States Environmental Protection Agency (USEPA) has set health-based standards in the form of the National Primary Drinking Water Regulations (NPDWR) to protect against analytes that may be found in drinking water. In accordance with the SDWA and the NPDWR, public water systems must conduct periodic analyses of drinking water served to the public.

As delegated by the USEPA, Ohio EPA has primary enforcement responsibility for the SDWA in Ohio. This includes the responsibility to certify laboratory facilities and personnel to perform analytical measurements of all analytes specified in the State primary drinking water regulations and parameters necessary for the operation of public water systems. Ohio EPA implements the drinking water laboratory certification program through the Laboratory Certification Section in the Division of Environmental Services (DES). The program is implemented in conjunction with Ohio EPA's Division of Drinking and Ground Waters.

Following rules in Chapters 3745-81, 3745-82 and 3745-89 of the OAC, the Laboratory Certification Section recommends to the Director of Ohio EPA whether to grant or deny certification to laboratories and laboratory personnel.

The "Ohio EPA Laboratory Manual for Chemical Analyses of Public Drinking Water 2020" and the "Ohio EPA Manual for Microbiological Analyses of Public Drinking Water 2020" outline requirements for obtaining and maintaining certification for the analysis of drinking water in the State. These manuals contain methods and general laboratory facility requirements for the analysis of drinking water necessary for public water system operation. They are subject to change when, in the judgment of the Ohio EPA, such a change will be more effective in fulfilling its responsibility under the law.

The drinking water laboratory certification program requirements are found in Chapter 3745-89 of the OAC.

The following information is a brief outline of the requirements and procedures necessary to obtain laboratory certification to analyze drinking water samples for the purpose of determining compliance with Chapters 3745-81 and 3745-82 and rules 3745-83-01, 3745-91-06 and 3745-9-09 of the OAC. This includes plant control test and other analyses required by the Director of the Ohio EPA.

B. Approval for Laboratory Floor Plans

Plans for any type of laboratory construction or remodeling must be submitted to the Laboratory Certification Section for review and approval. Laboratory plan approval is covered under rule 3745-89-03 of the Ohio Administrative Code. In addition, the "Laboratory Construction and Remodeling Requirements" document can be accessed under the "Laboratory Certification" tab on the Laboratory Certification webpage [[Laboratory Certification | Ohio Environmental Protection Agency](#)].

If you have questions or need assistance, contact the Laboratory Certification Section. Laboratories are encouraged to contact the Laboratory Certification Section staff early in the planning stages for construction or remodeling of a laboratory. For laboratory plan approval, contact the Laboratory Certification Section at DWLabCert@epa.ohio.gov.

C. Proficiency Test (PT) Samples

In accordance with rule 3745-89-03 of the OAC, laboratories seeking to obtain or maintain laboratory certification must participate in a proficiency test (PT) sample study at least once annually resulting in an “Acceptable” evaluation, as described by this rule, for all regulated analytes for which the laboratory is certified. Laboratories seeking initial certification must pass a PT sample for each analyte for which it is seeking certification prior to the scheduled survey. An annual basis is considered January 1 through December 31 of each year.

Arrangements must be made with the PT provider to order a make-up PT sample for any regulated analyte(s) resulting in a “Not Acceptable” evaluation.

Laboratories with an evaluation of “Not Acceptable” for the initial and make-up PT studies for any certified parameter must immediately cease analysis for the parameter, submit a corrective action report and obtain a second make-up PT sample study for the parameter in question. The corrective action must address why the “Not Acceptable” result occurred and how the problem was resolved. The corrective action must be submitted prior to ordering the second make-up PT sample study.

Per the Quality Assurance Plan (QAP), the laboratory must notify the Laboratory Certification Section of where samples will be sent for analysis. As stated on the certificate, certification will be placed on hold until an “Acceptable” PT evaluation is received from the PT provider.

All PT samples must be part of an accredited WS study and provided by an accredited PT Provider Accreditor meeting the National Environmental Laboratory Accreditation Conference requirements.

Arrangements must be made with the PT provider to submit all PT sample results to the Laboratory Certification Section either by e-mail or mail.

D. Requirements for the Quality Assurance Plan (QAP)

The QAP, as required by rule 3745-89-03(A)(2) of the OAC, must include the following information:

- Table of laboratory organization delineating responsibilities of all laboratory personnel.
- Standard operating procedures including identification of the reference methods used to perform the drinking water analysis. These standard operating procedures must be reviewed and/or revised at least annually.
- Sample handling procedures, including:
 - Directions for maintaining sample integrity from collection to receipt, testing to disposal.
 - Directions for sample preservation, as required by the reference method.
 - Directions to ensure sample information accuracy.
 - Chain of custody forms, where applicable.
 - Directions for rejection and notification of samples not meeting method requirements.
- Routine practices to maintain the precision and accuracy of data.
- Corrective analytical action procedures.
- Preventive instrument maintenance procedures.
- Documentation of standard preparation and reagent expiration dates.
- Reporting procedures

This manual may be used by public water system laboratories seeking certification for plant control tests and microbiological tests as their QAP. In addition, these laboratories may use the Analytical Methods Standard Operating Procedures (SOPs) located in Chapter 7 of these manuals as the SOP of record for each analytical method for which the laboratory and its personnel are certified.

Laboratories not using this manual as their QAP must develop a QAP as described in USEPA's "Manual for the Certification of Laboratories Analyzing Drinking Water", dated January 2005 and designated "EPA 815-R-05-004", as supplemented in June 2008 and designated "EPA 815-F-08-006". These documents are available at water.epa.gov/scitech/drinkingwater/labcert/index.cfm.

E. Laboratory Contingency Plan

Each certified laboratory must have in place a written contingency plan, with a course of action outlining steps to be taken during an event which might prevent the sample analyses required for daily operation of the public water system as required by rule 3745-85-01 of the OAC.

F. Applying for Certification and Paying Fees

Applications for certification to perform drinking water analysis are to be completed and include all materials and information as detailed in rule 3745-89-03 of the OAC. An application will be considered incomplete and may not be accepted if it is not accompanied by a laboratory plan approval letter or include the date which laboratory plans were approved by Ohio EPA.

Applications can be acquired at the Laboratory Certification Section website: [Laboratory Certification | Ohio Environmental Protection Agency](#)

1. Initial Certification

An application for initial certification must be submitted in writing to the Laboratory Certification Section indicating which analysis methods are requested for certification.

The requirements for initial drinking water laboratory certification, in accordance with rule 3745-89-03 of the OAC, include, but are not limited to:

- Obtain Ohio EPA Director's approval of a detailed laboratory floor plan.
- Submit a complete application and pay the appropriate fee.
- Submit with the application a method detection limit study and an initial demonstration of capability (IDC) study required for laboratories applying for the following base certifications: Standard Chemistry, Limited Chemistry, Limited Trace Metals, THM/HAA/VOC, SOC/Pesticides, Metals or Radionuclides.
- Submit an acceptable quality assurance plan.
- Submit documentation of initial QC procedures required by the methods.
- Successfully analyze required proficiency test samples.
- Pass an on-site survey.

2. Certification Renewal and Maintenance

The requirements to renew and maintain certification, in accordance with rules 3745-89-04 and 3745-89-05 of the OAC, include, but are not limited to:

- Maintain a valid and unexpired laboratory certification.
- Submit results of proficiency test sample analyses.
- Make required improvements in its quality assurance plan.
- Report significant changes in facility, equipment, personnel, or quality assurance plan.
- Submit a renewal application and pay the appropriate fee.
- Submit to required audits and implement any required corrective actions.

An application for certification renewal must be submitted no more than 120 days and no less than 30 days prior to the expiration of the current laboratory certification. When applications for renewal are submitted in accordance with rule 3745-89-04 of the OAC and are deemed complete, the laboratory certification will be extended until such time as an on-site survey is completed. Should failure to follow guidelines result in loss of certification for a period of time, it will be the laboratory's responsibility to have required water analysis completed by a certified lab during that time.

3. Fees

Fees are detailed in Section 3745.11 of the Ohio Revised Code (ORC) and shall be paid at the time of survey request.

Survey fees are detailed on the website at: [feeschedule.pdf \(ohio.gov\)](#).

G. Assistance for Questions

If there are any questions regarding this information, please contact the Laboratory Certification Section or consult the Ohio Administrative Code Chapter 3745-89. A copy of this chapter is also available upon request from the Ohio EPA Legal Office at (614) 644-2115.