Ohio Administrative Code

Rule 3745-300-04 Certified laboratories.

Effective: June 5, 2023

[Comment: For dates of non-regulatory government publications, publications of recognized organizations and associations, federal rules, and federal statutory provisions referenced in this rule, see rule 3745-300-15 of the Administrative Code titled "Incorporation by reference - voluntary action program."]

(A) Authority of a certified laboratory to perform analyses.

(1) A certified laboratory produces certified data under affidavit in accordance with rule 3745-300-13 of the Administrative Code only when the analyses are performed within the laboratory's current certification. Certification may limit the analysis of certain environmental media, as indicated on the laboratory's certificate issued by Ohio EPA under this chapter.

(2) In order to produce certified data to support a voluntary action under this chapter and Chapter 3746. of the Revised Code, the following shall occur:

(a) The certified laboratory shall be certified for each analyte, parameter group, and method at the time the laboratory performs the analyses.

(b) The certified laboratory's analyses shall remain consistent with the laboratory's standard operating procedures (SOPs) and quality assurance program plan (QAPP).

(c) The certified laboratory's SOPs and QAPP used to produce certified data shall be consistent with all of the following:

(i) Requirements in the published method published or endorsed by U.S. EPA.

(ii) The applicable minimum requirements in paragraph (D) of this rule.

(iii) Any additional requirements specified during approval for analysis using performance-based methods under paragraph (B)(1)(c) of this rule.

(iv) Where there is a conflict between paragraph (A)(2)(c)(i) of this rule and paragraph (A)(2)(c)(ii) of this rule or paragraph (A)(2)(c)(iii) of this rule, requirements consistent with paragraph (A)(2)(c)(ii) of this rule or paragraph (A)(2)(c)(iii) of this rule take precedence.

(3) Certification pursuant to this rule is applicable to analyses performed in support of a voluntary action, including but not limited to the issuance of a no further action letter under this chapter and Chapter 3746. of the Revised Code. Certification pursuant to this rule does not constitute certification under any other state or federal laboratory certification or accreditation program.

(4) For certification obtained that relies on third-party accreditation, the certified laboratory shall maintain in good standing the accreditation provided in paragraphs (B)(1)(d) and (B)(1)(e) of this rule.

(5) A volunteer may request that a certified laboratory analyze the constituents of a hazardous substance when a chemical testing method or technology does not exist to measure the concentration of the hazardous substance. When a hazardous substance is comprised of more than one constituent, the certified laboratory shall obtain certification for each constituent, even if the constituent is not listed as a hazardous substance.

(6) If a certified laboratory no longer intends to retain certification, the certified laboratory may return the certificate with a notice to Ohio EPA that indicates the certified laboratory's intent to withdraw from certification. Upon withdrawal, the laboratory shall not report data as certified data under this chapter.

(B) Methods for the analysis of analytes or parameter groups are the following:

(1) A laboratory certified pursuant to this rule for any method used for the analysis of any analyte or parameter group that meets the following criteria, except as provided in paragraph (B)(2) of this rule:

(a) Certification is restricted to hazardous substances or petroleum. If a chemical testing method or

technology does not exist to measure the concentration of the hazardous substance, then certification to test for constituents of the hazardous substance may be granted pursuant to paragraph (A)(5) of this rule.

(b) Chemical testing methods. A certified laboratory may apply for certification for any chemical testing method published or endorsed by U.S. EPA. A certified laboratory shall use a published or endorsed method only in the manner for which that method is designed.

(c) Performance-based methods. At the request of a laboratory, Ohio EPA may evaluate whether to certify a laboratory to perform analyses using a performance-based method. A laboratory shall demonstrate the laboratory's ability to perform the method using a proficiency testing sample as provided in paragraph (C)(1) of this rule, if available, and in accordance with the application requirements in paragraph (D)(4) of this rule.

(d) Asbestos accreditations. A laboratory holding certification for the analysis of asbestos shall have current accreditation in at least one of the following programs:

(i) American industrial hygiene association, asbestos analysts registry.

(ii) National institute of standards technology, national voluntary laboratory accreditation program for asbestos fiber analysis.

(iii) "The NELAC Institute" (TNI) recognized accreditation body.

(e) Accreditations for any constituent other than asbestos. A laboratory that holds certification for analysis of any constituent other than asbestos may rely on current accreditation from an accreditation body that is recognized by TNI.

(2) Testing for characteristic hazardous waste or for radioactive materials is not included for certification under this rule.

[Comment: Ohio EPA coordinates with the Ohio department of health for the Ohio department of health's review of any release of radioactive materials or substances.]

(3) Testing for sediment toxicity is not included for certification under this rule. Testing for sediment toxicity shall be performed in accordance with paragraph (F)(4)(b) of rule 3745-300-09 of the Administrative Code.

(C) Proficiency testing program.

(1) Use of proficiency testing samples; requirement to purchase proficiency testing samples through proficiency testing providers:

(a) Unless otherwise exempt from this requirement, a laboratory that holds certification under this rule shall do the following:

(i) Analyze proficiency testing samples representative of the analytes or parameter groups for certification.

(ii) Receive from the proficiency testing provider acceptable proficiency testing results pursuant to the criteria of this rule.

(b) The certified laboratory shall order proficiency testing samples from a proficiency testing provider that is approved to produce the proficiency testing samples and evaluate the proficiency testing results.

(c) For the purposes of this rule, a certified laboratory shall analyze a proficiency testing sample that was formulated and evaluated using the criteria established by TNI.

(i) If the laboratory holds certification for testing aqueous samples, the laboratory shall analyze a non-potable water sample or, if a non-potable water sample is not available, a drinking water sample.

(ii) If the laboratory holds certification for testing solid matrix samples, the certified laboratory shall analyze a solid matrix sample or, if a solid matrix sample is not available, an aqueous sample.

(d) Paragraph (C)(1) of this rule does not apply to certifications for asbestos or to the circumstances

provided in paragraph (C)(2) of this rule.

(2) Criteria for analysis of proficiency testing samples, exceptions, and waivers. To demonstrate compliance with this rule for any analyte or parameter group a certified laboratory shall analyze proficiency testing samples, which a proficiency testing provider prepared and evaluated using TNI criteria, except as follows:

(a) When a non-potable water proficiency testing sample is not available for an analyte or parameter group for which the laboratory holds certification, proficiency testing samples prepared and evaluated based on drinking water criteria may be used instead.

(b) For any analyte or parameter group for which TNI has not published any proficiency testing criteria or for which proficiency testing samples are not available, Ohio EPA may waive the proficiency testing sample analysis requirement in paragraph (C)(2) of this rule. In the case of a waiver, certification for the analyte or parameter group shall be limited to the use of a performance-based method as described in paragraph (B)(1)(c) of this rule.

(c) For any analyte or parameter group for which the certified laboratory holds NELAC accreditation in good standing pursuant to paragraph (B)(1)(e) of this rule, analysis of proficiency testing samples is not required unless Ohio EPA determines that proficiency testing is required.

(3) Use of existing proficiency testing results. A certified laboratory may use the proficiency testing results obtained for another state or federal certification or accreditation program to demonstrate compliance with this rule, provided that the proficiency testing samples comply with this rule.

(4) Analysis of proficiency testing samples.

(a) The certified laboratory shall analyze proficiency testing samples that include the analyte or parameter group which corresponds to the scope of the laboratory's certification.

(b) The certified laboratory may analyze a proficiency testing sample on more than one technology to demonstrate proficiency for an analyte or parameter group and method. For example, a laboratory that holds certification for volatile organic compounds by gas chromatography and mass

spectrometry may analyze the same proficiency testing sample on both technologies.

(c) Analysis of proficiency testing samples shall be conducted in accordance with the certified laboratory's SOPs and QAPP identified in paragraph (D) of this rule.

(d) The ordering and analysis of proficiency testing samples is based on a technology. To comply with this rule, a certified laboratory shall order a proficiency testing sample based on the technology that is representative of the certification. For example, to encompass the scope of a certification for volatile organic compounds, the certified laboratory shall ensure that the proficiency testing sample contains both aromatics and halocarbons.

(5) Reporting and time lines for proficiency testing studies are as follows:

(a) Reporting proficiency testing results. A laboratory that is certified for multiple technologies for an analyte or parameter group shall analyze and report proficiency testing results for each technology, and may use the same proficiency testing sample. For example, the same volatile organic compound proficiency testing sample may be analyzed on gas chromatography and mass spectrometry with a separate result reported for each technology.

(b) Ohio EPA may use periodic performance testing to assess a certified laboratory's ability to perform testing under this rule. Upon request, certified laboratories shall analyze proficiency testing samples and shall report the results to Ohio EPA.

(6) Proficiency testing reports submitted to Ohio EPA shall include the following:

(a) Name of proficiency testing provider.

(b) Certified laboratory name and address.

(c) Opening and closing dates of the proficiency testing study.

(d) Date proficiency testing report was issued.

(e) Analyte or parameter group with units, reported value, assigned value, and acceptance limits.

(f) Performance evaluation by proficiency testing provider.

(g) Technology code or method description.

(h) Sample matrix type.

(D) Minimum requirements for the QAPP and SOPs. Each certified laboratory shall have a written QAPP and written SOPs for every method and procedure used by the certified laboratory to produce certified data, and shall keep these documents at the certified laboratory for use by laboratory personnel. The QAPP and SOPs shall comply with paragraph (A)(2)(c)(iii) of this rule and the methods published or endorsed by U.S. EPA, except as specified in this rule.

(1) At a minimum, the QAPP shall include provisions that require the certified laboratory reports issued in compliance with this chapter to contain the following:

(a) An accompanying affidavit that complies with paragraph (P) of rule 3745-300-13 of the Administrative Code.

(b) At a minimum, a case narrative that includes the following:

(i) Discussion of any issues that impact the quality of the data with sample receipt, sample process, or sample analysis.

(ii) Discussion of any potential bias in sample results, as appropriate.

(c) A report of the analytical results determined by the methods indicated on the certified laboratory's certificate.

(d) A report of the quality control sample results and indication of whether applicable criteria were met.

(e) A copy of the chain of custody that accompanied the samples to the certified laboratory.

(f) At a minimum, a copy of the sample receipt form that records the following:

(i) Temperature of samples upon receipt by the certified laboratory, if the method requires monitoring.

(ii) Date and time the samples were received by the certified laboratory.

(iii) Notation of whether holding times specified in the SOPs for sampling preparation and analysis were exceeded.

(iv) Any exceptions or special instructions for sample handling, analysis, or reporting.

(v) Notation of whether samples include appropriate labeling, such as the date and time of sample collection and a sample identification notation.

(vi) Notation of whether sample containers contain appropriate sample preservatives, if applicable.

(vii) Description of the general condition of sample containers, including whether any containers were damaged or improperly filled.

(2) Data interpretation and reporting requirements. To ensure quality data interpretation and quality reporting of certified laboratory results, the QAPP or SOPs shall include, at a minimum, the following:

(a) SOPs shall include information regarding how the qualitative and quantitative analyses are performed and interpreted by the analysts.

(b) Certified laboratories shall report solid samples on a dry weight basis, unless otherwise dictated by the method or when inadequate sample volume limits the laboratory's ability to determine dry weight. The moisture content also shall be reported, when applicable. SOPs shall include processes and calculations for this purpose.

(c) Prior to issuance of the certified laboratory reports as certified data, certified laboratories shall complete peer review of applicable calibration, calibration verification, quality assurance, and quality control results, as well as sample laboratory results.

(d) SOPs for methods that include manual integration of chromatographic data to ensure that manual integrations are performed in a consistent and technically justifiable manner for standards, samples, and quality control solutions. The SOPs shall contain the following minimum requirements:

(i) Examples of proper and improper manual integrations.

(ii) Procedures to manually adjust data to ensure that obvious inaccuracies in automated integrations are corrected and that reported results accurately reflect the information contained in the analytical data.

(iii) Both original and modified chromatograms, including the chromatographic peaks and baselines, shall be peer reviewed.

(iv) The certified laboratory shall retain copies of the original and modified chromatograms. These shall be made available to Ohio EPA, or other interested parties, upon request.

(e) As appropriate, the QAPP or SOPs shall contain a provision that the certified laboratory shall narrate potential bias in sample results if the requirements in the SOP cannot be met, including, but not limited to, the following:

(i) Failure to meet required holding times.

(ii) Improper sample preservation.

(iii) Inability to perform corrective actions for calibration, calibration verification, or quality control outliers.

(iv) Insufficient sample amount.

(f) For dual column analysis, the following apply:

(i) Results shall only be reported if the analyte is detected in both columns.

(ii) If the certified laboratory does not designate a primary column, then the higher result shall be reported unless a matrix interference is causing the elevated concentration.

(iii) If the certified laboratory designates a primary column, then the results from the primary column shall be reported unless matrix interference is present.

(iv) In cases where matrix interference is present, the lower result, or both results, shall be included in the analytical report.

(g) Analytes reported as certified data shall meet all calibration, calibration verification, and quality control criteria. If analytes do not meet criteria, then the analytes shall not be reported as certified data except as provided in paragraph (D)(2)(e)(iii) or (D)(4)(c) of this rule. This applies to all analytes including, but not limited to, the following:

(i) Analytes traditionally known as poor performers or common laboratory contaminants.

(ii) Analytes that may meet method criteria through provisions of marginal exceedance.

(h) Certified laboratories shall not provide certified data for tentatively identified compounds.

(i) As appropriate, the QAPP or SOPs shall require the certified laboratory to report as certified data only for analytes specified in the method, unless the laboratory's certification specifically allows reporting of additional analytes for the method. If a certified laboratory report includes analytes that are not specified in the method and are not specifically allowed by the laboratory's certification, the laboratory shall identify the analytes as exceptions to the certified data attested to in the affidavit that is issued with the certified laboratory report.

(j) If a certified laboratory's certification relies on maintaining third-party accreditation in good

standing, the laboratory shall not report certified data under this rule when the relied-upon third-party accreditation is not in good standing with the issuing accreditation body.

(k) Samples for metals analysis that are filtered prior to digestion shall be reported as dissolved metals. Unfiltered samples or samples that are filtered after digestion may be reported as total metals.

(3) Instrument calibration requirements. To ensure the quality of the data to be analyzed, the QAPP or SOPs shall comply with the approved method and shall include the following minimum instrument calibration requirements:

(a) At a minimum, SOPs shall include all of the following calibration requirements:

(i) Information about the frequency of initial calibration and calibration verification.

(ii) Criteria to evaluate results of initial calibration and calibration verification, including calibration blanks.

(iii) Without exception, corrective actions the analyst shall follow for initial calibration, calibration verification, and calibration blanks when these standards do not meet the criteria required by paragraph (G)(3)(a)(ii) of this rule, as applicable.

(iv) A prohibition against forcing the initial calibration curve through the origin.

(v) A prohibition against use of the zero point in an initial calibration curve, unless specified by the method or there are instrument limitations.

(vi) Nonlinear initial calibrations (e.g., quadratic calibration model) may be used but are restricted to compounds that have historically exhibited a nonlinear response.

(vii) Nonlinear initial calibration models shall not be used to extend the calibration range for compounds that normally exhibit a linear response.

(viii) The lowest standard concentration used for initial calibration shall be at or below the certified

laboratory's practical quantitation limit.

(b) Standard operation procedures shall specify initial calibration models as follows:

(i) For quadratic calibration models, a minimum number of standard concentrations is six.

(ii) Unless otherwise specified by the method, for all other calibration models, the minimum number of standard concentrations is five.

(iii) If more than the minimum number of standard concentrations is used, only the lowest or highest standard concentrations may be omitted from the calibration model as long as the minimum number of standard concentrations from paragraph (G)(3)(b)(i) or (G)(3)(b)(ii) of this rule are retained for use.

(c) Calibration solutions shall meet the following minimum requirements:

(i) Unless the method allows for use of a different solution, the same solution used to prepare the initial calibration standards shall be used to prepare the continuing calibration verification standard.

(ii) Unless use of the same solution is specifically allowed by the method, when an initial calibration verification standard is included in a method, a different solution other than the one used to prepare the calibration curve shall be used.

(iii) A prohibition on the use of expired standards or spiking solutions, except for the analysis of air samples.

(iv) For analysis of air samples, expired standards or spiking solutions may be used if revalidated against an unexpired reference material or if recertified by the vendor. The certified laboratory shall keep on file the documentation of such revalidation or recertification.

(v) Retention time marker solutions shall be used for petroleum analysis. These solutions shall be analyzed before the instrument is calibrated.

(d) For all dual column analysis, the calibration criteria required by paragraphs (G)(3)(a) to (G)(3)(c) of this rule shall be met on the column used to report data as certified.

(4) Quality control. To ensure reliable data, the QAPP or SOPs shall comply with the approved method and shall include the following:

(a) Identify all reagents, standards, and spiking solutions to be used in sample preparation and analysis.

(b) Define criteria for the quality control solutions or provide reference as to where the information is available. When criteria are not met for all associated quality control solutions, including but not limited to the method blank and spiked laboratory control solutions, or when surrogate recoveries or internal standard recoveries fail to meet the defined criteria in samples or quality control solutions, corrective actions shall occur, except as provided in paragraph (G)(2)(e)(iii) or (G)(4)(c) of this rule. Upon re-analysis of the failed quality control solution once, appropriate corrective actions may include re-preparation of the entire batch, including re-digestion, re-distillation, or re-extraction.

(c) When surrogates, internal standards, method blanks, calibration verification solutions, or spiked laboratory control solutions are biased high and the associated samples are non-detect for the outlying analytes, corrective actions need not be taken, and reporting of certified data is acceptable.

(d) Include procedures to prepare initial, continuing, and calibration verification standard solutions and calibration blank solutions.

(e) Include procedures to prepare samples, including the weight or volume of the media.

(f) Calibration verification solutions shall contain all target analytes, except for the analysis of polychlorinated biphenyls. For polychlorinated biphenyl analysis, a spike mix that contains aroclors 1016 and 1260 is sufficient to represent the range of aroclors specified in the method.

(g) SOPs shall include information regarding quality control solutions, including all of the following:

(i) Frequency of analysis.

(ii) Weight or volume of the media used.

(iii) Criteria used to evaluate results.

(h) Quality control solutions shall be treated in the same manner as samples, including handling, preservation, preparation, and equipment use.

(i) All detections in the method blank equal to or greater than the reporting limit require corrective actions as specified in paragraph (G)(4)(b) of this rule.

(j) All calibration verification standards required by the method and evaluated for per cent recovery, as defined by the methods, shall be reported based on the true value of the standard.

(k) To report dual column analysis data as certified, criteria required by paragraph (G)(4)(b) of this rule for quality control solutions shall be met on the column used.

(5) Preparation of samples. To ensure the quality of the samples to be analyzed, the QAPP or SOPs shall comply with the approved method and shall include the following minimum requirements for preparation of samples:

(a) Identify requirements for sample preservation, storage, holding times (including beginning and ending times), and the proper sample collection container, including the following:

(i) If requirements from the approved method do not specify requirements for sample preservation, storage, holding times, and the proper sample collection container, the certified laboratory shall include such requirements in the QAPP or SOPs, as applicable.

(ii) Holding times described in the approved method shall not be increased by alternate preservation techniques or by alternate demonstrations.

(iii) Air samples from "Tedlar" bags shall not be reported as certified data. The transfer of air samples from "Tedlar" bags to a canister for air analysis shall be prohibited.

(b) Identify equipment used for sample preparation, and identify diluents used for all dilutions.

(c) Identify requirements to be followed for holding times for extracted, digested, or distilled samples, and the storage requirements and the proper storage containers for each.

(d) Include details to ensure that sample preparation specifications for digestion, distillation, clean-up, and extraction shall meet the final volume for analysis, either volumetrically measured or otherwise verified to meet volumetric specifications.

(e) If the preparatory batch standards (i.e., initial calibration or calibration verification standards) for digestion, distillation, or extraction are processed with the sample and the batch standards fail either quality control criteria or calibration criteria, upon re-analysis of the failed quality control solutions or calibration solutions once, the entire batch shall be prepared again. The corrective action shall occur except as provided in paragraph (G)(2)(e)(iii) or (G)(4)(c) of this rule.

(f) Analysis of non-aqueous samples for volatile organic compounds shall utilize a closed-system purge-and-trap process consistent with "SW-846" method 5035 or method 5035A, unless the analytical method pre-dates December 1996.

(g) For organic extraction methods that include instruction for drying solid matrix samples, surrogates or any other spiking compounds shall be added with the drying agent and into the homogenous mixture of sample or quality control sample. Surrogates or any other spiking compounds may not be added via the extraction solvent to samples and the associated quality control solutions.

(6) Analysis of samples. To ensure the quality of the samples to be analyzed, the QAPP or SOPs shall comply with the approved method and shall include the following minimum requirements:

(a) Identify equipment and instrumentation used for analysis of samples.

(b) For organic analysis methods, samples with failing internal standard or surrogate criteria require re-analysis of the samples. Dilutions shall be made only if matrix interference is present. Dilutions

shall not be made for the sole purpose to meet, or attempt to meet, internal standard or surrogate criteria.

(c) When mass spectrometry methods are used, designate the primary and secondary ions used for identification of compounds.

(d) Certified laboratories that report selective ion monitoring data shall include operating procedures for selective ion monitoring analysis within the associated SOP.

(7) At a minimum, the written QAPP shall meet any necessary requirements in paragraphs (G)(1) to (G)(6) of this rule and shall include provisions that describe the following:

(a) Procedures that require proper citation and use of method numbers, including the appropriate revision suffix, if applicable, shall be consistently identified and included on instrument printouts, logbooks, analytical reports, and any other laboratory documents. All method numbers plus the revision suffix, if applicable, shall correlate with the method number and revision suffix on the certificate issued under this rule.

(b) SOPs requirements shall be reviewed for potential updates at least once every two years.

(c) Describe storage requirements of samples during all phases of analysis.

(d) Provide details for the expiration of stock standards, solutions, and all working standards and solutions, or cross-reference to the location of that information.

(e) Identify how the certified laboratory shall establish quality control acceptance limits for the analysis of samples.

(f) Identify how the certified laboratory shall manage waste in accordance with all applicable federal, state, and local requirements.

(g) Include a provision to address initial and periodic training for personnel in sample receipt, preparation, analysis, and data interpretation and review:

(i) Certified laboratory personnel shall review the QAPP and applicable SOPs which relate to the tasks associated with laboratory personnel's duties at the laboratory. Laboratory personnel shall sign documentation that acknowledges review of the documents.

(ii) The certified laboratory shall maintain training records and documentation that the laboratory personnel reviewed the appropriate documents.

(E) Standards of performance and conduct to maintain certification. To maintain certification under this rule, a certified laboratory shall do the following:

(1) Produce results as certified data pursuant to paragraph (A) of this rule when the certified laboratory is requested to provide data in support of a voluntary action under this chapter or Chapter 3746. of the Revised Code.

(2) Disclose when the certified laboratory does not hold certification for a requested analyte, parameter group, or method included in a request for analysis. After this disclosure, if the requester still requests the analysis to be performed, the certified laboratory shall specify in the affidavit that accompanies the analytical report the analytes, parameter groups, or methods for which the laboratory is not providing certified data.

(3) Comply with the methods for which the laboratory is certified.

(4) Notify Ohio EPA in writing within thirty days after any of the following:

(a) A change in management personnel or quality assurance personnel.

(b) A change in certified laboratory operations that affects the laboratory's ability to perform analyses pursuant to this rule.

(c) A change in name or ownership of the certified laboratory.

(d) A relocation of the certified laboratory, in whole or in part, or a change of address of the

laboratory.

(e) Anything that results in the loss of accreditation, temporarily or permanently, that is relied upon for certification under paragraph (A)(4) of this rule for any analytes, parameter groups, or methods for which the certified laboratory holds certification.

(5) Perform acceptably on each certified laboratory audit conducted pursuant to this rule, and address in a timely manner the deficiencies that are identified by Ohio EPA.

(6) Perform analyses in accordance with the certified laboratory's QAPP and SOPs that are consistent with paragraph (D) of this rule when the laboratory produces certified data.

(7) Disclose when the certified laboratory cannot quantify at or below an applicable standard specified in a request for analysis as follows:

(a) The certified laboratory shall provide certified data that detects chemicals of concern in environmental media at or below the applicable standards, unless the certified laboratory discloses that the laboratory is incapable of achieving an applicable standard under the laboratory's certification.

(b) Unless the certified laboratory is otherwise informed of the need for a lower applicable standard, the certified laboratory shall quantify at or below the single chemical generic numerical standards in appendices A and B to rule 3745-300-08 of the Administrative Code.

(c) If a certified laboratory that performs analyses in support of a no further action letter but is not capable of detecting the chemicals of concern in environmental media at or below the applicable standards, the laboratory shall notify, in writing, the person who requests the analysis that the laboratory cannot quantify at or below an applicable standard using a method for which the laboratory is currently certified. The certified laboratory may disclose this information in the analytical report or by other means.

(8) Not falsify any information on any application, SOP, QAPP, or any proficiency testing result, or any certified data used in support of a no further action letter, or any other submittal to Ohio EPA.

(9) Not perform analyses in support of a request for a no further action letter for which the certified laboratory has a conflict of interest.

(10) Provide Ohio EPA access to the certified laboratory's facility and documents, data, or information related to any voluntary action, or laboratory certification, in order to determine compliance with this chapter and Chapter 3746. of the Revised Code.

(11) Promptly and completely respond to all document and data requests made by the director under this chapter and Chapter 3746. of the Revised Code.

(12) As required by this rule and rule 3745-300-13 of the Administrative Code, submit by affidavit all information, data, documents, and reports for use in support of a request for a no further action letter.

(13) Conduct laboratory operations in compliance with all applicable federal and state laws, regulations and rules, including but not limited to, requirements for management and disposal of samples that meet the definition of "hazardous waste" in rule 3745-51-03 of the Administrative Code and other hazardous wastes stored on property in compliance with Chapters 3745-52 and 3745-65 of the Administrative Code.

(14) Maintain in good standing any third-party accreditations relied upon for certification.

(F) All documentation provided to Ohio EPA in accordance with this rule shall be submitted to Ohio EPA in a format prescribed by Ohio EPA.

(G) Laboratory audits.

(1) At Ohio EPA's discretion, Ohio EPA shall audit certified laboratories to determine compliance with this rule. Laboratory audits may consist of a review of either documents or other information submitted to Ohio EPA. Laboratory audits may include an on-site visit to the laboratory to review the laboratory's operations and to evaluate the laboratory's facility and personnel.

(a) At any time and for any purpose, Ohio EPA shall evaluate a certified laboratory to determine a laboratory's compliance with the laboratory's obligations as a certified laboratory under this rule and the laboratory's ability to produce certified data in accordance with this rule. Ohio EPA may conduct this evaluation for any reason, including but not limited to, the following:

(i) When there is a change in laboratory personnel, management personnel, operational procedures, or other functional issue.

(ii) If Ohio EPA receives a complaint regarding the certified laboratory's performance.

(2) In order to determine compliance with this rule, an audit of a certified laboratory may include, but is not limited to, the following:

(a) Review of the certified laboratory's SOPs, QAPP, analytical reports and associated data, affidavits, and other documents.

(b) On-site visit and review of the certified laboratory's sample receiving area, waste storage area, analytical testing areas, and other pertinent areas of the certified laboratory. During the visit, Ohio EPA may review the following:

(i) Logbooks.

(ii) Sample storage procedures.

(iii) Instrumentation set-up and software programs.

(iv) Equipment calibration and maintenance procedures.

(v) Data review procedures.

(vi) Record filing and storage.

(vii) Project management and communication procedures.

(viii) Data reporting procedures.

(ix) Record files.

(x) Any other information or area of the laboratory deemed appropriate by Ohio EPA.

(c) Interviews of laboratory personnel to determine knowledge of personnel who perform the analyses.

(d) Review of any other documentation that Ohio EPA considers appropriate, including, if applicable, review of any documents related to third-party accreditation relied upon for certification.

(e) Review of performance testing results, as required by paragraph (C) of this rule.

(f) Evaluation of whether any violations of this rule are material in a laboratory's ability to report reliable, defensible, and representative data that satisfies the requirements for certified data under this rule.

(3) Ohio EPA shall prepare an audit report that indicates any deficiencies that are identified during the audit that require corrective actions by the laboratory. Failure to address the deficiencies in a timely manner may result in suspension or revocation of a laboratory's certification.

(4) If Ohio EPA identifies any deficiencies during a certified laboratory audit, the laboratory shall correct those deficiencies to Ohio EPA's satisfaction.

(H) Laboratory certifications:

(1) The certification, issued by the director, may limit the analysis of certain environmental media.

(2) The certification automatically expires three years after the date of issuance, unless the laboratory's certification is suspended or revoked, prior to the certification's expiration.

(3) The certification applies only to the individual certified laboratory facility identified in the certificate.

(4) The effective certificate shall be displayed in a prominent location in the certified laboratory.

(5) If a laboratory's certification is revised, the revised certification supersedes any prior certification.

(I) Retention of documents and data.

(1) A certified laboratory shall maintain all documents and data prepared or acquired in connection with a voluntary action for a period of at least ten years after the date that the laboratory's analyses were submitted to a certified professional or volunteer.

(2) The certified laboratory may retain the documents and data using any available technology, provided that the laboratory can readily retrieve the documents and data in legible condition when retrieval is requested by Ohio EPA during the ten-year retention period.

(3) If a certified laboratory does not intend to retain such documents and data after ten years, the laboratory shall notify Ohio EPA of such intent, and shall provide Ohio EPA the opportunity to obtain the documents and data.

(4) The documents and data shall be retained until the notice described in paragraph (I)(3) of this rule is provided to Ohio EPA, and Ohio EPA notifies the certified laboratory in writing whether Ohio EPA shall obtain the documents and data.

(5) Notification of Ohio EPA pursuant to this paragraph is not required as long as a certified laboratory continues to retain all documents and data.

(6) Failure to provide documents or data requested by Ohio EPA may result in permanent revocation of the laboratory's certification in accordance with paragraph (L)(3) of this rule.

(J) Out-of-state laboratories.

(1) As a condition of certification under this rule, certified laboratories located outside the state of Ohio consent to service of process and to personal jurisdiction of any Ohio court or the Ohio environmental review appeals commission in proceedings that adjudicate any rights or obligations under this chapter and Chapter 3746. of the Revised Code, or in which the cause of action involves, in whole or in part, the laboratory's performance under this chapter or Chapter 3746. of the Revised Code.

(2) Out-of-state certified laboratories consent to Ohio EPA's right of entry for inspection or investigation, and to the service of administrative warrants, inspection warrants, or other appropriate search warrants as a condition of certification under this rule.

(K) Appeal of certification determinations. The denial, suspension, or revocation of any laboratory certification is a final action of the director, which is subject to the procedure for appeal provided in Chapter 3745. of the Revised Code.

(L) Revocation or suspension of certification.

(1) The director may revoke or suspend a laboratory's certification issued pursuant to this rule, for a period to be determined by the director, upon finding that a laboratory failed to comply with paragraph (E) of this rule, except as provided in paragraphs (L)(2) and (L)(3) of this rule.

(2) The director may permanently revoke a laboratory's certification if the laboratory falsifies any information in connection with the laboratory's certification or any voluntary action, in violation of paragraph (E)(8) of this rule.

(3) The director shall permanently revoke a laboratory's certification if the laboratory does not comply with a request for documents and data, in violation of paragraph (E)(11) of this rule.

(4) If a laboratory's certification relies upon maintaining third-party accreditation in good standing, the director may revoke or suspend a laboratory's certification upon finding that the laboratory's third-party accreditation is no longer maintained in good standing.

(5) Upon revocation or suspension of certification, the laboratory shall promptly return to Ohio EPA the certificate to which the revocation or suspension applies.

(M) Procedure to request reinstatement of certification.

(1) Procedures to request reinstatement of certification after a suspension period are as follows:

(a) A suspended laboratory may request to reinstate the laboratory's certification for a suspension issued because of the laboratory's failure to comply with paragraphs (E)(1) to (E)(7), (E)(9) to (E)(10), and (E)(12) to (E)(14) of this rule.

(b) After the suspension period, the laboratory may request reinstatement of the laboratory's certification by providing a written request for reinstatement and any documentation to demonstrate that the laboratory resolved all findings which resulted in the suspension.

(2) Pursuant to rule 3745-300-03 of the Administrative Code, the certified laboratory is required to pay any costs incurred by Ohio EPA to review requests for reinstatement.

(3) If Ohio EPA conducts a certified laboratory audit of the laboratory the laboratory shall do one of the following:

(a) Perform acceptably on the audit.

(b) Prior to reinstatement of the laboratory's certification, shall correct any deficiencies that are identified during the audit. Laboratory audits shall be conducted consistent with paragraph (G) of this rule.

(4) A certification shall expire on the date listed in the original issuance.

(N) Procedures to request modifications to certifications.

(1) A laboratory shall request a modification to the laboratory's certificate to reflect changes in company name or address through use of a cover letter.