

Ohio Administrative Code

Rule 3745-89-03 Procedure for laboratory certification.

Effective: October 26, 2020

(A) General requirements. Laboratories applying for certification to perform analyses to determine compliance with Chapters 3745-81, 3745-82 and 3745-90, and rules 3745-91-06 and 3745-9-09, and as specified by paragraph (B) of rule 3745-83-01 of the Administrative Code, and with plant control tests for one or more public water systems, shall meet the following:

(1) The laboratory shall submit, for approval by the director, a detailed laboratory plan which includes the following:

(a) The analyses for which certification is sought and the number of individuals proposed to perform each analysis.

(b) Plans meeting the facility requirements as defined in the "Ohio EPA Laboratory Manual for the Microbiological Analyses of Public Drinking Water 2020" and the "Ohio EPA Laboratory Manual for the Chemical Analyses of Public Drinking Water 2020."

(c) The equipment proposed to be used in the laboratory, including specifications or names, descriptions, manufacturers, and model numbers for each type of equipment.

(d) The inventory of standards, reagents and media to be used in analyses for which certification is sought.

(2) The laboratory shall submit a quality assurance plan acceptable to the director when certification is sought for drinking water analysis. The "Ohio EPA Laboratory Manual for the Microbiological Analyses of Public Drinking Water 2020" and the "Ohio EPA Laboratory Manual for the Chemical Analyses of Public Drinking Water 2020" may be used by laboratories seeking certification for plant control and microbiological testing. Otherwise, an acceptable quality assurance plan shall be developed by the laboratory as described in the United States environmental protection agency's "Manual for the Certification of Laboratories Analyzing Drinking Water" fifth edition, dated January



2005 (designated "EPA 815-R-05-004"), as supplemented in both June 2008 (designated "EPA 815-F-08-006") and November 2012 (designated "EPA 815-F-12-006") by "the United States Environmental Protection Agency, Office of Ground Water and Drinking Water, Cincinnati, OH 45268." The quality assurance plan shall include at least the following parts:

(a) Table of laboratory organization which delineates the responsibilities of all laboratory personnel associated with drinking water analyses and designates the individuals responsible for quality assurance of drinking water analyses in the laboratory.

(b) Standard operating procedures including identification of the reference methods used to perform the drinking water analyses approved by the United States environmental protection agency.

(c) Sample handling procedures, including the following:

(i) Instructions for maintaining the integrity of the samples by tracking samples from collection to receipt, and testing to disposal.

(ii) Instructions for sample preservation, dechlorination, etc. as required by the reference method and the documentation used by the laboratory to verify that proper sample treatment is done.

(iii) Instructions to ensure that adequate sample information is obtained to allow the proper analysis and reporting of results.

(iv) Chain of custody forms, where applicable.

(v) Instructions for rejecting samples that do not meet shipping requirements, required reporting information, holding time or preservation requirements and instructions for notifying a public water system which submitted a sample that is rejected for failing to meet minimum requirements.

(d) Routine practices to maintain the precision and accuracy of data as specified by the director or required by each method of analysis.

(e) Corrective action procedures taken when unacceptable results are obtained from the analysis of



performance evaluation samples or quality control checks.

(f) Preventive maintenance procedures including directions and scheduling for instrumentation servicing.

(g) Documentation of the preparation and expiration of drinking water standards and reagents.

(h) Reporting procedures including directions followed to ensure that reporting is completed as specified in rule 3745-89-08 of the Administrative Code.

(3) The laboratory shall submit to the director an application for certification for drinking water analyses required of public water systems, on a form provided by the director. The application shall include the following parts:

(a) The name, address and telephone number of the laboratory and of the individuals responsible for the laboratory.

(b) A list of analyses for which certification is sought. This list shall designate which analytical methods in rule 3745-81-27 or 3745-90-04 of the Administrative Code shall be used for each analysis and shall include the name of each individual who shall perform each analysis.

(c) Documentation that the laboratory plan in paragraph (A)(1) of this rule has been accepted by the director.

(d) Documentation that the laboratory has obtained acceptable results described in paragraph (B) of this rule for analyses performed on all appropriate proficiency test samples provided by a proficiency testing provider accredited by a provider of PT samples accredited by a proficiency testing provider accreditor meeting the "National Environmental Laboratory Accreditation Program requirement (NELAP)", and documentation that proficiency test samples were analyzed at least annually for every contaminant by each method for which the laboratory desires certification. The director may designate other acceptable providers of proficiency test samples for analyses to meet this requirement.

(e) Payment of the appropriate laboratory survey fee established in accordance with section 3745.11



of the Revised Code. Fees for these surveys shall be paid via a method acceptable to the director. For the purposes of this rule, fees are as follows:

(i) The "organic chemicals" fee covers all surveys necessary to obtain laboratory certification for the analysis of drinking water for either of the following:

(a) Total trihalomethanes, haloacetic acids, or volatile organic chemicals.

(b) Pesticides and other organic chemicals.

(ii) The "trace metals" fee covers all surveys necessary to obtain laboratory certification for the analysis of drinking water for all metals identified by the United States environmental protection agency as primary contaminants, secondary contaminants and contaminants with action levels.

(iii) The "standard chemistry" fee covers all surveys necessary to obtain laboratory certification for the analysis of drinking water for bromate, chlorite, cyanide, fluoride, nitrate, nitrate-nitrite, nitrite, orthophosphate, total phosphorus, sulfate, total dissolved solids and plant control tests.

(iv) The "limited chemistry" fee covers all surveys necessary to obtain laboratory certification for the analysis of drinking water for the following:

(a) Any three of the analyses included in standard chemistry.

(b) Any two of the analyses included in trace metals.

(c) Asbestos.

(d) Radioactivity and radioactive chemicals.

(e) Beginning one year from the effective date of this rule, total microcystins and cyanobacteria screening.

(v) The "microbiological" fee covers all surveys necessary to obtain laboratory certification for the



analysis of drinking water for one of the following:

(a) MMO-MUG (Colilert or Colisure).

(b) Membrane filtration (MF).

(c) Most probable number (MPN) by MMO-MUG and MF.

(4) The director shall return any application which is not filed in accordance with paragraph (A)(3) of this rule.

(5) Upon the laboratory's successful completion of the requirements of paragraphs (A)(1), (A)(2) and (A)(3) of this rule, the laboratory shall demonstrate acceptable levels of performance during the initial and subsequent on-site surveys, including the following:

(a) Conformance by the laboratory to the "Ohio EPA Laboratory Manual for the Microbiological Analyses of Public Drinking Water 2020" and the "Ohio EPA Laboratory Manual for the Chemical Analyses of Public Drinking Water 2020."

(b) Proficiency in appropriate analytical procedures, methodologies, techniques, and use of equipment by analysts participating in the on-site survey.

(c) Analysis of proficiency test samples.

(d) Maintenance of laboratory records for at least thirty days prior to the scheduled on-site survey, with the records documenting the following:

(i) All appropriate laboratory equipment and auxiliary equipment is operational within prescribed limits.

(ii) Sufficient practice analyses have been conducted by each analyst participating in the on-site survey to demonstrate the analyst's proficiency.



(iii) An acceptable quality assurance plan has been documented and implemented, as required by paragraph (A)(2) of this rule.

(iv) The analyses, quality control procedures, and preparation of standards were correctly performed by each analyst participating in the on-site survey, as required for the certification being requested.

(v) Acceptable method detection limit studies have been completed as required by the director for each method and instrument in accordance with the procedures in the 40 Code of Federal Regulations (C.F.R.) Part 136.

(e) The laboratory conforms to the laboratory plan as approved by the director.

(f) The laboratory is able to meet the analytical reporting limits listed in tables 1, 2, 3, 4 and 5 in the appendix to this rule. Laboratories shall report to the minimum level that they can consistently quantify but shall not have a minimum reporting limit any higher than the level in the appendix to this rule. Unless stated in this rule, the detection limits listed and defined in Chapter 3745-81 of the Administrative Code shall also be used as reporting limits.

(g) Correction of violations noted in previous survey reports.

(6) The survey report shall be issued to the applicant by the Ohio environmental protection agency within forty-five days of any on-site survey, shall indicate the acceptability of the applicant's performance during the survey, and shall state violations that are required to be corrected prior to certification of the laboratory. If the survey report notes violations the director may deny, suspend, or revoke certification in accordance with rule 3745-89-06 of the Administrative Code.

(B) Specific requirements for proficiency testing (PT). Laboratories applying for certification to perform drinking water analyses to determine compliance with Chapters 3745-81 and 3745-82, rules 3745-91-06 and 3745-9-09, and as specified by paragraph (B) of rule 3745-83-01 of the Administrative Code, as well as plant control tests shall, in addition to the requirements of paragraph (A) of this rule, include with the application the appropriate required reports as follows:



(1) Applicants for laboratory certification for analytes referenced in paragraphs (C) to (K) of rule 3745-81-27 of the Administrative Code shall report PT results in accordance with paragraph (A)(3)(d) of this rule with no unacceptable results.

(2) Total trihalomethanes. Applicants for laboratory certification to perform analyses for analytes to determine compliance with rules 3745-81-12 and 3745-81-24 of the Administrative Code shall report bromodichloromethane, bromoform, chloroform and dibromochloromethane analysis in accordance with paragraph (A)(3)(d) of this rule with no unacceptable results. Total trihalomethanes analysis requires reporting all of the compounds established in the definition of total trihalomethanes in rule 3745-81-01 of the Administrative Code.

(3) Volatile organic chemicals. Applicants for laboratory certification for analytes referenced in rules 3745-81-12 and 3745-81-24 of the Administrative Code shall report PT analyses for volatile organic chemicals with maximum contaminant levels (except vinyl chloride) in accordance with paragraph (A)(3)(d) of this rule, with not more than twenty per cent unacceptable results.

(4) Microbiological contaminants. Applicants for laboratory certification to perform analyses for analytes to determine compliance with rules 3745-81-14, 3745-81-21, and 3745-81-41 to 3745-81-45 of the Administrative Code shall report microbiological contaminants analyses in accordance with paragraph (A)(3)(d) of this rule with no more than one unacceptable total coliform result, no more than one unacceptable E. coli result, and no false negative reported values.

(5) Haloacetic acids (five). Applicants for laboratory certification to perform analyses for analytes to determine compliance with rules 3745-81-12 and 3745-81-24 of the Administrative Code shall report haloacetic acids (five) analysis in accordance with paragraph (A)(3)(d) of this rule with no more than one unacceptable result. Haloacetic acids (five) analysis requires reporting all of the compounds listed in the definition of haloacetic acids (five) in rule 3745-81-01 of the Administrative Code.

(C) The director may issue, deny, suspend or revoke a laboratory certificate in accordance with rule 3745-89-06 of the Administrative Code.

[Comment: This rule incorporates the "Ohio EPA Laboratory Manual for the Microbiological Analyses of Drinking Water 2020" and "Ohio EPA Laboratory Manual for the Chemical Analyses



of Public Drinking Water 2020" by reference. Copies are available at www.epa.ohio.gov/ddagw/labcert.aspx and at the "Ohio EPA, Lazarus Government Center, 50 West Town Street, Suite 700, Columbus, OH, 43215." Copies can also be obtained by contacting the laboratory certification office at 614-644-4245.]

[Comment: This rule incorporates the United States environmental protection agency's "Manual for Certification of Laboratories Analyzing Drinking Water" fifth edition, dated January 2005 (designated "EPA 815-R-05-004"), as supplemented in both June 2008 (designated "EPA 815-F-08-006") and November 2012 (designated "EPA 815-F-12-006) by the United States environmental protection agency, office of ground water and drinking water, Cincinnati, OH 45268 by reference. Copies are available at http://www.epa.gov/dwlabcert and also at the "Water Resource Center (RC-4100), United States Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, D.C., 20460, (202) 566-1729." Copies can also be obtained by contacting the "Safe Drinking Water Hotline" at 1-800-426-4791. This document is available for review at "Ohio EPA, Lazarus Government Center, 50 West Town Street, Suite 700, Columbus, OH, 43215."]