3745-300-04 Certified laboratories.

(A) Definitions. As used in this rule:

(1) "Acceptance limit" means the numerical range within which an analyte must be quantitated to receive an acceptable result on a performance evaluation sample.

(2) "Analyte" means a hazardous substance or petroleum that is tested in a sample.

(3)"Certificate" means the document issued by the director to an individual laboratory facility certified under this rule that authorizes it to perform analyses in support of a request for a no further action letter for a particular analyte(s) or parameter group(s), using the specific method(s), for which it is certified.

(4) "Certified or certification" means that the director authorizes a laboratory to perform analyses on those individual analyte(s) or parameter group(s) using the method(s), for which the director has determined that the laboratory meets all requirements as set forth in this rule.

(5) “Compliance audit” means an inspection of a laboratory, any documents, or property on which a voluntary action was conducted and for which the laboratory performed analyses, to determine compliance with this rule, this chapter and all applicable requirements of Chapter 3746. of the Revised Code. Audits must be conducted pursuant to paragraph (J) of this rule.

(6) "Conflict of interest" means 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.

(7) “Method” means an analytical procedure included in the document(s) referenced in paragraph (E) of this rule, or approved by the director under paragraph (O) of this rule to quantitate an analyte(s) or parameter group(s).

(8)"Parameter group" means a group of analytes similar in chemical characteristics that can be quantitated using similar techniques.

(9) “Performance evaluation sample” means a material spiked with known concentrations of specific target analytes that is used to evaluate a laboratory's ability to identify and quantitate for an individual analyte or parameter group using a chosen approved method.

(10) “Quality assurance program plan” means a written document detailing the methods by which a laboratory implements a quality assurance program.

(11) “Standard operating procedure” means a laboratory's written method for performing routine administrative and technical operations.

(12) "System audit" means a scheduled on-site inspection of a laboratory's administrative and technical procedures, instrumentation, and personnel to become certified or to renew certification under this rule.

(B) Authority to perform analyses of a parameter group(s) or analyte(s) used to support a no further action letter; retention of documents.

(1) A laboratory may perform analyses to support a no further action letter only when consistent with its certificate. A laboratory must possess a current certificate and may only perform analyses for a parameter group(s) or analyte(s) using the method(s) set forth in its certificate, or as set forth in writing by the director. This certification is applicable only to analyses conducted to support no further action letters under this chapter and does not constitute certification to perform analyses under any other state or federal laboratory certification program.

(2) A laboratory must retain all documents prepared or acquired in connection with a voluntary action for a period of ten years from the date that the laboratory's analyses were submitted to a certified professional. After ten years, if a laboratory does not intend to retain such documents, it must notify the director by certified mail of such intent and provide the director the opportunity to retain all documents. The documents must be retained until the notice described above is provided to the agency, and the director notifies the laboratory in writing that the agency will not retain the documents. Notification of the director is not required as long as a laboratory continues to retain all documents.

(C) Preliminary procedures for laboratories to request certification.

(1) Before a laboratory may apply for certification for participation in the voluntary action program the laboratory must:

(a) Submit on company letterhead:

(i) An identification of the methods, parameter group(s) or analyte(s), for which the laboratory seeks certification;

(ii) A request to receive procedures and costs to participate in the performance evaluation program for the identified method(s), parameter group(s) or analyte(s); and

(iii) A request to receive a certification application;

(b) Pay the costs to participate in the performance evaluation program to the agency, or to the agency's contractor. Following receipt of full payment, the laboratory will receive a performance evaluation sample(s). the laboratory must submit all payments related to participation in the performance evaluation program, by certified mail, to the agency, or to the agency's contractor, as instructed by the agency; and

(c) Demonstrate acceptable analyte results in the performance evaluation program established in paragraph (D)(1)(a) of this rule. A laboratory may not apply for certification for an analyte(s) or parameter group(s) using method(s) for which it did not receive an acceptable performance evaluation result under paragraph (D)(1)(a) of this rule.

(2) The laboratory must submit all application requests, by certified mail or any other form of mail accompanied by a receipt, to the Ohio Environmental Protection Agency.

(D) Performance evaluation program.

(1) All laboratories must participate in the following performance evaluation studies.

(a) Initial performance evaluation sample(s) will be used to determine if a laboratory is qualified to apply for certification for an analyte(s) or parameter group(s), using the methods included in the documents referenced in paragraph (E) of this rule, or as approved in paragraph (O) of this rule. For the purpose of applying for certification, an acceptable result(s) is determined as follows:

(i) Each individual analyte, or all analytes within a parameter group, must be quantitated within the acceptance limit(s) before a laboratory may apply for certification for an analyte(s) or parameter group(s). A laboratory will be given two attempts to quantitate within the acceptance limit(s) the analyte(s) for which it seeks certification. If a laboratory fails to quantitate any analyte(s) within the acceptance limit(s) in the initial performance evaluation sample(s), it must analyze a second performance evaluation sample(s) within thirty days from receipt of the first performance evaluation sample result(s). Analytes outside acceptance limits in the first performance evaluation sample(s) must be quantitated within the acceptance limits in the second performance evaluation sample(s) to apply for certification for a parameter group(s) or analyte(s), using approved methods.

(ii) Laboratories failing to meet the above criteria, for an analyte(s) or parameter group(s) using an approved method(s), must wait a period of three months from the receipt date of the results of the second performance evaluation

sample(s) to request an additional performance evaluation sample(s), for which it failed the acceptance criteria.

(b) Periodic performance evaluation sample(s) will be used to maintain and renew certification, and will be administered semi-annually by the agency, or its contractor. For the purposes of maintaining and renewing certification, an acceptable result means that the same analyte(s) cannot be outside the acceptance limit(s) in two consecutive performance evaluation samples. Laboratories failing to meet the above criteria for an analyte or parameter group will not receive from the agency or its contractor another performance evaluation sample prior to the next semi-annually administered performance evaluation sample.

(2) The director may revoke or suspend a laboratory's certification for a particular analyte, parameter group or method, in accordance with paragraph (K) of this rule, if acceptable results are not received for the same analyte(s) in two consecutive performance evaluation sample(s).

(3) The performance evaluation program will be based on selecting specific analytes which are representative of a parameter group(s). The agency will determine the analytes to be used to evaluate a laboratory's performance.

(4) The laboratory must submit all payments for the initial and periodic performance evaluation programs as set forth in paragraph (C)(1)(b) of this rule.

(E) Approved methods for the analysis of an analyte or parameter group.

(1) Laboratories conducting analyses in support of a no further action letter [or for performance evaluation samples], may only analyze for hazardous substances or determine toxicity using the methods included in the following documents, except as provided in paragraphs (E)(3) and (O) of this rule:

(a) United States Environmental Protection Agency, “test methods for evaluating solid waste, physical/chemical methods,” third edition, (September 1986), and as amended by update I (July1992), update II (September 1994), update IIA (August 1996), and update IIB (January 1995)

(b) United States Environmental Protection Agency, “Methods for chemical analysis of water and wastes,” (March 1983);

(c) United States Environmental Protection Agency, “Methods for the determination of metals in environmental samples,” (April 1991), and as amended by supplement 1 (1994)**;**

(d) United States Environmental Protection Agency "Methods for the determination of organic compounds in drinking water", (April 1988), and as amended by supplement 1 (April 1990) and supplement 2 (1992);

(E) Ohio EPA, "*Hyalella Azteca* Solid Phase Toxicity Testing Procedure," September, 1994;

(F) United States Environmental Protection Agency, "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-Associated Contaminants with Freshwater Invertebrates," June, 1994; and

(G) United States Environmental Protection Agency, "Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Water to Freshwater Organisms," July, 1994.

[Comment: if requested, the agency will provide assistance on method selection. Testing for characteristic hazardous waste and radioactive materials are excluded from the "Voluntary Action Program" certification].

(2) A laboratory may apply for certification for the analysis of total petroleum hydrocarbon typing using the following:

(A) Method 418.1 for diesel range organics; and

(B) Modified method 8015 for diesel range organics or gasoline range organics.

(3) The agency may approve methods included in united states environmental protection agency documents which are not listed in paragraph (e)(1) of this rule, provided that the laboratory demonstrates to the agency's satisfaction that the method will produce reliable results.

(F) Procedures for laboratory certification.

(1) To be considered for certification under this rule, a laboratory must submit, to the director, all of the following, except as provided in paragraphs (o), (p) and (q) of this rule:

(a) A completed certification application on a form provided by the agency;

(b) A written copy of a quality assurance program plan;

(c) An original copy of the laboratory's acceptable performance evaluation result(s) for the analyte(s) or parameter group(s), using the method(s), for which the laboratory seeks certification pursuant to this rule;

(d) The non-refundable laboratory certification fee established in paragraph (C) of rule 3745-300-03 of the Administrative Code. The laboratory must submit to the agency a check made payable to the "treasurer of the state of Ohio"; and

(e) The standard operating procedure(s) for the analyte(s) or parameter group(s) and method(s) for which the laboratory seeks certification pursuant to this rule.

(2) The director will not consider any laboratory certification request which does not contain all of the information required by this rule.

(3) The information submitted under this rule must be accompanied by an affidavit, signed by a person authorized to bind the laboratory, affirming that upon knowledge, information, and belief, all information submitted in support of its certification request is truthful, complete, and accurate.

(4) All laboratory certification fees, and documents described above must be submitted, by certified mail or any other form of mail accompanied by a receipt, to the Ohio environmental protection agency.

(G) Certification of laboratories.

(1) The agency will complete the evaluation process required in paragraph (G)(5) of this rule in one hundred twenty days following receipt of a complete certification application and its supporting documents.

(2) The director will conduct a system audit in accordance with paragraph (J) of this rule prior to certification.

(3) A laboratory will receive a report within forty-five days after the system audit which will indicate the laboratory's acceptability, un-acceptableness or any deficiencies of the laboratory and any corrective actions required of the laboratory in order to receive certification.

(4) The director may request that the laboratory provide in writing an explanation of all corrective actions that were implemented to resolve the deficiencies noted. The agency may conduct a follow-up system audit to determine if the corrective actions implemented by the laboratory resolved all deficiencies identified.

(5) To become certified, a laboratory must demonstrate to the director's satisfaction all of the following, except as provided in paragraphs (o), (p) and (q) of this rule:

(a) Acceptable performance evaluation result(s) for an analyte(s) or parameter group(s), using an approved method(s), for which a laboratory has applied for certification

pursuant to the requirements established in paragraph (D)(1)(a) of this rule;

(b) Acceptable performance on a laboratory system audit as set forth in paragraph (J) of this rule, AND timely correction of any deficiencies identified by the agency;

(c) Payment of all applicable fees and costs as set forth in paragraphs (C), (D) and (F) of this rule, and rule 3745-300-03 of the Administrative Code; and

(d) The laboratory is capable of providing reliable and representative data and possesses the integrity to satisfy the requirements of this rule and Chapter 3746. of the Revised Code, using the information provided on and included with the application, information gathered from a system audit, and any other information as deemed appropriate by the director.

(6)Following successful completion of the requirements of this rule, the director will provide a certificate to a laboratory identifying the analyte(s) or parameter group(s), and methods, for which the laboratory may perform analyses in support of a request for a no further action letter. This certificate only applies to the individual laboratory facility identified in the certificate. This certificate will automatically expire two years from the date of issuance if not timely renewed in accordance with paragraph (H) of this rule, unless the laboratory's certificate is suspended, revoked, or denied renewal prior to that time.

[Comment: Entities that own or operate multiple laboratory facilities must obtain a separate certification for each facility that will be performing analyses in support of a voluntary action.]

(H) Renewal of laboratory certification.

(1) A laboratory may renew its certification for an analyte(s) or parameter group(s), and method(s), by submitting a renewal application form, as provided by the director, between ninety and one hundred and twenty days prior to the expiration date of the certificate(s). The certified laboratory must maintain continuous certification for a method(s), analyte(s) or parameter group(s) used in support of a request for a no further action letter. Laboratories seeking certification renewal must submit all of the following to the director:

(a) The two most recent periodic performance evaluation sample results as set forth in paragraph (D) of this rule for an analyte(s) or parameter group(s), and using the methods for which the laboratory seeks certification renewal;

(b) A completed certification renewal application form, as provided by the agency, with an affidavit signed by an individual authorized to bind the laboratory

affirming that upon knowledge, information, and belief, all information submitted in support of the certification renewal is truthful, complete and accurate; and

(c) The annual renewal certification fee as established in paragraph (C)(4) of rule 3745-300-03 of the Administrative Code, by submitting a check payable to the "treasurer of the state of Ohio."

(2) At the time of renewal of laboratory certification or payment of the annual renewal certification fee a laboratory may also add an analyte(s) or parameter group(s), and method(s) by submitting the items listed in paragraphs (R)(1)(a), (R)(1)(b), and (R)(1)(d) of this rule.

(3) All renewal documents and payments required by this rule must be submitted, by certified mail or any other form of mail accompanied by a receipt, to the Ohio environmental protection agency.

(4) The director may deny a laboratory certification renewal if the laboratory fails to satisfy one or more of the requirements of this paragraph, or the laboratory fails to meet all standards of performance and conduct, as determined by the director, as set forth in paragraph (I) of this rule.

(5) The agency may perform system audits for certification renewals in accordance with paragraph (J) of this rule, if the agency determines during its review of the renewal application that the laboratory is requesting certification for methods, instruments, and personnel that were not evaluated by the agency during the initial system audit.

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

Certification status may be maintained provided that the laboratory:

(1) Does not perform analyses for which it is not certified pursuant to this rule, when these analyses are done in support of a request for a no further action letter;

(2) Notifies the director, in writing, of any changes in managerial personnel, or procedures which affect its ability to perform analyses pursuant to this rule;

(3) Performs acceptably on all compliance conducted pursuant to the requirements established under this rule, or corrects any deficiencies identified by the director prior to certification renewal;

(4) Notifies the director, in writing, prior to any proposed relocation to a separate facility. The

agency will conduct a system audit of the new facility in accordance with paragraph (J) of this rule, prior to the laboratory performing analyses at the new facility which will be used to support requests for no further action letters;

(5) Does not perform analyses used in support of requests for no further action letters for which it has a conflict of interest;

(6) Performs analyses in support of requests for no further action letters in accordance with its approved standard operating procedures and approved quality assurance program plan to ensure representative data;

(7) Performs acceptably on the periodic performance evaluation sample(s);

(8) Provides the director access to its facility and documents, data, or information related to any voluntary action for the purposes of determining compliance with the requirements of this chapter, and Chapter 3746. of the Revised Code;

(9) Provides data which is representative of the sample for which the laboratory is performing analyses, and will not cause no further action letters to be inconsistent with applicable standards developed under this chapter;

[Comment: a certified laboratory conducting analyses in support of a voluntary action needs to be aware that the applicable standards calculated for a property in accordance with rules 3745-300-08 and 3745-300-09 of the administrative code, may not be within the laboratory's reporting limits. The certified laboratory which performs analyses in support of the no further action letter needs to be capable of detecting the chemical(s) of concern on the property at or below the applicable standards.]

(10) Does not falsify sample results or any information on its application(s), standard operating procedure, quality assurance program plan, performance evaluation sample(s), or any other information requested by the director or required by this rule;

(11) Complies with the methods for which it is certified;

(12) Promptly and completely responds to all document requests made by the agency under this chapter and Chapter 3746. of the Revised Code; and

(13) Pays all costs and fees required by this rule and rule 3745-300-03 of the Administrative Code.

(J) Compliance and system audits.

(1) The agency may conduct compliance audits of a laboratory and its documentation to determine if a laboratory has performed in compliance with this rule, and Chapter

3746. of the Revised Code. Compliance audits will consist of all of the following:

(a) A review of ~~all~~ laboratory documentation including but not limited to, standard operating procedures, logbooks, record files, and data packages to determine compliance with the requirements of this rule;

(b) Interviews of laboratory personnel to determine qualifications and knowledge of personnel performing analyses pursuant to this rule and compliance of the laboratory with this rule; and

(c) An on-site inspection 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 any analyses in support of requests for no further action letters in accordance with the requirements established in this rule. The agency may also conduct system audits to determine whether to renew a laboratory certification or for certified laboratories seeking to add an analyte(s), parameter group(s), or method(s) to their certificate.

(a) System audits will consist of all of the following:

(i) A review of laboratory documentation including but not limited to: standard operating procedures, logbooks, record files, and data packages to determine if the laboratory meets the requirements of this rule;

(ii) Interviews with laboratory personnel to determine qualifications and knowledge of personnel performing analyses pursuant to this rule and compliance of the laboratory with this rule; and

(iii) An on-site inspection to determine if the laboratory is qualified to perform analyses pursuant to the requirements established in this rule.

(b) In order to become certified or TO receive certification renewal, any deficiencies of the laboratory identified by the agency in a system audit must be corrected by the laboratory to the satisfaction of, and within the time limits specified by, the director.

(K) Revocation or suspension of laboratory 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 (K)(2) and (K)(3) of this rule.

(2) The director must permanently revoke a laboratory's certification if the laboratory does not comply with document or data requests made by the agency, in violation of paragraph (I)(12) of this rule, or falsifies any information in connection with its certification or any voluntary action in violation of paragraph (I)(10) of this rule.

(3) The director must suspend a laboratory's certification for an analyte(s) or parameter group(s) if the laboratory fails to comply with the requirements set forth in paragraphs (D)(1)(b) and (I)(7) of this rule.

(4) The laboratory must surrender its certificate(s) to the director upon revocation or suspension of its certification.

(L) Display of laboratory certificate(s).

The certified laboratory must display its original certificate(s) in a prominent location on the laboratory's premises.

(M) 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 board of review in proceedings which 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 director's, or his authorized representative'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) Performance-based method.

(1) at the request of the laboratory, the agency may evaluate whether to approve performance-based method(s) for an analyte(s) or parameter group(s) which cannot be analyzed under paragraph (E) of this rule.

(A) Laboratories seeking initial certification under this rule, must submit the items listed in

paragraph (f)(1) of this rule, unless the agency waives in writing any of the items required in paragraph (f)(1) of this rule. The laboratory must also submit the following information:

(i) The method detection limit study for the analyte(s) or parameter group(s);

(ii)Any historical quality control data that will assist the agency in evaluating the accuracy and precision of the method; and

(iii)A justification, to the agency's satisfaction, that the methods contained in the documents listed in paragraph (E) of this rule are not appropriate to analyze the analyte(s) or parameter group(s) of concern.

(b) Certified laboratories seeking to add a performance-based method(s) to their existing certification must submit the information and fee contained in paragraph (r)(1) of this rule, unless the agency waives in writing the requirement for any of the information contained in paragraph (r)(1) of this rule. The laboratory must also submit the following information:

(i) The method detection limit study for the analyte(s) or parameter group(s);

(ii) Any historical quality control data that will assist the agency in evaluating the accuracy and precision of the method; and

(iii) A justification to the agency's satisfaction that the method(s) contained in the documents listed in paragraph (e) of this rule are not appropriate to analyze for the analyte(s) or parameter groups(s) present of suspected to be present at the property.

(2) A performance-based method is only permitted to be used in support of a no further action letter by the laboratory which applied for and received approval by the director pursuant to this paragraph, and only when consistent with the terms and conditions which the director has attached to such approval.

(P) Procedures for laboratory certification for asbestos analyses.

(1) To qualify for certification for asbestos, a laboratory must be accredited with one of the following:

(a) The "American Industrial Hygiene Association", asbestos analysts registry; or

(b) The "National Institute of Standards Technology", national voluntary laboratory accreditation program for asbestos fiber analysis.

(2) To apply for asbestos certification, a laboratory must submit, to the director, the information as set forth in paragraphs (R)(1)(a), (R)(1)(c), (R)(1)(d) AND (R)(1)(e) of this rule.

(Q) Procedures for laboratory certification for sediment toxicity analyses.

to apply for sediment toxicity certification, a laboratory must submit, to the director, the items and fee set forth in paragraphs (r)(1)(a), (r)(1)(c), (r)(1)(d) and (r)(1)(e) of this rule. The director may require that additional information be provided to the agency to further evaluate their ability to perform sediment toxicity testing.

(R) Procedures for a certified laboratory to add an analyte(s) or parameter group(s), and method(s), to a certificate.

(1) Certified laboratories requesting to add to their certificate any method(s), analyte(s), or parameter group(s), must submit the following:

(a) A completed additional analyte(s) or parameter group(s), and method(s), application form as provided by the agency;

(b) Acceptable performance evaluation result(s), as provided in paragraph (D)(1)(a) of this rule, for the additional analyte(s), or parameter group(s), and method(s) for which a laboratory is requesting certification;

(c) A written quality assurance program plan. If the laboratory provided a satisfactory quality assurance program plan with the initial certification application form an additional quality assurance program plan is not required;

(d) The standard operating procedure(s) for the analyte(s) or parameter group(s), and method(s), for which the laboratory seeks to apply for additional certification under this rule; and

(e) The fee for certification for an additional analyte(s) or parameter group(s), and method(s), established in paragraph (C)(5) of rule 3745-300-03 of the Administrative Code. The laboratory must submit to the agency a check made payable to the "treasurer of the state of Ohio."

(2) The director will not consider any certification requests for additional analyte(s) or parameter group(s), and method(s), that do not contain all of the above information.

(3) The information submitted under this paragraph must be accompanied by an affidavit, signed by an individual authorized to bind the laboratory, affirming that upon knowledge,

information, and belief, all information submitted is truthful, complete and accurate.

(4) The certification expiration date for additional analyte(s) or parameter group(s) is the same as that of the initial certificate or of the last renewed certificate, as appropriate.

(5) All payments and certification documents described above must be submitted, by certified mail or any other form of mail accompanied by a receipt, to the Ohio Environmental Protection Agency.

Effective:_____

Certification:_____

Date:_____

Promulgated under: RC Chapter 119.

Rule amplified: RC Chapter 3746.

Rule authorized by: RC Chapter 3746.

Prior effective dates: 4/14/95 (emer), 7/13/95, 12/29/95