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

(A) Definitions. As used in this rule:

(1) "Acceptance limit" is the numerical range in which an analyte must be quantitated in a proficiency testing sample.

(2) "Additional certification" is supplemental certification to perform analyses of specific analytes or parameter groups, using designated methods, for which the laboratory is not already certified pursuant to the laboratory's current certification under this rule.

(3) "Analyte" is a hazardous substance or petroleum, or a constituent of a hazardous substance or petroleum.

(4) "Certificate" is the document issued by the director to an individual laboratory certified under this rule that authorizes it to perform analyses in support of a request for a no further action letter for the specified analytes or parameter groups, and using the methods listed on the document.

(5) "Certified" or "certification" is the authorization of a laboratory to perform analyses in support of a request for an no further action letter, for the specific analytes or parameter groups and using the methods for which the director has determined the laboratory meets the requirements set forth in this rule.

(6) "Chemical testing method" is a method used for the preparation and analysis of an environmental sample to quantify for hazardous substances or petroleum, or constituents of hazardous substances or petroleum.

(7) "Compliance audit" is an inspection of a laboratory, any documents, interviews with laboratory personnel in which the laboratory performed analyses on a property on which a voluntary action was or is being conducted, or to determine compliance with this rule, this chapter and all applicable requirements of Chapter 3746. of the Revised Code.

(8) "Conflict of interest" is any circumstances which would affect the laboratory's ability to objectively analyze samples in connection with a voluntary action, including circumstances similar to those set forth in paragraph (F)(3) of rule 3745-300-05 of the Administrative Code for certified professionals.

(9) "Initial certification" is any first certification issued to a laboratory to perform analyses of specific analytes or parameter groups, using designated methods, under this rule.

(10) "Method" is a laboratory procedure provided for in paragraph (C) of this rule used to prepare samples and to quantitate analytes or parameter groups.

(11) "Method detection limit study" or "MDL study" is a procedure, performed consistent with 40 CFR Part 136, Appendix B (effective June 30, 1986), with a final spiking concentration not to exceed the laboratory's reporting limit. Further, the procedure is that used by a laboratory to determine its ability to reliably and accurately report to a specific concentration for an analyte or parameter group using the method for which it is applying for certification.

(12) "Parameter group" is a group of analytes similar in chemical characteristics quantitated using a specific method and technology.

[Comment: Parameter group is also known as an analyte group by the National Environmental Laboratory Accreditation Program.]

(13) "Proficiency testing provider" or "PT provider" is any entity that is accredited to provide PT samples and evaluate PT results by a Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor designated by the National Environmental Laboratory Accreditation Program.

(14) "Proficiency testing result" or "PT result" is the result derived by the laboratory from the analysis of a proficiency testing sample.

(15) "Proficiency testing sample" or "PT sample" is a material or matrix spiked with a known concentration of one or more specific analytes representative of the analyte or parameter group, and method for which the laboratory is applying for or maintaining certification. The PT sample is used to evaluate a laboratory's ability to identify and quantitate an analyte or parameter group using a specific method or technology.

(16) "Quality assurance program plan" is a written document detailing the data collection, storage, analysis, and quality assurance/quality control procedures used by a laboratory to assure that all data generated are scientifically valid, defensible, and of known precision and accuracy.

(17) "Renewal certification" is the renewal of a laboratory's current certification under this rule.

(18) "Standard operating procedures" are a laboratory's written procedures to prepare samples and perform measurements of analytes or parameter groups.

(19) "System audit" is an inspection of laboratory facilities, documents including administrative and technical procedures, and instrumentation. System audit also includes interviews with laboratory personnel to evaluate the laboratory's qualifications for certification under this rule.

(20) "Technology" is the laboratory instrument used to quantify for an analyte or parameter group.

[Comment: Examples of laboratory instruments that meet the definition of technology include but are not limited to: gas chromatography, gas chromatography / mass spectrometry, and inductively coupled plasma.]

(B) Certified data; authority of a certified laboratory 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 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 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 (C)(1)(d) of this rule.

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

(1) A laboratory may apply for certification pursuant to this rule for any method used for the analysis of any analyte or parameter group that meets the criteria listed below, except as provided in paragraph (C)(2) of this rule:

(a) Chemical testing methods. A laboratory may apply for certification for any chemical testing method published or endorsed by the United States environmental protection agency (USEPA) or Ohio EPA. The method must be published or endorsed as of the effective date of this rule or otherwise approved, at the discretion of the director, in a certification issued to the laboratory pursuant to this rule. For the purpose of this rule, "endorsed" means any method referenced for use in a rule adopted by USEPA or the director. "Published" means any chemical testing method posted on a USEPA or Ohio EPA web site that indicates the method is approved for public use.

(b) Sediment toxicity methods. In addition to any methods provided for in paragraph (C)(1)(a) of this rule, a laboratory may apply for certification to quantify for sediment toxicity using any method from USEPA, "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates," March 2000, or any other published or endorsed method as provided in paragraph (C)(1)(a) of this rule for the analysis of sediment toxicity.

(c) Performance-based methods. At the request of a laboratory, the agency may evaluate whether to certify the laboratory to perform analyses using a performance-based method. A "performance-based method" means a method designed to quantitate any analyte or parameter group that is not listed in a published or endorsed method as provided in paragraph (C)(1)(a) of this rule. The laboratory must demonstrate its ability to perform the method using a PT sample as provided in paragraph (D)(1) of this rule, if available, and in accordance with the application requirements contained in paragraph (E)(4) of this rule.

(d) Asbestos accreditations. A laboratory applying for certification for the analysis of asbestos must have current accreditation from 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.

[Comment: Any certification issued under this rule for the analysis of asbestos in environmental media will be restricted to the procedures approved for use under either of the accreditation programs listed above.]

(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 review of any release of radioactive materials or substances.]

(D) Proficiency testing program.

(1) Use of PT samples; requirement to purchase PT samples through PT providers.

(a) A laboratory applying for certification under this rule must analyze PT samples representative of the analytes or parameter groups for certification,

and receive from the PT provider acceptable PT results pursuant to the criteria of this rule.

(b) The PT samples must be purchased from a PT provider that is approved to produce the PT samples and evaluate the PT results.

(c) For the purposes of this rule, a laboratory must analyze either a non-potable water ("NPW") or drinking water ("DW") PT sample that was formulated and evaluated using the criteria established by the "National Environmental Laboratory Accreditation Conference" ("NELAC") and adopted by the "National Environmental Laboratory Accreditation Program" ("NELAP").

[Comment: The NELAC criteria may be accessed from USEPA's web site, at http://www.epa.gov/nelac/. NELAC is a voluntary association of state and federal agencies with full opportunity for input from the private sector. NELAC establishes and promotes mutually acceptable performance standards for the operation of environmental laboratories. USEPA's NELAP office provides support to NELAC and evaluation of the accrediting authority programs.]

(d) This rule provision does not apply to certifications for asbestos, sediment toxicity, or to the circumstances provided in paragraph (D)(2) of this rule.

(2) Criteria for analysis of PT samples; exceptions. To demonstrate compliance with this rule for any analyte or parameter group a laboratory must analyze PT samples, which a PT provider prepared and evaluated using NELAC NPW criteria, except as indicated below:

(a) When a NPW PT sample is not available for an analyte or parameter group for which the laboratory applies for certification, PT samples prepared and evaluated based on DW criteria may be used instead.

(b) For any analyte or parameter group for which NELAC has not published any NPW or DW PT criteria or for which PT samples are not available, the agency may, at its discretion, evaluate the use of another PT sample or waive the PT sample analysis prerequisite under this paragraph. In the case of a waiver, the laboratory must apply for certification for the use of a performance-based method under paragraph (C)(1)(c) of this rule.

(c) At the request of a laboratory, the agency may evaluate the laboratory's use of other aqueous PT samples available from a PT provider when NELAC NPW or DW PT sample criteria are not available for an analyte or parameter group. The agency may also evaluate the use of an equivalent PT sample, or may evaluate the analyte as a performance-based method as provided in paragraph (E)(4) of this rule. The agency's evaluation of the acceptablity of PT samples may include:

(i) Review of spiking concentration and analytes spiked in the PT sample;

(ii) Review of statistical procedures used to derive acceptance limits including review of the acceptance limits;

(iii) Review of evaluation criteria used by the PT provider; and

(iv) Review of any other information deemed appropriate by the agency.

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

(4) Analysis of PT samples.

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

(b) One PT sample may be used to demonstrate proficiency for all methods used to measure an analyte or parameter group that use the same or similar technology.

(c) For a certified laboratory applying for reinstatement of a suspended certification for a method to measure an analyte or parameter group, the laboratory may analyze a PT sample only after the end of the suspension period as provided in the director's final findings and orders.

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

[Comment: The ordering and analysis of PT samples is based on a technology. To comply with this rule, a laboratory should order a PT sample based on the technology that is representative of the certification. For example, to encompass the scope of a certification for volatile organic compounds would require the laboratory to ensure that the PT sample contains both aromatics and halocarbons.]

(5) Reporting and time lines for PT studies.

(a) Reporting PT results. A laboratory that is certified or applying for certification for multiple technologies for an analyte or parameter group must analyze and report PT results for each technology using the same PT sample.

[Comment: For example, the same volatile PT 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 PT samples. A laboratory that intends to apply for any certification or reinstatement of certification under this rule, must first obtain supporting PT results in compliance with the following time lines:

(i) Initial and additional certification. A laboratory must have analyzed the PT sample(s) within the six months prior to the date the laboratory submits its application to the agency to use those PT results to apply for certification, except as provided in paragraph (D)(2) of this rule.

(ii) Renewal certification. A certified laboratory maintaining its certification must analyze PT samples approximately every six months for the analytes, or parameter groups, using the methods or technologies listed on its current certificate to apply for renewal of its certification, except as provided in paragraph (D)(2) of this rule.

[Comment: A certified laboratory may not comply with this rule using any "corrective" action PT reports or "remediation" PT reports for any unacceptable PT results reported during a PT study.]

(iii) Reinstatement of certification. A certified laboratory requesting reinstatement of certification must analyze the applicable PT sample(s) after the suspension period.

[Comment: The final findings and orders issued by the director to the laboratory as a suspension action specify the suspension period for the suspended analyte or parameter group and corresponding method. PT results from the laboratory's analysis of PT samples during the suspension period are unacceptable under this rule.]

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

(a) Timing of submissions. A laboratory applying for initial or additional certification, or a certified laboratory renewing or reinstating certification must comply with the following procedures.

(i) Initial or additional certification. A laboratory that is applying for initial or additional certification must submit to the agency a copy of the required PT reports along with the documentation listed in paragraph (E)(1) of this rule.

(ii) Renewal or maintenance of certification. A certified laboratory analyzing PT samples to maintain or renew its certification must submit to the agency, or may direct the PT provider to submit to the agency, a copy of the PT report upon completion of each six-month PT study. The certified laboratory is responsible to direct the PT provider to submit the laboratory's PT reports to the agency in the manner directed by the agency.

(iii) Reinstatement of certification. A certified laboratory requesting reinstatement of certification for an analyte or parameter group that has been suspended must submit a copy of the PT report that provides an acceptable PT result for the analyte or parameter group along with the documentation listed in paragraph (Q) of this rule.

(iv) The certified laboratory is responsible for the submission of PT reports. Failure of a PT provider to submit a PT report does not waive the certified laboratory's obligation under this rule.

[Comment: This rule requires the laboratory, not the PT provider, to submit to the agency the PT reports with any application for initial, additional, and reinstatement of certification. For analysis for purposes of certification maintenance or renewal, the laboratory may direct the PT provider to directly submit the PT reports to Ohio EPA.]

[Comment: Please contact the voluntary action program for instructions on the submission of PT reports to Ohio EPA. Instructions may be posted on the agency's web site, at http://www.epa.state.oh.us, or otherwise made available from the voluntary action program.]

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

(i) Name of PT provider;

(ii) Laboratory name and address;

(iii) Opening and closing dates of the PT study;

(iv) Date PT report was issued;

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

(vi) Performance evaluation by PT provider; and

(vii) Technology code or method description.

[Comment: The PT report may contain any other information supported by guidance developed by NELAC. NELAC guidance may be accessed on USEPA's web site at http://www.epa.gov/nelac.]

(7) Agency evaluation of PT results. A laboratory maintaining current certification or applying for certification must meet the PT requirements provided below.

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

(b) The laboratory has obtained acceptable PT results for each analyte and parameter group using the methods and technologies for which it is certified, reinstating certification, maintaining current certification or applying for certification.

[Comment: A certified laboratory requesting reinstatement of certification must obtain an acceptable PT result for the analyte or parameter group which resulted in the suspension. A certified laboratory is responsible to analyze PT samples that include the analyte or its parameter group. The director's final findings and orders issued to the laboratory identify the analyte or parameter group that is the subject of the suspension and the period for the suspension.]

(c) The laboratory has submitted to the agency the PT report(s) for PT samples analyzed within the time lines provided in paragraph (D) of this rule.

(d) A certified laboratory has met the requirements under paragraph (D) of this rule.

(e) At the director's discretion, the agency may require a laboratory that is maintaining current certification or applying for certification for a performance-based method to analyze NPW PT samples, DW PT samples, or other PT samples. These PT results will be used to evaluate a laboratory’s qualifications to apply, renew, maintain, or reinstate certification for the performance-based method.

[Comment: Under this rule, a laboratory that is maintaining current certification or applying for certification for n-Hexane by gas chromatography/mass spectrometry would provide acceptable PT results for a NPW volatile PT sample analyzed using the same technology and method.]

(f) A certified laboratory must obtain acceptable PT results to maintain or renew certification for the certified analytes or parameter groups and corresponding methods. The certified laboratory must analyze the PT samples based on the criteria and at the frequency specified in paragraph (D) of this rule. The failure of the same analyte or parameter group in two consecutive PT samples submitted under this rule will result in a suspension of the laboratory's certification for that analyte or parameter group pursuant to paragraph (P) of this rule.

[Comment: Paragraph (Q) of this rule provides the procedures for the reinstatement of a suspended analyte or parameter group and method based on PT failures. A certified laboratory may seek reinstatement of its certification for a suspended analyte, parameter group, and method after the suspension period provided in the final findings and orders.]

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

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

[Comment: A laboratory applying for certification for asbestos or a performance-based method as provided in paragraph (C) of this rule, must also submit the information listed in paragraph (E)(3) or (E)(4) of this rule.]

(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, at http://www.epa.state.oh.us, or are otherwise available upon request from the voluntary action program.]

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

[Comment: For additional certification, the laboratory's current approved quality assurance program plan may fulfill the requirement of paragraph (E)(1)(b) of this rule .]

(c) A hard copy of the laboratory's PT report, in accordance with paragraph (D) 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 PT samples are not required as described in paragraph (D)(2) 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 (MDL) study performed as described by paragraph (A) of this rule for each analyte and parameter group, and corresponding method, except for the analytes or parameter groups provided under paragraphs (C)(1)(b) and (C)(1)(d) of this rule. The following information must be provided for each analyte and parameter group in spreadsheet format:

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

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

[Comment: The laboratory must digest, extract, or distill all MDL study samples using the same procedures included in the standard operating procedures submitted under paragraph (E)(1)(d) of this rule.]

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

(iv) Individual results of the MDL study samples along with the calculated standard deviation, calculated method detection limit, and reporting limit for each analyte or parameter group;

(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; and

(g) A photocopy of the laboratory's check for the payment of the non-refundable certification fee submitted pursuant to rule 3745-300-03 of the Administrative Code.

[Comment: Rule 3745-300-03 of the Administrative Code calls for fee payment by check or money order payable to "Treasurer, State of Ohio" with the reason for the payment marked in the memo field. The applications for laboratory certification provide instructions for submission of the fee payment to Ohio EPA.]

(2) Applications for renewal certification. A certified laboratory must submit to the agency a complete application at least ninety but no more than one hundred and twenty 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 (E)(6) 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) A photocopy of the laboratory's check for the payment of the non-refundable annual fee, submitted pursuant to rule 3745-300-03 of the Administrative Code; and

[Comment: Rule 3745-300-03 requires payment of fees by check or money order payable to the "Treasurer, State of Ohio" with the reason for the payment marked in the memo field. A certified laboratory should also include its voluntary action program-assigned certification number on the checks that the laboratory submits to Ohio EPA.]

(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.

[Comment: A laboratory may not apply to renew certification for any analyte or parameter group using a method for which it fails to meet the prerequisites provided in paragraph (D) of this rule.]

[Comment: A certified laboratory applying for renewal of certification for asbestos must also submit the information required by paragraph (E)(3) of this rule.]

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

[Comment: A laboratory applying for initial or additional certification pursuant to this rule for analytes and parameter groups in addition to asbestos may include the required asbestos information as part of a single application submitted pursuant to paragraph (E)(1) of this rule.]

(4) Applications for performance-based method certifications. A laboratory applying for initial or additional certification for any performance-based method as

provided in paragraph (C)(1)(c) of this rule, must submit the documents and fee listed in paragraph (E)(1) of this rule, and 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 (E)(4)(a) of this rule; and

(c) Any other information the agency deems appropriate.

(5) A laboratory applying for initial or additional certification for any of the sediment toxicity methods provided in paragraph (C)(1)(b) of this rule, must submit the information listed in paragraph (E)(1) of this rule, except for the information listed in the paragraphs (E)(1)(c) and (E)(1)(e) of this rule.

(6) 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 or reinstatement of a suspended certification. The certified laboratory may only make such requests pursuant to paragraph (R) of this rule.

(7) Requests for agency review and approval of revised standard operating procedures or a quality assurance program plan must be made in accordance with paragraph (H) 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.

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

(1) Ohio EPA's review of a laboratory's application for certification begins sixty days from submission of a complete application. An application that contains all of the information listed in paragraph (E) 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, PT results, and any other information as provided in paragraphs (E)(1), (E)(3), and (E)(4) of this rule;

[Comment: The agency will contact the laboratory to schedule a system audit, as needed, following receipt of the laboratory's response to the agency's comments related to its application. Additional comments or document revisions may be needed in response to the system audit.]

(b) A system audit 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 (K) of this rule;

[Comment: The agency will provide the laboratory an audit report within forty-five days from completion of the audit. The audit report will indicate any deficiencies identified during the audit that require corrective actions by the laboratory in order to proceed with its application for initial or additional certification.]

(c) Review of laboratory responses to correct deficiencies identified during the system audit; and

(d) The laboratory has paid all fees including costs for performing the system audit as established in rule 3745-300-03 of the Administrative Code.

(2) To be recommended for initial or additional 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 (D), (E), (F) and (K) 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.

[Comment: 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.]

(G) 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 (E)(2) of this rule, a certified laboratory must submit a complete renewal application at least ninety days, but not more than one hundred twenty days, prior to the expiration date listed on its current certificate. Any application received by Ohio EPA after the certificate's expiration date requires the laboratory to re-apply for initial certification in accordance with paragraphs (E)(1) and (S) of this rule. The agency's review of a laboratory's application for renewal certification begins forty-five days from submission of a complete application. An application that contains all of the information listed in paragraph (E) of this rule is considered complete. 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 the laboratory's PT reports to ensure compliance with paragraph (D) of this rule;

(c) Review of agency findings from a system or compliance audit conducted in accordance with paragraph (K) of this rule; and

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

[Comment: Any renewal application submitted less than ninety days before the certificate's expiration date risks a lapse in certification.]

(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 paragraphs (E)(2), (G), or (I) of this rule.

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

(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 all changes summarized on a change order or summary sheet. The revised document may be submitted in either a hard copy format or electronically using an electronic file formatted in a manner recommended by the agency;

[Comment: The preferred format for an electronic submission is a portable document file (.pdf); however, the laboratory may use other formats with prior approval from 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, as 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) The agency may recover its actual costs in reviewing the revised standard operating procedures or quality assurance program plans pursuant to rule 3745-300-03 of the Administrative Code.

[Comment: Ohio EPA's review under this rule is performed under a technical assistance account. A form letter for requesting the technical assistance may be downloaded from the agency's web site, at http://www.epa.state.oh.us, for the voluntary action program. All letters may be mailed to the address provided the form letter or sent electronically as instructed by the agency.]

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

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

(1) Produce results as certified data pursuant to paragraph (B) 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;

[Comment: Whenever the laboratory is not currently certified for any analyte, parameter group or method included in a request, the laboratory should identify

within the analytical report the results for which the laboratory is not providing certified data.]

(2) Comply with the methods for which the laboratory is certified;

(3) Notify Ohio EPA, in writing, of:

(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.

(4) Perform acceptably on each compliance audit and system audit conducted pursuant to this rule, and correct in a timely manner the deficiencies identified by Ohio EPA;

(5) 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;

[Comment: The procedures for seeking agency approval for proposed revisions to approved standard operating procedures or quality assurance program plan are contained in paragraph (H) of this rule.]

(6) Obtain acceptable PT results, in accordance with paragraph (D) of this rule;

(7) Provide certified data that will not cause a no further action letter to be inconsistent with an applicable standard developed under this chapter, unless the laboratory discloses, to the requester and the agency, that it is incapable of achieving the applicable standard under its certification;

[Comment: The applicable standards calculated for a property in accordance with rules 3745-300-07, 3745-300-08 and 3745-300-09 of the Administrative Code may not be within the certified laboratory's reporting limits. A certified laboratory that performs analyses in support of a no further action letter must be 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 or the certified professional with the voluntary action, if the laboratory cannot quantify at or below an applicable standard using a method for which it is currently certified.]

(8) Not falsify any information on any application, standard operating procedure, quality assurance program plan, or any PT 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;

(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 rule 3745-300-03 of the Administrative Code; and

(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.

[Comment: This rule requires use of an affidavit with applications for certification. To produce certified data, a certified laboratory must submit an affidavit with each analytical report, consistent with paragraph (B) of this rule. Contents of affidavits are provided in rule 3745-300-13 of the Administrative Code.]

(J) Procedures for submittals under this rule.

All applications and payment of fees under this rule must be submitted to the agency by certified mail, courier delivery or any other form of mail or delivery accompanied by a receipt.

(K) Compliance and system audits.

(1) The agency will conduct 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. Compliance audits will be conducted at a frequency of at least every five years from the date the laboratory received initial certification. A compliance audit 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; or

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

[Comment: The agency may conduct a compliance audit of any laboratory relocating its facility to a new location, or when there is a change in laboratory or management personnel or operational procedures.]

(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. 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 paragraph (K)(1) 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 limits specified by the agency. Prior to applying for renewal of certification, the laboratory must correct the deficiencies, if any, identified by the agency during a 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.

(L) Display of laboratory certificates.

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

(M) 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. After ten years, if a laboratory does not intend to retain such documents and data, the laboratory must notify the agency by certified mail 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.

[Comment: Compliance with this rule requires the laboratory to retain the documents and data through any manner that enables reliable access to them by readily available technology. For example, the laboratory may retain the documents and data by hard copy, microfiche or electronically as long as the laboratory can retrieve the documents and data in legible condition during the retention period. The director may request a certified laboratory to provide documents and data for the purposes of verifying the qualifications of the laboratory or auditing the performance of the laboratory in connection with voluntary actions under this chapter and Chapter 3746. of the Revised Code. See also paragraphs (I)(11) and (P)(2) of this rule.]

(N) Out-of-state laboratories.

As a condition of certification under this rule, 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. 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.

(O) 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.

(P) 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 (I) of this rule, except as provided in paragraphs (P)(2) and (P)(3) of this rule.

[Comment: For example, the director may suspend or revoke certification based on a laboratory's failure, in accordance with paragraph (I) of this rule, to: (a) perform only the analyses for which the laboratory is certified pursuant to this rule; (b) comply with the methods for which the laboratory is certified; (c) perform acceptably on a compliance audit and correct deficiencies identified by the agency in timely manner; or (d) perform analyses, for which a laboratory attests to as certified data in accordance with the laboratory's standard operating procedures and quality assurance program plan as approved by the agency.]

(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 (I)(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 (I)(8) of this rule.

(3) The director must suspend or revoke a laboratory's certification for an analyte or parameter group, and the corresponding method, if the laboratory fails to comply with the requirements set forth in paragraphs (D)(2) and (I)(6) of this rule.

(4) Upon revocation or suspension of an analyte or parameter group and the corresponding method, the laboratory must return to the agency each certificate that identifies the analyte or parameter group and method.

(Q) Procedures to request reinstatement of certification.

(1) A certified laboratory may request to reinstate its certification for a suspended analyte or parameter group and corresponding method after the suspension period of the certification.

(2) After the suspension period, the certified laboratory may analyze a PT sample for the suspended analyte or parameter group and corresponding method. The certified laboratory must achieve acceptable PT results in accordance with paragraph (D) of this rule.

(3) To request reinstatement of certification, the certified laboratory must submit, in the manner directed by the agency, the following:

(a) A written request identifying the analytes, parameter groups and corresponding methods for which the certified laboratory is requesting reinstatement; and

(b) A copy of the PT report for each analyte or parameter group and corresponding method for which the certified laboratory is requesting reinstatement.

[Comment: The instructions for submitting requests for reinstatement using electronic files are available by contacting the voluntary action program at Ohio EPA or by accessing the agency's web site at http://www.epa.state.oh.us.]

(4) The agency may recover its actual costs in reviewing requests for reinstatement, pursuant to rule 3745-300-03 of the Administrative Code.

(R) Procedures to request modifications to certificates.

(1) Any laboratory that requests a modification to its certification 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.

[Comment: A certified laboratory applying for renewal certification may indicate on its application any changes in company name or address, or to add or remove methods from its certificate.]

(2) The agency may recover its actual costs in 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.

(S) Recertification following expiration of certification.

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

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Certification

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Date

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