

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE A: GENERAL PROVISIONS
CHAPTER II: ENVIRONMENTAL PROTECTION AGENCY

PART 186
ACCREDITATION OF ENVIRONMENTAL LABORATORIES

Section	
186.105	Purpose
186.110	Scope and Applicability
186.115	Incorporation by Reference
186.120	Definitions
186.125	Accreditation
186.130	Application Process
186.135	TNI Standard
186.140	Personnel Requirements (Repealed)
186.145	Laboratory Equipment and Materials (Repealed)
186.150	Laboratory Facilities (Repealed)
186.155	Calibration (Repealed)
186.160	Quality Assurance/Quality Control (Repealed)
186.165	Quality Assurance Plan (Repealed)
186.170	Performance Evaluation Sample Testing (Repealed)
186.175	Performance Evaluation Testing Programs (Repealed)
186.180	Scope of Accreditation
186.185	Sample Acceptance and Receipt (Repealed)
186.190	Record Keeping, Sample Tracking and Reporting (Repealed)
186.195	Subcontracting (Repealed)
186.200	Reciprocity (Repealed)
186.205	Acceptance of Out-of-State Accreditation (Repealed)
186.210	Suspension, Revocation and Denial of Accreditation (Repealed)
186.215	Hearing, Decision and Appeal
186.220	Confidential Documents
186.225	Severability
186.230	On-site Assessment and Proficiency Testing Laboratory Expenses
APPENDIX A	Required Method Detection Limits (MDL) or Pattern Recognition Levels (PRL) for Drinking Water Laboratory Accreditation (Repealed)

AUTHORITY: Implementing and authorized by Section 1401(1)(D) of the Safe Drinking Water Act [42 USC 300f(1)(D)], Subpart C of the National Interim Primary Drinking Water Regulations [40 CFR 141.21 through 141.30], the Clean Water Act [32 USC 1251], the Illinois Environmental Protection Act [415 ILCS 5], and authorized by Section 4(n) and (o) of the Illinois Environmental Protection Act [415 ILCS 5/4(n) and (o)].

SOURCE: Adopted at 22 Ill. Reg. 5546, effective March 4, 1998; amended at 26 Ill. Reg. 12167, effective July 29, 2002; amended at 30 Ill. Reg. 2507, effective February 10, 2006; amended at 34 Ill. Reg. 9064, effective June 24, 2010; amended at 38 Ill. Reg. 18627, effective September 1, 2014; amended at 43 Ill. Reg. 6175, effective July 1, 2019; amended at 46 Ill. Reg. 3152, effective February 8, 2022; amended at 48 Ill. Reg. 5271, effective March 19, 2024.

Section 186.105 Purpose

The purpose of this Part is to *establish and enforce minimum standards for the operation of laboratories relating to analyses and laboratory tests for air pollution, water pollution, noise emissions, contaminant discharges onto land, and sanitary, chemical, and mineral quality of water distributed by a public water supply, and to issue certificates of competency to persons and laboratories meeting the minimum standards established by the Agency.* [415 ILCS 5/4(n) and (o)]

(Source: Amended at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.110 Scope and Applicability

- a) This Part establishes general provisions applicable to the accreditation program for laboratories administered by the Agency. Requirements of this Part are applicable to all laboratories that are accredited or seeking accreditation, regardless of their size, volume of business or field of testing.
- b) Nothing in this Part shall prevent laboratories from performing any quality control or other tests when the State has not required those tests to be performed by an accredited laboratory.

(Source: Amended at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.115 Incorporation by Reference

- a) The Agency incorporates the following documents by reference.
 - 1) The NELAC Institute (TNI) Standard titled Requirements for the National Environmental Laboratory Accreditation Program, consisting of Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis, EL-V1-2016-Rev.2.1; and Volume 2, General Requirements for Accreditation Bodies Accrediting Environmental Laboratories, EL-V2-2016-Rev.2.0, P.O. Box 2439, Weatherford TX 76086, (817)598-1624.
 - 2) "Test Methods for Evaluating Solid Waste, SW846", "Laboratory

Manual Physical/Chemical Properties", volumes 1A, 1B and 1C, 3rd edition (July 2014), Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, available from the National Technical Information Service (NTIS), (703)605-6000 (available at <https://www.epa.gov/hw-sw846/sw-846-compendium>).

1000 Series: Waste Characteristics and Leaching/Extracting Methods

3000 Series: Inorganic Sample Preparation

3500 Series: Organic Sample Extraction

3600 Series: Organic Extract Cleanup

5000 Series: Sample Preparation and Introduction for Volatile Organic Compounds

6000 Series: Inorganic Determinative Methods – Inductively Coupled Plasma (ICP) and Other Methods

7000 Series: Inorganic Determinative Methods – Atomic Absorption (AA) and Other Methods

8000 Series: Chromatographic Separation Methods

9000 Series: Miscellaneous Test Methods

- 3) USEPA, NSCEP. United States Environmental Protection Agency, National Service Center for Environmental Publications, P.O. Box 42419, Cincinnati OH 45242-0419 (available from <http://www.epa.gov/nscep/>).

Method 218.7, "Determination of Hexavalent Chromium in Drinking Water by Ion Chromatography with Post-Column Derivatization and UV – Visible Spectroscopic Detection", Revision 1.0, November 2011, EPA 815-R-11-005.

- 4) "Manual for the Certification of Laboratories Analyzing Drinking Water", "Criteria and Procedures Quality Assurance", 5th edition (EPA 815-R-05-004, January 2005), Office of Water, Office of Ground Water and Drinking Water, Environmental Protection Agency, available from the National Service Center for Environmental Publications (NSCEP), (800) 490-9198 (available at <https://www.epa.gov/dwlabcert/laboratory-certification-manual->

drinking-water).

"Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water" (Supplement 1 to EPA 815-R-05-004, 2008), Office of Water, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, available from the National Service Center for Environmental Publications (NSCEP), (800) 490-9198 (available at <https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water>).

- 5) EPA PFAS Drinking Water Laboratory Methods (available at www.epa.gov/pfas/epa-pfas-drinking-water-laboratory-methods).

Method 533, "Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry," November 2019, EPA 815-B-19-20.

Method 537.1, "Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)," Revision 2.0, March 2020, EPA 600/R-20/006.

- 6) Environmental Sampling and Analytical Methods (ESAM) Program (available at <https://www.epa.gov/esam/method-546-determination-total-microcystins-and-nodularins-drinking-water-and-ambient-water>).

Method 546, "Determination of Total Microcystins and Nodularins in Drinking Water and Ambient Water by Adda Enzyme-Linked Immunosorbent Assay," August 2016, EPA 815-B-16-011.

- 7) The SW-846 Compendium (available at <https://www.epa.gov/hw-sw846/sw-846-compendium>).

Method 8327, "Per- and Polyfluoroalkyl Substances (PFAS) By Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS), SW-0846 Update VII, Revision 0, July 2021.

Method 3512, "Solvent Dilution of Non-Potable Waters,"
SW-846 Update VII, Revision 0, July 2021.

- 8) CWA Analytical Methods for Per- and Polyfluorinated Alkyl Substances (PFAS) (available at <https://www.epa.gov/cwa-methods/cwa-analytical-methods-and-polyfluorinated-alkyl-substances-pfas>).

Method 1633 "Analysis of Per- and Polyfluoroalkyl Substances (PFAS) in Aqueous, Solid, Biosolids, and Tissue Samples by LC-MS/MS".

- b) The Agency incorporates the following Sections of federal regulations by reference:

- 1) 40 CFR 136.3 Table IB, Table IC, Table ID, Table IF, Table IG, Table II (2020)

40 CFR 136.4 (2020)

40 CFR 136.5 (2020)

40 CFR 136.6 (2020)

40 CFR 136.7 (2020)

40 CFR 136 appendix A (2020)

40 CFR 136 appendix B (2020)

40 CFR 136 appendix C (2020)

40 CFR 136 appendix D (2020)

Clean Water Act Methods Update Rule for the Analysis of Effluent, 86 Fed. Reg. 27226-27260 (May 19, 2021) (updating 40 CFR 136)

- 2) 40 CFR 141.23(k) (2020)

40 CFR 141.24(e) (2020)

40 CFR 141.24(f)(20) (2020)

40 CFR 141.27 (2020)

40 CFR 141.74 (2020)

40 CFR 141.131 (2020)

40 CFR 141 subpart C, appendix A (2020)

40 CFR 143.4 (2020)

Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act: Analysis and Sampling Procedures, 86 Fed. Reg. 28277-28290 (May 26, 2021) (updating 40 CFR 141)

c) This Section incorporates no later amendments or editions.

(Source: Amended at 48 Ill. Reg. 5271, effective March 19, 2024)

Section 186.120 Definitions

For the purposes of this Part, unless otherwise specifically defined or the context clearly requires a different meaning:

"Act" means the Illinois Environmental Protection Act [415 ILCS 5].

"Accrediting Body" means the territorial, state or federal agency having responsibility and accountability for environmental laboratory accreditation and that grants NELAP accreditation.

"Agency" means the Illinois Environmental Protection Agency. The Agency administers the environmental laboratory accreditation program. The Agency serves as the accrediting body (primary and secondary), and the assessor body, unless the Agency designates a third party assessor body.

"Biennial Basis" means every two years, plus or minus six months.

"NELAP" means the National Environmental Laboratory Accreditation Program.

"Primary Accreditation" means an accreditation granted by a primary accreditation body.

"Primary Accreditation Body" means the accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and proficiency test performance tracking for fields of accreditation.

"Secondary Accreditation" means an accreditation granted by a secondary accreditation body.

"Secondary Accreditation Body" means an accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of accreditation from a primary accreditation body for the same field of accreditation.

"TNI" means The NELAC Institute.

"TNI Standard" means The NELAC Institute (TNI) Standard titled "Requirements for the National Environmental Laboratory Accreditation Program", incorporated by reference in Section 186.115.

(Source: Amended at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.125 Accreditation

- a) Primary Accreditation. The Agency shall issue initial or renewal primary accreditation if the laboratory has met the following criteria:
 - 1) completed the application process as specified in Section 186.130;
 - 2) paid the fees required by 35 Ill. Adm. Code 185;
 - 3) employs qualified personnel, as required by the TNI Standard;
 - 4) implemented and maintains a quality system, as required by the TNI Standard;
 - 5) successfully analyzed proficiency testing samples, as required by this Part and the TNI Standard;
 - 6) passed an on-site assessment, as required by this Part and the TNI Standard; and
 - 7) implemented corrective action detailed in a corrective action report, if any.

- b) Secondary Accreditation. The Agency will issue initial or renewal secondary accreditation if the laboratory has met the following criteria:
 - 1) completed the application process as specified in Section 186.130;
 - 2) paid the fee required by 35 Ill. Adm. Code 185; and

- 3) submitted evidence of primary accreditation from a NELAP accreditation body.
- c) Laboratory accreditation issued pursuant to this Part is valid for one year and may be renewed on an annual basis.
 - d) When an accredited laboratory has made a timely and complete application for the renewal of accreditation pursuant to this Section, the existing accreditation shall continue in full force and effect until the final Agency decision on the application has been made, unless a later date is fixed by order of the Board or a reviewing court. An application will be considered timely only when received by the Agency prior to the expiration of the laboratory's accreditation.
 - e) Accreditation remains in effect until:
 - 1) suspended or revoked by the Agency according to the TNI Standard;
 - 2) withdrawn at the written request of the accredited laboratory; or
 - 3) the accreditation expires.
 - f) An accredited laboratory may make a written request to add to its scope of accreditation. The Agency will conduct an on-site assessment if the additional fields of testing or test methods require the use of a chemical process, an analytical process, instrument or piece of equipment that the laboratory has not been previously accredited to use.
 - g) Laboratories shall post or display their most recent certificate of accreditation and scope of accreditation in a prominent place in the laboratory facility.
 - h) A laboratory shall notify the Agency in writing within 30 days after a change of any matter that may affect the ability of the laboratory to fulfill the requirements for accreditation, including, but not limited to, any change in the following:
 - 1) its legal, commercial, ownership or organizational status;
 - 2) the organization, top management and key personnel, including, but not limited to, laboratory director, quality assurance officer, supervisor, analyst;
 - 3) main policies, including, but not limited to, its quality system;

- 4) resources and premises, including, but not limited to, a major remodeling of a laboratory or relocation of the physical facility.
- i) Transfer of Accreditation
 - 1) Accreditation shall be transferrable when the following conditions are in effect:
 - A) the transferring owner agrees in writing with the transferee, before the transfer of ownership takes place, to be accountable and liable for any analyses, data and reports generated up to the time of legal transfer of ownership; and
 - B) the transferee agrees in writing with the transferring owner to be accountable and liable for any analyses, data and reports generated after the legal transfer of ownership occurs.
 - 2) The laboratory shall submit a copy of the agreement entered under subsection (i)(1) to the Agency prior to transfer of ownership.
 - 3) Transfer of accreditation pursuant to this subsection (i) will not alter the laboratory's accreditation status or scope of accreditation.
 - 4) If ownership is transferred, the transferee will not be responsible for payment of fees to the Agency during the remainder of the yearly period, provided that the transferring owner has fully paid the required fees to the Agency pursuant to 35 Ill. Adm. Code 185.

(Source: Old Section repealed at 26 Ill. Reg. 12167, effective July 29, 2002; new Section added at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.130 Application Process

The application process consists of the submission of a written application package, completion of an on-site assessment, and proficiency test sample evaluations.

- a) Application Package
 - 1) All laboratories seeking initial accreditation or renewal accreditation shall annually submit a completed application package. A complete application package includes an application on forms prescribed by the Agency and payment of the appropriate fees required by Section 17.8 of the Act and 35 Ill. Adm. Code 185.

- 2) The Agency shall send, no later than 60 days prior to the anniversary date of initial certification, an application package to the accredited laboratories. Upon request, the Agency shall send an application package to those laboratories seeking initial accreditation.
- 3) If the Agency receives an incomplete application package, the Agency will provide written notice of the incomplete application, specifying the missing information. The Agency review of the application package will not commence until the Agency receives the missing information.
- 4) The following information shall be included in the application:
 - A) laboratory information, including laboratory name, address, telephone number, e-mail address, fax number, hours of operation, laboratory owner, laboratory contact person, name of the laboratory director, and name of the laboratory quality assurance officer;
 - B) the type of laboratory, for example commercial, federal or public water system;
 - C) the fields of testing and test methods for which the laboratory is requesting accreditation, pursuant to Section 186.180;
 - D) the laboratory's quality assurance plan, if the laboratory is seeking initial primary accreditation;
 - E) a statement of laboratory personnel qualifications;
 - F) the primary accrediting body, if the laboratory is seeking secondary accreditation; and
 - G) a copy of the laboratory's primary accreditation certificate, if the laboratory is seeking secondary accreditation.
- 5) The laboratory director shall sign and date the application package and attest in writing to the validity of the information contained within the entire application package.
- 6) Information required in the application package must be complete and accurate.
- 7) Falsification of any information in the application package shall

result in denial of the application.

- b) Within 30 days after receipt of the complete application package, the Agency will review the complete application package. If the complete application package does not meet the TNI Standard as set forth in Section 186.135, the Agency may deny the application or request additional information. The Agency shall review any additional information submitted by the laboratory within 30 days after receipt.
- c) Initial Primary Accreditation Application. If the complete application package meets the TNI Standard, the Agency will conduct an on-site assessment and the laboratory shall complete the proficiency test sample evaluation process.
- d) Renewal Primary Accreditation Application. If the complete application package meets the TNI Standard, the Agency will conduct an on-site assessment on a biennial basis.
- e) Secondary Accreditation. If the complete application package meets the TNI Standard, the Agency will issue secondary accreditation.
- f) Procedures for the on-site assessment and the proficiency test sample evaluation process are set forth in the TNI Standard.

(Source: Old Section repealed at 26 Ill. Reg. 12167, effective July 29, 2002; new Section added at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.135 TNI Standard

All accredited laboratories or any laboratory seeking initial or renewal accreditation shall comply with the following portions of the TNI Standard:

- a) Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis:
 - 1) Module 1: Proficiency Testing;
 - 2) Module 2: Quality Systems General Requirements;
 - 3) Module 3: Quality Systems for Asbestos Testing; and
 - 4) Module 4: Quality Systems for Chemical Testing.
- b) Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories:

- 1) Module 1: General Requirements;
- 2) Module 2: Proficiency Testing; and
- 3) Module 3: On-Site Assessment.

(Source: Old Section repealed at 26 Ill. Reg. 12167, effective July 29, 2002; new Section added at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.140 Personnel Requirements (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.145 Laboratory Equipment and Materials (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.150 Laboratory Facilities (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.155 Calibration (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.160 Quality Assurance/Quality Control (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.165 Quality Assurance Plan (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.170 Performance Evaluation Sample Testing (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.175 Performance Evaluation Testing Programs (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.180 Scope of Accreditation

- a) The Agency offers the following scope of accreditation:
 - 1) public water supply analysis for organic and inorganic parameters;

- 2) water pollution analyses for organic and inorganic parameters; and
 - 3) analyses for organic and inorganic parameters of solid or liquid samples for hazardous or other waste.
- b) The Agency offers accreditation for the test methods incorporated by reference in Section 186.115.

(Source: Amended at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.185 Sample Acceptance and Receipt (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.190 Record Keeping, Sample Tracking and Reporting (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.195 Subcontracting (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.200 Reciprocity (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.205 Acceptance of Out-of-State Accreditation (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.210 Suspension, Revocation and Denial of Accreditation (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.215 Hearing, Decision and Appeal

- a) The following procedures apply to suspension, revocation and denial of accreditation.
- b) Prior to revocation, suspension or denial of accreditation, the Agency shall give written notice of the action by certified mail and email. The notice shall state the facts or conduct and the Sections of the TNI Standard that form the basis for the decision. The notice shall set forth the procedures for appealing the Agency's decision.

- c) Any suspension, revocation or denial of accreditation is effective immediately. The laboratory may file a written notice of appeal within 15 days after its receipt of the notice.
- d) A laboratory may request a hearing in the notice of appeal. All hearings pursuant to this Part shall be held in Springfield, Illinois. When a hearing is requested, the Director of the Agency shall appoint one or more persons to act as hearing officers. The hearing shall be conducted in accordance with the Agency's Procedures for Contested Case Hearings (35 Ill. Adm. Code 168).
- e) The Director of the Agency shall make a decision within 30 days after receiving the hearing transcript. The Director shall give written notice by certified mail or personal service of the decision, including its basis, to the laboratory.
- f) Within 35 days after its receipt of a notice of decision, the laboratory may file an appeal to the Illinois Pollution Control Board.

(Source: Amended at 38 Ill. Reg. 18627, effective September 1, 2014)

Section 186.220 Confidential Documents

Information maintained or obtained by the Agency concerning each accredited or applicant laboratory is available for public inspection pursuant to the terms of the Freedom of Information Act [5 ILCS 140], Section 7 and Section 7.1 of the Act and regulations promulgated pursuant to those Acts (2 Ill. Adm. Code 1828). Information identified as trade secret or confidential business information that meets the requirements of the Act, the Freedom of Information Act or the regulations will not be subject to release under the Freedom of Information Act. Those asserting the confidentiality of documents are urged to follow the procedures of 2 Ill. Adm. Code 1828.

(Source: Amended at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.225 Severability

If any provision of this Part is adjudged invalid, or if its application to any person or in any circumstance is adjudged invalid, such invalidity does not affect the validity of this Part as a whole, or any other Subpart, Section, subsection, sentence or clause not adjudged invalid.

Section 186.230 On-site Assessment and Proficiency Testing Laboratory Expenses

- a) Out-of-state laboratories shall pay all costs for Agency employees or designees to conduct on-site assessments. This includes the following:
 - 1) Round trip transportation costs, by airplane, train, or automobile,

from the Agency's home office to the laboratory. These transportation costs include gas mileage if using the Agency's Division of Laboratories' vehicle or assessor's personal vehicle;

- 2) Lodging;
 - 3) Car rental, as applicable; and
 - 4) Per diem.
- b) The laboratory shall pay all costs relating to proficiency testing.

(Source: Added at 26 Ill. Reg. 12167, effective July 29, 2002)

Section 186.APPENDIX A Required Method Detection Limits (MDL) or Pattern Recognition Levels (PRL) for Drinking Water Laboratory Accreditation (Repealed)

(Source: Repealed at 26 Ill. Reg. 12167, effective July 29, 2002)