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3745-300-04 **Certified laboratories.**

[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 paragraph (B) of rule 3745-300-01 of the Administrative Code titled "Incorporation by reference."]

(A) Certified data; authority of a certified laboratory, as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code, to perform analyses.

(1) A certified laboratory produces certified data only when the analyses are performed within the laboratory's current certification.

(2) In order to produce certified data to support a voluntary action under this chapter and Chapter 3746. of the Revised Code, the laboratory must be certified for each analyte, parameter group and method, as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code, used at the time it performs the analyses. Further, the laboratory's analyses must remain consistent with the laboratory's standard operating procedures and quality assurance program plan as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code approved by the agency.

(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 asbestos analyses performed in support of a no further action letter, the certified laboratory must maintain the accreditation provided in paragraph (B)(1)(c) 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, as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code, 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 must obtain certification for each constituent, even if the constituent is not listed as a hazardous substance, as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code.

(B) Methods for the analysis of analytes or parameter groups.

(1) A laboratory may apply for certification pursuant to this rule for any method

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used for the analysis of any analyte or parameter group that meets the following criteria ~~listed below~~, except as provided in paragraph (B)(2) of this rule:

(a) Chemical testing methods, as defined in paragraph (A) of 3745-300-01 of the Administrative Code. A laboratory may apply for certification for any chemical testing method published or endorsed by the U.S. EPA or Ohio EPA. For the purpose of this rule, "endorsed" means any method referenced for use in a rule adopted by U.S. EPA or the director. "Published" means any chemical testing method posted on a U.S. EPA or Ohio EPA web site that indicates the method is approved for public use. A laboratory must only use a published or endorsed method in the manner for which it is designed. A laboratory may apply for performance-based certification under paragraph (B)(1)(b) of this rule if an analyte or parameter group was listed in a published or endorsed method, but the design of the method prohibits the analysis of the analyte or parameter group.

(b) Performance-based methods as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code. At the request of a laboratory, the agency may evaluate whether to certify a laboratory to perform analyses using a performance-based method. A laboratory must demonstrate its 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 contained in paragraph (D)(4) of this rule.

(c) Asbestos accreditations. A laboratory applying for certification for the analysis of asbestos must have current accreditation and is restricted to the procedures approved for use under one or both of the following programs:

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

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

(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 its

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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, as required under paragraph (F)(2)(b) of rule 3745-300-09 of the Administrative Code, must follow all of the requirements for the "Hyalella azteca" bioassay and the "Chironomus tentans" bioassay following the methods contained in "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates."

[Comment: Ohio EPA coordinates the review of sediment toxicity testing results when required under paragraph (F)(2)(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, as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code.

(a) A laboratory applying for certification under this rule must analyze proficiency testing samples representative of the analytes or parameter groups for certification, and receive from the proficiency testing provider acceptable proficiency testing results pursuant to the criteria of this rule.

(b) The proficiency testing samples must be purchased 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 laboratory must analyze either a non-potable water or drinking water proficiency testing sample that was formulated and evaluated using the criteria established by the national environmental laboratory accreditation conference institute.

(d) This paragraph 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; waiver. To demonstrate compliance with this rule for any analyte or parameter group a laboratory must analyze proficiency testing samples, which a proficiency testing provider prepared and evaluated using national environmental

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laboratory accreditation conference non-potable water criteria, except as ~~indicated below~~follows:

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

(b) For mobile laboratories applying for initial or additional certification, each proficiency testing sample must be analyzed while the laboratory is mobilized on location for a project and not at the laboratory's base of operations.

(c) For any analyte or parameter group for which the national environmental laboratory accreditation conference has not published any non-potable water or drinking water proficiency testing criteria or for which proficiency testing samples are not available, the agency may, at its discretion, waive the proficiency testing sample analysis prerequisite under this paragraph. In the case of a waiver, certification for the analyte or parameter group will be limited to the use of a performance-based method as described in paragraph (B)(1)(b) of this rule.

(3) Use of existing proficiency testing results. A 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 meet the requirements of this rule.

(4) Analysis of proficiency testing samples.

(a) The laboratory must analyze proficiency testing samples that include the analyte or parameter group which corresponds to the scope of its certification or application for certification.

(b) The 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 applying for certification for volatile organic compounds by gas chromatography and gas chromatography/mass spectrometry may analyze the same proficiency testing sample on both technologies.

(c) Analysis of proficiency testing samples must be conducted in accordance

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with the laboratory's standard operating procedures and quality assurance program plan identified in paragraph (D) of this rule, and in accordance with paragraph (C)(2)(b) of this rule if the proficiency testing analysis is being conducted by a mobile laboratory.

(d) Compliance with this rule does not allow a laboratory to analyze more than one concentration level for a proficiency testing sample.

(e) The ordering and analysis of proficiency testing samples is based on a technology. To comply with this rule, a laboratory must 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 laboratory must ensure that the proficiency testing sample contains both aromatics and halocarbons.

(5) Reporting and time lines for proficiency testing studies.

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

(b) Time lines for the analysis of proficiency testing samples. A laboratory that intends to apply for any initial or additional certification under this rule, must have analyzed the proficiency testing ~~sample(s)~~sample within the six months prior to the date the laboratory submits its application to use those proficiency testing results to apply for certification, except as provided in paragraph (C)(2)(c) of this rule.

(6) Providing proficiency testing reports to Ohio EPA. A laboratory must submit proficiency testing reports to the agency as directed by this rule.

(a) Applications for initial or additional certification. A laboratory applying for initial or additional certification must submit to the agency a copy of each required proficiency testing report along with the documentation listed in paragraph (D)(1) of this rule.

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(b) Proficiency testing report content. Each proficiency testing report submitted to the agency must include of the following:

(i) Name of proficiency testing provider~~;~~.

(ii) Laboratory name and address~~;~~.

(iii) Opening and closing dates of the proficiency testing study~~;~~.

(iv) Date proficiency testing report was issued~~;~~.

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

(vi) Performance evaluation by proficiency testing provider~~; and~~.

(vii) Technology code or method description.

(7) Agency evaluation of proficiency testing results. A laboratory applying for initial or additional certification must meet the proficiency testing requirements provided as follows:

(a) The proficiency testing samples are acceptable for use based on the criteria provided in this rule for the analyte or parameter group for which the laboratory is applying for certification.

(b) The laboratory has obtained acceptable proficiency testing results for each analyte and parameter group using the methods and technologies for which it is applying for certification.

(c) The laboratory has submitted to the agency the proficiency testing ~~report(s)~~report for proficiency testing samples analyzed within the time frame provided in paragraph (C) of this rule.

(d) At the director's discretion, the agency may require a laboratory applying for certification for a performance-based method to analyze non-potable water proficiency testing samples, or drinking water proficiency testing samples. These proficiency testing results will be used to evaluate a laboratory’s qualifications to apply for the performance-based method. For example, a laboratory applying for initial or additional certification

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for n-Hexane by gas chromatography/mass spectrometry must provide acceptable proficiency testing results for a non-potable water volatile proficiency testing sample analyzed using the same technology and method.

(D) Procedures to apply for initial, additional, or renewal certification.

(1) Applications for initial or additional certification. To apply for initial or additional certification, a laboratory must submit to the agency a complete application, which consists of the following:

(a) A hard copy of the completed original application for initial or additional certification, as appropriate, on the form provided by the agency~~;~~.

[Comment: All applications for certification under this rule may be downloaded from Ohio EPA's web site or are otherwise available upon request from the voluntary action program. In the case of initial certification for mobile laboratories, Ohio EPA may develop an application form that is different from the form designed for fixed-based laboratories.]

(b) A hard copy of the laboratory's quality assurance program plan~~;~~.

(c) A hard copy of the laboratory's proficiency testing report, in accordance with paragraph (C) of this rule, for the analytes and parameter groups for which it is applying for certification. This requirement does not apply to sediment-toxicity methods and asbestos, or when proficiency testing samples are not required as described in paragraph (C)(2)(c) of this rule~~;~~.

(d) A hard copy of the standard operating procedures for each analyte, parameter group and corresponding method for which the laboratory is applying for certification~~;~~.

(e) A hard copy or electronic copy of the laboratory's method detection limit study performed as described by paragraph (A) of rule 3745-300-01 of the Administrative Code for each analyte and parameter group, and corresponding method, except for the analytes or parameter groups provided under paragraph (B)(1)(c) of this rule. The following information must be provided for each analyte and parameter group in spreadsheet format:

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(i) Spiking concentration for each analyte or parameter group including units~~;~~.

(ii) Method numbers for which the laboratory is applying for certification~~;~~.

(iii) Extraction, digestion, distillation, preparatory, and analysis dates~~;~~.

(iv) Individual results of the method detection limit study samples as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code along with the calculated standard deviation, calculated method detection limit, and reporting limit for each analyte or parameter group~~; and~~.

(v) The laboratory must digest, extract, or distill all method detection limit study samples using the same procedures included in the standard operating procedures submitted under paragraph (D)(1)(d) of this rule.

(f) A hard copy of an affidavit, signed by a person authorized to submit the affidavit on behalf of the laboratory, affirming based upon knowledge, information, and belief that all information provided in the application and associated documentation is true, accurate, and complete~~;~~.

(g) For a fixed-base laboratory applying for initial certification, ~~the~~ payment of the non-refundable certification fee required by ~~paragraph (B)(3) of~~ rule 3745-300-03 of the Administrative Code~~;~~. ~~and~~

(h) For a mobile laboratory applying for initial certification or a certified laboratory applying for additional certification, the actual costs incurred by the agency as required by rule 3745-300-03 of the Administrative Code.

~~(h)~~(i) The information listed in paragraph (D)(3) of this rule, if the laboratory is applying for certification for asbestos, or paragraph (D)(4) of this rule, if the laboratory is applying for certification for a performance-based method, as provided in paragraph (B) of this rule.

~~[Comment: For a mobile laboratory, the agency will invoice the laboratory to recover its actual costs pursuant to paragraph (E) of rule 3745-300-03 of the Administrative Code.]~~

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(2) Applications for renewal certification. A certified laboratory must submit to the agency a complete application at least ninety days prior to the expiration date listed on the laboratory's current certificate. A certified laboratory requesting certification changes must comply with the requirements provided in paragraph (D)(5) of this rule. A complete application consists of the following:

(a) A hard copy of the original completed application for renewal certification on the form provided by the agency~~;~~.

(b) The payment of the non-refundable annual fee, required by rule 3745-300-03 of the Administrative Code~~; and~~.

(c) A hard copy of an affidavit, signed by a person authorized to submit the affidavit on behalf of the laboratory, affirming based upon knowledge, information, and belief that all information provided in the application and associated documentation is true, accurate, and complete.

(3) Applications for asbestos certification. A laboratory applying for initial or additional certification for the analysis of asbestos under paragraph (B)(1)(c) of this rule must submit a photocopy of a current certificate, or other form of documentation issued by either accreditation program listed in paragraph (B)(1)(c) of this rule. The submission must include the documentation required by paragraph (D)(1), excluding paragraphs (D)(1)(c) and (D)(1)(e) of this rule. A certified laboratory applying for renewal of its asbestos certification must submit a photocopy of a current certificate or other form of documentation issued by either asbestos accreditation program.

(4) Applications for performance-based method certifications. A laboratory applying for initial or additional certification for any performance-based method as provided in paragraph (B)(1)(b) of this rule, must submit the documents listed in paragraph (D)(1) of this rule and pay the fee required by rule 3745-300-03 of the Administrative Code , and provide the following:

(a) Laboratory check sample data. At a minimum, seven data points for each analyte or parameter group and matrix~~;~~.

(b) Quality control limits derived from the data points collected under paragraph (D)(4)(a) of this rule~~; and~~.

(c) Any other information the agency deems appropriate.

*** DRAFT - NOT YET FILED ***

(5) Modifications to certification. A certified laboratory may submit a request for a modification to the laboratory's certification, provided that the requested change is not subject to a requirement for initial, additional or renewal certification. The certified laboratory may only make such requests pursuant to paragraph (Q) of this rule.

(6) Requests for agency review ~~and approval~~ of revised standard operating procedures or a quality assurance program plan must be made in accordance with paragraph (G) of this rule.~~, and submitted as a request independent from an application for additional or renewal certification. A laboratory may implement the revised standard operating procedures or quality assurance program plan upon Ohio EPA's approval of the revisions.~~

(E) Procedures used to evaluate laboratory applications for initial or additional certification.

(1) Ohio EPA's review of a laboratory's application for certification begins within thirty days from receipt of a complete application. An application that contains all of the information listed in paragraph (D) of this rule is considered complete. The agency's review of a complete application includes the following:

(a) A detailed review of the laboratory's standard operating procedures, quality assurance program plan, method detection limit studies, proficiency testing results, and any other information as provided in paragraphs (D)(1), (D)(3), and (D)(4) of this rule~~;~~.

(b) A system audit, as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code, of the laboratory applying for initial certification. The agency may, at its discretion, conduct a system audit of a certified laboratory applying for additional certification. System audits will be conducted in accordance with paragraph (J) of this rule~~;~~.

(c) An audit report prepared by the agency within forty-five days from completion of the system audit. The audit report will indicate any deficiencies identified during the audit that require corrective actions by the laboratory in order for the agency to proceed with the laboratory's application for initial or additional certification~~;~~.

(d) A review of laboratory responses to correct deficiencies identified during the system audit~~; and~~.

*** DRAFT - NOT YET FILED ***

(e) A determination that the laboratory has paid ~~all fees~~ the fee or costs ~~including costs for performing the system audit~~ as established in ~~certification fees under~~ rule 3745-300-03 of the Administrative Code.

(2) To be recommended for certification, a laboratory must demonstrate to the director's satisfaction that the laboratory meets the requirements provided for certification under this rule and rule 3745-300-03 of the Administrative Code. The laboratory must also possess the ability to provide reliable, defensible, and representative data that satisfies the requirements for certified data under this rule and Chapter 3746. of the Revised Code using the standard operating procedures and documentation approved for use under this rule.

(3) Following successful completion of the requirements specified in paragraphs (C), (D), (E), and (J) of this rule, the director will provide to the laboratory a certificate identifying the analytes, parameter groups, and methods, for which the laboratory may perform analyses. These analyses may be used to produce certified data for use in support of a voluntary action, including a request for a no further action letter. The certificate automatically expires two years after the date of issuance, unless the laboratory's certificate is suspended, revoked, or renewed prior to the certificate's expiration. The certification expiration date for additional certification is the same as that of the laboratory's initial certification or renewal certification, as applicable. The certificate only applies to the individual laboratory facility identified in the certificate.

(4) Entities that own or operate multiple laboratories must apply for certification for each laboratory that will be performing analyses used in support of a request for a no further action letter.

(F) Procedures used to evaluate certified laboratory applications for renewal certification.

(1) A certified laboratory may only renew its certification under this rule for the analytes, parameter groups, and methods for which the laboratory is currently certified.

(2) As provided in paragraph (D)(2) of this rule, a certified laboratory must submit a complete renewal application at least ninety days prior to the expiration date listed on its current certificate. Any application received by Ohio EPA after the certificate's expiration date may require the laboratory to re-apply for initial certification in accordance with paragraphs (D)(1) and (R) of this rule. The agency's review of the application for renewal certification begins thirty days from receipt of a complete application. An application that contains all of the information listed in paragraph (D) of this rule is considered complete.

*** DRAFT - NOT YET FILED ***

The agency's review includes the following:

(a) Review of the laboratory's application to ensure that the laboratory is certified for the analytes, parameter groups and methods listed on the application~~;~~.

(b) Review of agency findings from a system or laboratory compliance audit~~, as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code,~~ conducted in accordance with paragraph (J) of this rule~~; and~~.

(c) Review the laboratory's history on payment of its annual fee, as established in rule 3745-300-03 of the Administrative Code.

(3) The director may deny a laboratory's application for renewal certification if the director determines that the laboratory failed to satisfy any of the requirements of paragraph (D)(2), (F), or (H) of this rule.

(G) Procedures on how to request review of revised standard operating procedures or quality assurance program plan.

(1) A certified laboratory must notify the agency of any revisions to approved standard operating procedures or quality assurance program plan that is the subject of a certification under this rule prior to implementing any revision.

(2) A certified laboratory must submit to the agency the revised document along with a summary of any changes made to the document, including deletions and additions. The agency will notify the certified laboratory within fifteen calendar days either of the following:

(a) A technical review of the revised document is not necessary based upon the agency's review of the information submitted in accordance with paragraph (G)(2) of this rule. Upon receiving this notification, the certified laboratory may implement the revised document for use under its certification; or

(b) A technical review of the revised document is required by the agency. Once the technical review is complete, the agency will do either of the following:

(i) Send comments on the revised document to the certified laboratory.

(ii) Notify the certified laboratory that the revised document may be implemented for use under its certification.

*** DRAFT - NOT YET FILED ***

(3) Upon receipt of the notification under paragraph (G)(2)(b)(ii) of this rule, the certified laboratory must provide final copies of all documents to the agency.

(4) The certified laboratory may not implement any revised document used in support of a request for a no further action letter until receipt of the agency's notification as provided in paragraphs (G)(2)(a) and (G)(2)(b)(ii) of this rule.

~~(1) A certified laboratory must receive prior approval from Ohio EPA before implementing any revision to approved standard operating procedures or a quality assurance program plan that is the subject of a certification under this rule.~~

~~(2) To request agency review of a proposed revision, the certified laboratory must submit to the agency a cover letter that requests the review. The submission must include the following:~~

~~(a) The revised document with the deleted or added text clearly identified in the revised standard operating procedure or quality assurance program plan, or a summary of all changes including deletions and additions. The revised document may be submitted in either a hard copy format or electronically using an electronic file formatted in a portable document file (.pdf). The laboratory may use other formats with approval by Ohio EPA;~~

~~(b) The agency may send any comments or approvals electronically; and~~

~~(c) The laboratory must send a signed and dated paper copy of the final, revised standard operating procedures or quality assurance program plan within forty-five calendar days from the date the documents were approved by the agency.~~

~~(3) Upon receipt of Ohio EPA's written approval of the proposed revisions, the certified laboratory may conduct activities pursuant to the revised standard operating procedures or quality assurance program plan. The certified laboratory may not implement any proposed revisions to a standard operating procedures or an approved quality assurance program plan in support of a request for a no further action letter until receipt of the agency's written approval of the revisions.~~

~~(4)~~(5) ~~The agency may recover its actual~~The laboratory may be required to pay for any actual costs that the agency incurred ~~costs~~ in reviewing the revised standard operating procedures or quality assurance program plans pursuant to rule 3745-300-03 of the Administrative Code.

(H) Standards of performance and conduct for maintaining certification.

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To maintain certification under this rule, a certified laboratory must do the following:

(1) Produce results as certified data pursuant to paragraph (A) of this rule whenever the 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 it does not hold certification for a requested analyte, parameter group or method included in a request for analysis. If the requester still requests the analysis to be performed, the laboratory must identify within the analytical report the results 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, of any of the following:

(a) A change in managerial or quality assurance personnel~~;~~.

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

(c) A change in name or ownership of the laboratory~~; and~~

(d) A relocation of the laboratory, in whole or in part, to a separate location.

(e) A change in personnel responsible for signing affidavits.

(5) Perform acceptably on each laboratory compliance audit and system audit conducted pursuant to this rule, and correct in a timely manner the deficiencies identified by Ohio EPA. Certified laboratories must correct all deficiencies within the timeframe provided by Ohio EPA~~;~~.

(6) Perform analyses in accordance with the laboratory's standard operating procedures and quality assurance program plan approved by Ohio EPA whenever the laboratory produces certified data~~;~~.

(7) Disclose when it cannot quantify at or below an applicable standard specified in a request for analysis. The certified laboratory must provide certified data that detects chemicals of concern in environmental media at or below the applicable standards, unless the laboratory discloses that it is incapable of

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achieving an applicable standard under its certification. For example, if a certified laboratory that performs analyses in support of a no further action letter is not capable of detecting the chemicals of concern in environmental media at or below the applicable standards, the certified laboratory must notify the person requesting the analysis that the laboratory cannot quantify at or below an applicable standard using a method for which it is currently certified. The laboratory may disclose this information in the analytical report or by other means~~;~~.

(8) Not falsify any information on any application, standard operating procedure, quality assurance program plan, or any proficiency testing result, or any certified data used in support of a no further action letter, or any other submittal to the agency~~;~~.

(9) Not perform analyses in support of a request for a no further action letter for which the laboratory has a conflict of interest.~~, as defined in paragraph (A) of 3745-300-01 of the Administrative Code;~~

(10) Provide the agency access to the laboratory's facility and documents, data, or information related to any voluntary action, or laboratory certification, for the purposes of determining compliance with the requirements of this chapter, and Chapter 3746. of the Revised Code~~;~~.

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

(12) Pay all costs and fees required by rule 3745-300-03 of the Administrative Code~~;~~.

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

(14) 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, and other hazardous wastes stored on property in compliance with Chapters 3745-52 and 3745-65 of the Administrative Code.

(I) Procedures for submittals under this rule.

All applications and payment of fees under this rule must be submitted to the

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agency by certified mail, courier delivery or any other form of mail or delivery accompanied by a receipt.

(J) Compliance and system audits.

(1) The agency will conduct laboratory compliance audits of a certified laboratory and its documentation to determine if the laboratory has performed in compliance with this rule, and Chapter 3746. of the Revised Code. The performance of laboratory compliance audits will be at the discretion of the agency, in accordance with this rule. For a certified mobile laboratory, a laboratory compliance audit will be conducted while the laboratory is mobilized on a project or at its headquarters. ~~and analyzing samples.~~ The agency will also conduct a laboratory compliance audit of the location where the data undergoes quality assurance review if not performed in the mobile laboratory. The agency may also conduct a laboratory compliance audit of any laboratory relocating its facility to a new location, or when there is a change in laboratory personnel, management personnel, operational procedures, or other functional issue or a complaint received regarding the laboratory's performance under the voluntary action program. A laboratory compliance audit may include, but is not limited to the following: ~~consists of the following:~~

(a) Review of the laboratory's standard operating procedures, logbooks, sample storage procedures, instrumentation set-up and software programs, equipment calibration and maintenance procedures, data review procedures, record filing and storage, project management and communication procedures, data reporting procedures, record files, and data packages to determine compliance with the requirements of this rule~~;~~.

(b) Interviews of laboratory personnel to determine knowledge of personnel who perform the analyses for compliance with this rule~~; and~~.

(c) Review of any other documentation that the agency considers appropriate to determine compliance with the requirements established pursuant to this rule.

(2) The agency will conduct system audits to evaluate a laboratory's qualifications to become certified to perform analyses used in support of requests for no further action letters in accordance with the requirements established in this rule. For a mobile laboratory, a system audit will be conducted while the laboratory is either mobilized on a project ~~and analyzing samples~~or at its headquarters. The agency will also conduct a system audit of the location

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where the data undergoes quality assurance review if not performed in the mobile laboratory. The agency may also conduct a system audit in review of a certified laboratory applying for additional certification. System audits will be conducted in accordance with the criteria established in paragraphs ~~paragraph (J)(1)~~(J)(1)(a) to (J)(1)(c) of this rule.

(3) In order to receive initial or additional certification, the laboratory must correct the deficiencies, if any, identified by the agency during a system audit to the satisfaction of and within the time frame provided by the agency. Prior to applying for renewal certification, the laboratory must correct the deficiencies, if any, identified by the agency during either a compliance audit or system audit to the satisfaction of the agency.

(4) The agency may recover its actual costs for conducting audits pursuant to rule 3745-300-03 of the Administrative Code.

(K) Display of laboratory certificates.

All current certificates must be displayed in a prominent location in the laboratory.

(L) Retention of documents and data.

A laboratory must 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. The 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 requested by the agency, during the ten-year retention period. After ten years, if a laboratory does not intend to retain such documents and data, the laboratory must notify the agency by ~~certified~~ mail or electronic submission of such intent and provide the agency the opportunity to obtain the documents and data. The documents and data must be retained until the notice described above is provided to the agency, and the agency notifies the laboratory in writing that the agency will or will not obtain the documents and data. Notification of the agency pursuant to this paragraph is not required as long as a laboratory continues to retain all documents and data.

(M) Out-of-state laboratories.

As a condition of certification under this rule, laboratories, or companies owning mobile 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

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action involves, in whole or in part, the laboratory's performance under this chapter or Chapter 3746. of the Revised Code. Out-of-state laboratories also consent to the agency'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.

(N) Appeal of certification determinations.

The issuance, denial, suspension, or revocation of any laboratory certification is a final action of the director, which is subject to the procedure for appeal set forth in Chapter 3745. of the Revised Code.

(O) 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 any of the requirements set forth in paragraph (H) of this rule, except as provided in paragraphs (O)(2) ~~and (O)(3)~~ of this rule.

(2) The director must permanently revoke a laboratory's certification if the laboratory does not comply with a request for documents and data made by the agency, in violation of paragraph (H)(11) of this rule. The director may permanently revoke a laboratory's certification if the laboratory falsifies any information in connection with its certification or any voluntary action, in violation of paragraph (H)(8) of this rule.

~~(3) The director must suspend or revoke a laboratory's certification if the laboratory fails to maintain any of the standards of performance and conduct required for maintaining certification under paragraphs (H)(1) to (H)(7), (H)(9) to (H)(10) and (H)(12) to (H)(14) of this rule.~~

~~(4)~~(3) Upon revocation or suspension, the laboratory must promptly return to the agency the ~~certificate(s)~~certificate to which the revocation or suspension applies.

(P) Procedure to request reinstatement of certification.

(1) Procedures to request reinstatement of certification after a suspension period based on audit deficiencies or other noncompliance issues.

(a) A certified laboratory may request to reinstate its certification for a

*** DRAFT - NOT YET FILED ***

suspension issued because of the laboratory's failure to comply with paragraphs (H)(1) to (H)(7), (H)(9) to (H)(10) and (H)(12) to (H)(14) of this rule.

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

(2) ~~The agency may recover its actual~~The laboratory may be required to pay any costs incurred by the agencyin reviewing requests for reinstatement, pursuant to rule 3745-300-03 of the Administrative Code.

(Q) Procedures to request modifications to certificates.

(1) Any laboratory that requests a modification to its certificate to reflect changes in company name, address, or to update or remove methods from a certificate, must submit such requests on its application when applying for renewal certification, or through use of a cover letter when requesting a modification during a non-renewal period.

(2) ~~The agency may recover its actual~~The laboratory may be required to pay any costs incurred by the agencyin processing a request for modification of certification when such request is not submitted with an application for renewal certification. The agency may recover these costs pursuant to rule 3745-300-03 of the Administrative Code.

(R) Recertification following expiration of certification.

A laboratory whose certification has expired may be required by the director to apply for recertification. The laboratory's application for recertification must comply with the requirements for initial certification set forth in paragraphs (D) and (E) of this rule.