



## Ohio Administrative Code

### Rule 3701-82-02 Application procedures for environmental lead analytical laboratory and clinical laboratory approval and standards of conduct.

Effective: November 3, 2019

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(A) Except as provided in paragraphs (H) and (I) of this rule, and except for the performance of real time analysis of lead content in paint film, no person shall provide or offer to provide analysis of lead content in air, dust, soil, paint film or other substances, for the purposes of meeting the requirements set forth in Chapter 3742. of the Revised Code and the rules adopted thereunder, unless that person is approved by the director as an environmental lead analytical laboratory or employed by an environmental lead analytical laboratory approved by the director.

(B) The director shall not approve an application for environmental lead analytical laboratory approval unless the applicant meets all the following criteria:

(1) The applicant submits a complete application for approval as an environmental lead analytical laboratory in accordance with paragraph (K) of this rule;

(2) The applicant demonstrates successful quarterly performance in the Environmental Lead Proficiency Testing program and is currently accredited by an accrediting organization that participates in the National Lead Laboratory Accreditation Program (NLAPP) as provided for in the "Housing and Community Development Act of 1992," 106 Stat. 3672, 42 U.S.C., 15 U.S.C. 2601 et seq, 15 U.S.C. 2681 et seq, and 15 U.S.C 2683;

(3) The applicant demonstrates compliance with the record-keeping and reporting requirements of rule 3701-32-14 of the Administrative Code; and

(4) The applicant certifies that the laboratory will comply with all the requirements of its NLLAP recognition.

(C) An approved environmental lead analytical laboratory engaging in analysis of air, dust, soil, water, paint, film, or other substances, other than substances derived from the human body, for the presence and concentration of lead shall:



- (1) Notify the director within twenty-four hours if the approved environmental lead analytical laboratory has its NLLAP recognition denied, revoked, suspended or limited;
  - (2) Notify the director within five business days each time the laboratory's NLLAP accreditation as an environmental lead analytical laboratory is renewed or modified;
  - (3) Implement the use of documented methodologies that incorporate adequate quality control measures when analyzing environmental samples. The laboratory shall use methods acceptable under their NLLAP approval for environmental samples being analyzed for the purpose of meeting the requirements set forth in Chapter 3742. of the Revised Code and Chapters 3701-30, 3701-32 and 3701-82 of the Administrative Code;
  - (4) Comply with the record-keeping and reporting requirements set forth in rules 3701-30-05 and 3701-32-14 of the Administrative Code;
  - (5) Comply with all requirements of its NLLAP recognition; and
  - (6) Accurately, truthfully and competently perform lead analysis and record keeping.
- (D) Except as provided in paragraph (G) of this rule, no person shall provide or offer to provide analysis of lead content in blood, for the purpose of meeting the requirements set forth in Chapter 3742. of the Revised Code and the rules adopted thereunder, unless that person is approved by the director as a clinical laboratory or employed by a clinical laboratory approved by the director.
- (E) The director shall not approve an application for a clinical laboratory unless the applicant meets all the following criteria:
- (1) The applicant submits a complete application for approval as a clinical laboratory in accordance with paragraph (L) of this rule;
  - (2) The applicant demonstrates possession of a current CLIA certification or certificate of waiver by the U.S. department of health and human services as set forth in the "Clinical Laboratory



Improvement Amendments of 1988," 102 Stat. 2903, 42 U.S.C. 263a;

(3) The applicant demonstrates compliance with the record-keeping and reporting requirements set forth in rules 3701-30-05 and 3701-32-14 of the Administrative Code;

(4) The applicant certifies that the laboratory will comply with all the requirements of its CLIA accreditation by signing the application; and

(5) An applicant that analyzes blood for lead content under a CLIA certificate of waiver, must successfully participate in a proficiency testing program that is also acceptable for CLIA non-waived blood lead analysis procedures.

(F) An approved clinical laboratory engaging in biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of substances derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or in the assessment or impairment of the health of human beings shall:

(1) Notify the director within twenty-four hours if the approved clinical laboratory has its CLIA accreditation revoked, suspended or limited;

(2) Notify the director within five business days each time the laboratory's CLIA certification or certificate of waiver as a clinical laboratory is renewed or modified;

(3) Comply with all the requirements of its CLIA accreditation by signing the application;

(4) Comply with the record-keeping and reporting requirements set forth in rules 3701-30-05 and 3701-32-14 of the Administrative Code; and

(5) Accurately, truthfully and competently perform analysis and record keeping.

(G) A laboratory operated by the federal government is exempt from approval by the director as an environmental lead analytical laboratory or a clinical lead laboratory.



(H) Environmental samples of water collected for the purpose of meeting the requirements set forth in Chapter 3742. of the Revised Code and Chapters 3701-30, 3701-32, and 3701-82 of the Administrative Code shall be analyzed by a laboratory certified to analyze lead in drinking water by the Ohio environmental protection agency pursuant to Chapter 3745-89 of the Administrative Code. Laboratories certified pursuant to Chapter 3745-89 of the Administrative Code are exempt from the requirements of this rule for the purposes of analyzing lead in drinking water.

(I) Initial approval of an environmental lead analytical laboratory or clinical lead laboratory expires twelve months from the date of issuance and annually thereafter. Expiration of an approval is not subject to appeal.

(J) If at any time an environmental lead analytical laboratory or clinical laboratory does not meet the requirements set forth in Chapter 3742. of the Revised Code or of this rule, the director, in accordance with Chapter 119. of the Revised Code may:

(1) Refuse to issue or renew an approval of an environmental lead analytical laboratory or clinical laboratory; or

(2) Suspend or revoke the approval of an environmental lead analytical laboratory or clinical laboratory.

(K) For the purposes of this rule, an application is considered complete when the director has received from the applicant:

(1) A completed application;

(2) Documentation required by paragraphs (B) and (F) of this rule; and

(3) An application fee of three hundred dollars, payable to the "Treasurer, State of Ohio."

(L) If the director receives an incomplete application for laboratory approval, the applicant has ninety days from the date of the request for information letter to complete the application. If the



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director does not receive the requested information within the ninety day period, the director may consider the application abandoned. Any further consideration for laboratory approval shall be subject to another application accompanied by another nonrefundable application fee.