Terms Used to Describe the Standing of U.S. EPA Methods

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TERMS USED TO DESCRIBE THE STANDING OF U.S. EPA METHODS

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Preface

The U.S. Environmental Protection Agency (EPA or the Agency) relies on methods for the analysis of samples for environmental contaminants for both regulatory and non-regulatory purposes. These methods are developed by EPA or adopted from external parties for Agency use.

The purpose of this document is to compile terms (e.g., regulatory, promulgated, etc.) used by EPA to describe and designate the standing of its methods (includes aspects like status and type) and promote a better understanding of these terms. Specifically, this document is intended for use by EPA personnel, states, regulated industry, laboratories and testing organizations, instrument vendors, and the public who want a better understanding of the meanings of these terms and their application by EPA.

This document was prepared by the Environmental Methods Forum (EMF) "Method Terms" Workgroup. The EMF is a cross-Agency forum chartered under EPA's Laboratory Enterprise Council (LEC). For more information on the EMF and LEC, please go to: https://www.epa.gov/labs/national-program-manager-regional-laboratories-activities#collaboration.

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Contents

1. Introduction, Purpose, and Scope

The U.S. Environmental Protection Agency (EPA or the Agency) relies on methods for the analysis of samples for environmental contaminants for both regulatory and non-regulatory purposes. These methods are developed by the Agency or adopted from external parties for Agency use. EPA uses many terms (e.g., regulatory, promulgated, approved, etc.) to describe the standing of a method (includes aspects like status and type). The decentralized nature of method development and adoption at EPA, as well as the different needs of EPA's various programs, have sometimes led to nuanced uses for similar terms by its different offices to describe the standing of US EPA methods.

The purpose of this document is to:

(a) compile terms (e.g., regulatory, promulgated, approved) used by EPA to describe/designate the standing of its methods, and

(b) promote a better understanding of these terms for both EPA personnel and external parties (e.g., states, regulated industry, laboratories and testing organizations, instrument vendors, the public etc.).

This document only addresses terms that describe method standing and does not include terms that describe technical characteristics of a method (e.g., detection limits).

1.1 Intended Audience

This document is intended for use by both EPA personnel and external parties (e.g., states, regulated industry, laboratories and testing organizations, instrument vendors, the public) who want a better understanding of the meanings of terms used by EPA to describe the standing of its methods and how they are applied.

1.2 Note

This document explains terms used by different offices within EPA for their methods. These explanations have been provided by the respective EPA offices and are intended to provide a general overview and applicability of the terms.

2. Background

2.1 EPA Method Definitions

EPA does not have a single definition for a method used for environmental analysis. Examples of general method definitions used at EPA include:

- Absolute Method: a body of procedures and techniques for performing a task (e.g., sampling, characterization, quantification) systematically presented in the order in which they are to be executed (1).
- Method: procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) and producing a result, and the procedures are usually presented in the order in which they are to be executed (1).

- Test Method: adoption of a scientific technique for a specific measurement problem, as documented in a laboratory Standard Operating Procedure (SOP) or published by a recognized authority (2).

Examples of EPA Office-specific definitions include:

- Office of Air and Radiation Stationary Source Emissions Test Method Program under the Clean Air Act (CAA): the validated procedure for sampling, preparing, and analyzing for an air pollutant specified in a relevant standard as the performance test procedure (3).
- Office of Water Safe Drinking Water Act (SDWA) Analytical Method: a procedure used to measure the amount of particular contaminants in drinking water samples (4).
    - Analytical methods generally describe how to:
        - Collect, preserve, and store the sample
        - Separate, identify, and measure contaminants in the sample
        - Meet quality control criteria
        - Report the results of the analysis

2.2 Other Method Definitions

Standards organizations like ASTM International, American Public Health Association (APHA), American Water Works Association (AWWA), Water Environment Federation (WEF), and the International Organization for Standardization (ISO) develop methods that are frequently adopted or designated by EPA for use in its regulatory programs. Definitions for methods used by these organizations vary and some examples are given below:

- Test Method (ASTM): definitive procedure that produces a test result and requires a precision and bias statement (5).
- Measurement Method (ISO): generic description of a logical organization of operations used in a measurement (measurement methods may be qualified in various ways such as: substitution measurement method, differential measurement method, and null measurement method; or direct measurement method, and indirect measurement method) (6).
- Measurement Procedure (ISO): detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result (a measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement, can include a statement concerning a target measurement uncertainty, and is sometimes called a Standard Operating Procedure (SOP) (6).
- Standard Methods for the Examination of Water and Wastewater (APHA, AWWA, WEF): a procedure qualifies as a Standard Method in one of two ways: (a) The procedure must undergo development and validation and collaborative testing that meet the requirements set forth in Sections 1040B and C of 'Standard Methods', respectively, and it is 'widely used' by members of the Standard Methods Committee; or (b) The procedure is 'widely used' by the members of the

Standard Methods Committee and it has appeared in two previous editions of 'Standard Methods' (7).

- Method of Analysis (Association of Official Analytical Collaboration (AOAC) International): the method of analysis is the detailed set of directions, from the preparation of the test sample to the reporting of the results, that must be followed exactly for the results to be accepted for the stated purpose (8).

It is important to note that a Standard Operating Procedure should not be confused with a method. A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organization. SOPs are often used by EPA and other organizations in conjunction with published methods; the SOP will specify the procedures to be followed in greater detail than the method and include any particular procedures and/or equipment that the organization uses in conducting the method. Citing published methods in SOPs is not always acceptable, because cited published methods may not contain pertinent information for conducting the procedure-in-house (9).

2.3 Statutes

EPA's Offices develop or adopt/designate methods for environmental analysis to support programs operated under the statutory authority listed in this section. Additional information on these statutes is given in Appendix B.

Office of Land and Emergency Management (OLEM):

- The Resource Conservation and Recovery Act of 1976 (RCRA)
  - SW-846 Compendium
- Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)
- The Superfund Amendments and Reauthorization Act of 1986 (SARA)

Office of Water (OW):

- Safe Drinking Water Act (SDWA)
- Clean Water Act (CWA)

Office of Air and Radiation (OAR):

- Clean Air Act (CAA)

Office of Chemical Safety and Pollution Prevention (OCSPP):

- Toxic Substances Control Act (TSCA)
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Federal Food, Drug, and Cosmetic Act (FFDCA)
- Pollution Prevention Act (PPA)

2.4 How EPA Methods are Developed or Adopted

Methods published by EPA have different requirements and processes for development, approval, and acceptance, often depending on their application and the EPA Office with which they are affiliated. These methods are developed or adopted by an Office or Region for their respective program. For additional information about specific method development and adoption requirements, please contact the responsible program.

2.4.1 Internal and External Methods

EPA utilizes both internal (EPA-developed) methods and external methods in its regulatory and other programs. Internal methods are developed by EPA Offices and Regions, usually for their respective programs. Sources of external methods include those developed by Voluntary Consensus Standards Bodies (VCSB). In its regulatory programs, EPA typically uses Incorporation by Reference when it wants to designate or adopt a method for compliance.

The National Technology Transfer and Advancement Act requires EPA to use technical standards developed by Voluntary Consensus Standards Bodies (VCSB), when practical, to carry out the Agency's policy objectives and other EPA activities, including the development of regulations. Examples of VCSBs include but are not limited to: ASTM International, International Organization for Standardization (ISO), and Water Environment Federation (WEF) (10).

In the context of this document, voluntary consensus standards are standardized methods that are used for environmental sample collection and/or analysis and are published by a recognized VCSB. Voluntary consensus standards are developed, validated, and reviewed according to the requirements of the VCSB, and they are published based on the consensus decision of a committee of technical experts from industry, academia, government, and/or non-governmental organizations. Some EPA regulations allow or require the use of specified voluntary consensus standards to demonstrate compliance (11).

2.4.2 Method Formats

The format of EPA methods may be different than that of external parties, but much of the terminology is similar. As noted previously, acceptable analytical methods can come from EPA or from outside organizations such as VCSBs. Generally, Agency methods are expected to address the sections listed in the Environmental Monitoring Management Council (EMMC) Methods Format document, a method format template developed in the 1990s that established a consistent framework for writing and updating methods. The EMMC format can be found in Appendix C.

2.4.3 Naming Convention for EPA Methods

EPA does not have an Agency-wide standardized naming convention for all methods. Instead, EPA Offices and Regions develop and employ their own specific naming conventions for their respective programs. See Section 4 for program-specific naming conventions. For a compilation of many of EPA's method numbers and method descriptions, please refer to the Index to EPA Test Methods at https://www.epa.gov/sites/default/files/2015-03/documents/testmeth.pdf.

3. Publications Associated with Method Terms

The following are federal and Agency publications in which EPA makes methods available to the public.

3.1 Federal Register

The Federal Register (FR) is the official daily publication for proposed and final rules, and other notices of Federal agencies and organizations, executive orders, and other presidential documents. EPA methods may appear in the Federal Register to notify the public of their existence for both regulatory and non-regulatory applications.

In some cases, publishing methods in the Federal Register promulgates the methods, or formally puts them into effect by public declaration (e.g. as in 2018-24747.pdf (govinfo.gov) (12). A method published in the Federal Register may not be included in the Code of Federal Regulations (CFR) if it is non-regulatory (see Section on EPA Guidance below).

3.2 Code of Federal Regulations

The Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government. The CFR is divided into 50 titles (e.g., Title 40 is "Protection of Environment") that represent broad areas subject to Federal regulation. Each title is divided into chapters, which usually bear the name of the issuing agency. Each chapter is further subdivided into subchapters and parts that cover specific regulatory areas (e.g., Chapter 1 is "Environmental Protection Agency", Subchapter D is "Water Programs", and Part 141 is "National Primary Drinking Water Regulations) (13).

Regulatory methods addressed by the CFR are typically incorporated by reference and identified to support the respective regulation. These test methods may be required to be used to demonstrate compliance with regulations promulgated under the relevant environmental statutes (See Appendix B for additional information) that the various EPA programs administers. Establishment of regulatory method requirements via final rules in the FR (and subsequent codification of the action in the CFR) promotes consistency and comparability in environmental measurements as regulated entities are legally bound to use the methods.

The following website provides a list of methods have been published in the Federal Register and codified in the Code of Federal Regulations (CFR): EMC Promulgated Test Methods | US EPA

3.3 EPA Docket

A docket is a collection of documents made available by an agency for public viewing. Often associated with an opportunity for public comment, EPA dockets consist of materials used to support a rulemaking or other agency action. These may include documents specifically referenced in the Federal Register, public comments received, and other information used by the Agency to explain or support its decisions. EPA dockets may support rulemaking or non-rulemaking actions (15).

Rulemaking (sometimes referred to as "regulatory") dockets support EPA's efforts to propose, amend, repeal, or promulgate a rule or regulation. Rulemaking dockets contain: Federal Register Notices (Notice

of Proposed Rulemaking, Final Rule Notice, and/or Direct Final Rule Notice), proposed rule text, supporting documents, and/or submitted public comments. Non-rulemaking dockets (also known as "general' dockets) contain information on any agency process or action not related to the development of a rule. (15).

EPA posts publicly-available docket materials to Regulations.gov. The public may search, view, and comment on those materials. Dockets, and the documents in them, can be identified by their unique ID code. Docket IDs have five parts: AGENCY-LOCATION-OFFICE-YEAR-DOCKET NUMBER (15).

3.4 EPA Guidance

In some cases, EPA programs publish methods as guidance. Guidance has been defined by Executive Order 13422 (2007) as “an agency statement of general applicability and future effect, other than a regulatory action that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue”. Guidance is categorized as a non-legislative rule under the Administrative Procedure Act which governs how agencies develop regulations (16). Publication of a test method as guidance is generally not part of a rulemaking process because it does not involve changes to a regulation, which reduces the number of steps required and enables more timely publication and revision. To ensure quality, transparency, and accountability, guidance methods may nevertheless be subject to many of the process steps used for publication of regulatory methods, such as internal agency review and public participation, but the methods are not required by regulation. For example, the SW-846 Compendium includes examples of both regulatory and guidance (“non-regulatory”) methods. The SW-846 Compendium is a collection of test methods and related guidance published by EPA’s Office of Resource Conservation and Recovery to support implementation of the Resource Conservation and Recovery Act (RCRA). Updates to regulatory methods specified in RCRA regulations are made through the Agency rulemaking process, while updates to non-regulatory methods and other guidance are made through a streamlined process (17).

4. Method Standing and Related Terms

This section provides an overview of EPA offices and their programs that develop methods, the statutes under which the methods are developed and their method naming conventions. Each overview is followed by the terms used within that Office to describe the standing of their methods. Please note that the decentralized nature of method development and adoption at EPA, as well as the different needs of EPA’s various programs, have sometimes resulted in nuanced uses for similar terms between different offices.

4. 1 Office of Air Quality Planning and Standards Programs

The Office of Air and Radiation (OAR) develops national programs, policies, and regulations for controlling air pollution and radiation exposure. OAR is responsible for administering the Clean Air Act, the Atomic Energy Act, and other applicable environmental laws. The Office of Air Quality Planning and Standards within OAR has two primary programs that require environmental measurements and thus

rely heavily on test methods: the Stationary Source Program and the Ambient Air Monitoring Program. These programs are described below.

4.1.1 Stationary Source Program

The Stationary Source Program regulates stationary sources of air pollution using emission standards including those in 40 CFR Part 59, 60, 61, 63, and 65. The regulated facilities conduct environmental measurements to demonstrate compliance with the emissions standards for criteria pollutants -- particulate matter, sulfur dioxide, nitrogen oxides, carbon monoxide, lead, and volatile organic compounds -- and hazardous air pollutants also termed air toxics. EPA promulgates many of the test methods and continuous monitoring performance specifications used in the stationary source program. For additional information, please refer to the Air Emission Measurement Center (EMC) internet page at https://www.epa.gov/emc.

4.1.1.a Stationary Source Program Methods Naming Convention

The stationary source methods promulgated by EPA carry an xx, 1xx, 2xx, or 3xx alphanumeric designation depending upon whether they are published in, Part 60, Part 61, Part 51, or Part 63, respectively, of Title 40. Some stationary source test methods include letter designations (e.g., A, B, C, etc.) which typically designate other methods for the same pollutant; these letter designations are not an indication of an update or an automatically approved alternative. The continuous monitoring performance specifications promulgated by EPA are currently numbered from 1 through 18. Some include letter designations (e.g., A, B, C, etc.) which designate other continuous monitoring performance specifications for the same pollutant. The continuous monitoring performance specifications are published in 40 CFR 60, Appendix B.

4.1.1.b Stationary Source Program Method Terms

Term	*Explanation*
Methods Promulgated in the Federal Register	These methods have been proposed and promulgated in the Federal Register and codified in the Code of Federal Regulations (CFR). The methods are directly cited by specific regulations for determining compliance under 40 CFR Parts 51, 59, 60, 61, 62, 63, and 65 and may be used by regulated sources for application as cited by the regulations without further EPA approval. The 200 series methods are promulgated primarily to facilitate incorporation in applicable State Implementation Plans but have also been occasionally cited in other regulations.
Methods Proposed in the Federal Register	These methods have been proposed in the Federal Register but have not yet finalized (promulgated).
Source Category/Broadly Approved Alternative Methods	These methods are approved alternatives and modifications to the methods and testing procedures required by 40 CFR

Source Category/Broadly Approved Alternative Methods	Parts 59, 60, 61, 63, and 65 as described by the General Provisions or Subparts of the corresponding Parts and as further explained in the Federal Register notice at https://www.govinfo.gov/content/pkg/FR-2007-01-30/pdf/E7-1338.pdf. As such, the methods may be used by sources for determining compliance with the requirements of these Parts per their specified applicability provisions without further EPA approval. The Administrator, or designee has approved these methods for the specified applications; this approval has been documented through an official EPA determination letter. These methods include quality control and quality assurance procedures that must be met. For additional information, please refer to the Emission Measurement Center Guideline Document at https://www.epa.gov/sites/default/files/2020-08/documents/gd-022.pdf.
Facility-specific Approved Alternative Test Methods	These methods are also approved alternatives or modifications to the methods and testing procedures required by the same CFR Parts listed above; however, they apply only to the one or more specific facilities named in the official EPA determination letter.
Conditional Methods	This category includes methods that were categorized as conditional test methods before the method categories were revised. Today these methods would be included in the Other Test Methods category, but because some of these methods have been cited in state rules and permits under their Conditional Test Method (CTM) designation, we have created a category for them and called it "Historic Conditional Methods". This category is closed, and no new methods will be added to it.
Other Methods	This category includes test methods which have not yet been subject to the Federal rulemaking process. Each of these methods, as well as the available technical documentation supporting them, have been reviewed by staff of the Measurement Technology Group in EPA's Office of Air Quality Planning and Standards and have been found to be potentially useful to the emission measurement community. The types of technical information reviewed include field and laboratory validation studies; results of collaborative testing; articles from peer-reviewed journals; peer-review comments; and quality assurance (QA) and quality control (QC) procedures in the method itself. Information summarizing the available technical information for each method can be found

Other Methods	at the link below. EPA strongly encourages the submission of additional supporting field and laboratory data as well as comments regarding these methods. These methods may be considered for use in Federally enforceable State and local programs (e.g., Title V permits, State Implementation Plans (SIP)) provided they are subject to an EPA Regional SIP approval process or permit veto opportunity and public notice with the opportunity for comment. The methods may also be considered as candidates for alternative methods to meet Federal requirements under 40 CFR Parts 59, 60, 61, and 63. However, they must be approved as alternatives under 40 CFR 60.8, 61.13, or 63.7(f) before an affected source may use them for this purpose. Consideration of a method's applicability for a particular purpose should be based on the stated applicability as well as the supporting technical information outlined in the table. The methods are available for application without EPA oversight for other non-EPA program uses including state permitting programs and scientific and engineering applications. https://www.epa.gov/emc/emc-other-test-methods

4.1.2 Ambient Air Monitoring Program

For the Ambient Air Monitoring Program, pollutants in the ambient air of the U.S. are measured by State, local, and Tribal programs to show compliance with the National Ambient Air Quality Standards or (NAAQS) for the specific criteria pollutants listed in 40 CFR Part 50. Federal Reference Methods for the criteria pollutants are promulgated by EPA. Though there are no national standards for ambient air toxics, there are EPA led programs for air toxics measurement, and EPA has published methods for air toxics in the ambient air in the Inorganic (IO) or Toxic Organic (TO) compound compendiums (18). For additional information, please refer to the Ambient Monitoring Technology Information Center (AMTIC) page at https://www.epa.gov/amtic.

4.1.2.a Ambient Air Monitoring Methods Naming Convention

The Federal Reference Methods for the criteria pollutants are not numbered but are published in separate appendices of 40 CFR Part 50. The Inorganic (IO) and Toxic Organic (TO) methods are numbered starting at 1 within each compendium document as follows: IO-1, IO-2, IO-3… and TO-1, TO-2, TO-3…

4.1.2.b Ambient Air Monitoring Method Terms

Term	*Explanation*
Federal Reference Methods	Defined in 40 CFR Part 53.1: *Federal reference method (FRM)* means a method of sampling and analyzing the ambient air for an air pollutant that is specified as a reference method in an appendix to part 50 of this chapter, or a method that has been designated as a reference method in accordance with this part; it does not include a method for which a reference method designation has been canceled in accordance with Part 53.11 or Part 53.16. The Federal Reference Methods apply to criteria pollutants regulated under the National Ambient Air Quality Standards. Those FRM codified in the appendices to 40 CFR Part 50 have undergone a rulemaking process; other FRM are announced via a Federal Register Notice according to the provisions codified in 40 CFR Part 53 and are listed on the EPA website.
Federal Equivalent Methods	Defined in 40 CFR Part 53.1: *Federal equivalent method (FEM)* means a method for measuring the concentration of an air pollutant in the ambient air that has been designated as an equivalent method in accordance with this part; it does not include a method for which an equivalent method designation has been canceled in accordance with Part 53.11 or Part 53.16. Federal Equivalent Methods are announced via a Federal Register Notice according to the provisions codified in 40 CFR Part 53 and are listed on the EPA website at: https://www.epa.gov/amtic/air-monitoring-methods-criteria-pollutants.
Non-Regulatory Methods termed as IO and TO Methods ***EPA Compendium of Methods for the Determination of Inorganic Compounds in Ambient Air*** and ***EPA Compendium of Methods for the Determination of Organic Compounds in Ambient Air***	These two Compendiums contain methods presented in a standardized format, with applicable sampling methods and analytical techniques, for (1) specific classes of inorganic pollutants appropriate to their ambient levels and potential interferences and (2) volatile, semi-volatile, and selected toxic organic pollutants, respectively. EPA developed these compendiums to assist Federal, State, and local regulatory personnel in developing and maintaining necessary expertise and up-to-date monitoring technology for characterizing inorganic and organic pollutants in the ambient air that are

Non-Regulatory Methods termed as IO and TO Methods ***EPA Compendium of Methods for the Determination of Inorganic Compounds in Ambient Air*** and ***EPA Compendium of Methods for the Determination of Organic Compounds in Ambient Air***	not regulated under the National Ambient Air Quality Standards. (1) https://www.epa.gov/amtic/compendium-methods-determination-inorganic-compounds-ambient-air (2) https://www.epa.gov/amtic/compendium-methods-determination-toxic-organic-compounds-ambient-air

4.2 Office of Chemical Safety and Pesticide Prevention Programs

The Office of Chemical Safety and Pesticide Prevention (OCSPP) implements the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), the Toxic Substances Control Act (TSCA), and the Pollution Prevention Act, as well as portions of other statutes. The OCSPP includes three offices: Office of Pesticide Programs (OPP), Office of Pollution Prevention and Toxics (OPPT), and Office of Program Support. In the course of their mission, OCSPP offices require the submission of scientific data to support (1) the registration of a pesticide under FIFRA; (2) setting of a tolerance or tolerance exemption for pesticide residues under FFDCA; and (3) other decision-making process for potential regulation of an industrial chemical under TSCA. For additional information, please refer to the OSCPP internet page at https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic.

4.2.1 Chemical Safety and Pesticide Prevention Methods Naming Convention

EPA establishes test guidelines of accepted scientific methods and protocols to be used to generate data for submission to the Agency in support of regulatory decisions under TSCA, FIFRA and/or FFDCA. OCSPP's Master List of Test Guidelines for Pesticides and Toxic Substances provides naming convention organization and can be found at https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/master-list-test-guidelines-pesticides-and-toxic.

4.2.2 Chemical Safety and Pesticide Prevention Method Terms

Term	*Explanation*
Accepted Standardized Method/ Approved Standard Method/ Recommended Method	Methods recommended for use in testing pesticides and chemical substances to develop data for submission to the agency under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601, et seq.), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, et seq.), and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a). These methods are intended to provide data to inform regulatory decisions under TSCA, FIFRA, and FFDCA. The methods are referenced in a series of test guidelines

Accepted Standardized Method/ Approved Standard Method/ Recommended Method	established by the United States Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention (OCSPP).
Product Label Enforcement Method	An analytical method suitable for enforcement purposes of the pesticide product labels for each active ingredient in the product and for each other ingredient or impurity that is toxicologically significant.
Residue Analytical Methods	Analytical methods for determining all components of the total toxic residue (TTR). Residue analytical methods are used to obtain residue data on which dietary exposure assessments and tolerances are based, and to enforce the tolerance after it is established. The methods for residue analyses should serve two functions: They must provide the residue data upon which judgements are made as to the identity and magnitude of residues resulting from the proposed use, and they must provide a means for enforcement of the tolerance.
Multiresidue Analytical Methods	Analytical methods capable of determining many pesticide residues in a single analysis to assess the incidence of the pesticide residues remaining on agricultural commodities, food, and feeds.
New/Other/Modified Method	The agency recognizes that novel technologies and claims may evolve over time and would potentially involve test methods that are not referenced in OCSPP test guideline series. If there is no existing agency-approved standard method, registrants may, in consultation with the agency, develop and submit protocols for tests to support desired claims. If a standard method must be modified for testing, the modified protocol should be developed and submitted to the agency for review prior to testing. All new or modified protocols should be submitted to the agency with a justification for the need for a new or modified method for review and approval prior to data generation and collection.
Final/Draft/Interim Method/ Guidance	If EPA accepts the data from the new/other/modified method and approves the claim requested by the registrant, then EPA will post the new protocol (as "final", "draft", "interim" etc.) on its Web site for other registrants to use.

4.3 Office of Land and Emergency Management Programs

EPA's Office of Land and Emergency Management (OLEM) houses several program offices that are responsible for regulatory or voluntary programs to limit risk to human health and the environment from chemical exposure. These programs rely on testing data to support environmental management decisions related to emergency response, waste management, accidental chemical releases, contaminated site cleanup and redevelopment, and more. To support these regulatory and testing needs, OLEM program offices publish the SW-846 Compendium and maintain methods-based analytical services contracts as part of the Contract Laboratory Program, which are described in more detail below.

4.3.1 The SW-846 Compendium

Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, also known as SW-846, is a collection of test methods and related guidance published by EPA's Office of Resource Conservation and Recovery (ORCR). SW-846 is used to support implementation of the Resource Conservation and Recovery Act (RCRA), and SW-846 methods are used by the regulated community, other EPA program offices and other federal, state, and local agencies (19). RCRA provides a national regulatory framework for management of hazardous and non-hazardous solid wastes in the United States. Under RCRA, SW-846 methods are used to support compliance with regulatory requirements such as identification of hazardous waste (40 CFR Part 261 Subpart C), emissions testing at hazardous waste incinerators (40 CFR Part 266) and evaluation of treatment effectiveness of hazardous waste at RCRA permitted facilities (40 CFR Part 268). RCRA regulations incorporate some SW-846 methods and voluntary consensus standards by reference in 40 CFR Part 260.11, and these methods are required to be followed without deviation to generate definitive data for the purpose of evaluating regulatory compliance. For RCRA applications, SW-846 methods that are not incorporated by reference in RCRA are published as guidance and may be modified as needed to meet the needs of the project, or other methods may be used, provided the laboratory or facility demonstrates the methods are appropriate (i.e., they are capable of meeting any project-specific data quality objectives) (20). SW-846 methods are also referenced in state regulations and other federal regulations (e.g., 40 CFR Part 503.8, 40 CFR Part 761.61) (20) and may be required to demonstrate compliance with these regulations. Use of SW-846 methods may also be required when specified in a RCRA permit or other legal document such as a consent decree. For additional information, please refer to the SW-846 internet page at https://www.epa.gov/hw-sw846.

4.3.1.a SW-846 Methods Naming Convention

ORCR employs a specific naming convention for SW-846 Methods that includes a unique four-digit method number based on the method series for published/final methods. A letter suffix is also appended to or incremented at the end of significant method revisions; See 'Revised Methods' explanation in the following Table. SW-846 methods are organized in series that address similar topics, technologies, or classes of chemicals, as follows:

- 0010-0100 Series: Air Sampling and Stack Emissions
- 1000 Series: Waste Characteristics and Leaching/Extraction Methods

- 3000 Series: Inorganic Sample Preparation
- 3500 Series: Organic Sample Extraction
- 3600 Series: Organic Extract Cleanup
- 4000 Series: Immunoassay Methods
- 5000 Series: Sample Preparation and Introduction for Volatile Organic Compounds (VOC)
- 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

Many SW-846 methods are modular, i.e., multiple aqueous and solid sample preparation methods can be used in conjunction with a given determinative method. SW-846 Chapters provide guidance related to how SW-846 methods are used, including project planning, sample collection, holding times, and quality assurance.

4.3.1.b SW-846 Method Terms

Term	*Explanation*
Methods Proposed in the Federal Register	New or revised methods that are proposed to be incorporated in Resource Conservation and Recovery Act (RCRA) regulations but have not been finalized; see Method Defined Parameters.
Methods Incorporated by Reference in RCRA	New or revised methods that have been incorporated by reference in Resource Conservation and Recovery Act (RCRA) regulations; see Method Defined Parameters.
Validated Methods	Methods that have been tested and validated by EPA and independent laboratories, and have been through extensive review by EPA, but have not been through the public comment process or formally incorporated into SW-846. EPA encourages the use of a validated method as the most current version, where possible. While validated methods may be added to SW-846 in the future, authorized states may have regulatory restrictions regarding which version of a method can be used.
Method-Defined Parameters (MDPs)	Method-defined Parameters (MDPs) are physical or chemical properties of materials determined with specific methods used to evaluate whether the materials comply with certain RCRA Subtitle C regulations. Method-defined parameters can only be determined by the methods prescribed in RCRA regulations because the methods are part of the regulations.

Method-Defined Parameters (MDPs)	These methods must be followed exactly as written, or the resulting data cannot be used to ensure regulatory compliance. A list of method-defined parameters may be found at 40 CFR Section 260.11. SW-846 methods for MDPs are published according to EPA's rulemaking process, which includes public involvement through Federal Register notice and comment. https://www.epa.gov/hw-sw846/final-rule-methods-innovation-rule-mir
Non-Regulatory Methods	SW–846 methods not required by the Resource Conservation and Recovery Act (RCRA) regulations to be used for compliance purposes. All SW-846 methods are considered guidance unless they are otherwise required by regulation (see method-defined parameters above). Non-regulatory SW-846 methods are published through a streamlined process (21).
Published (or Final) Methods	New or revised SW-846 methods that have been formally incorporated in the SW-846 Compendium after EPA has completed all required process steps, including responding to comments from the public. Once a method and the associated response to comments document is published on the SW-846 website, it has been fully incorporated into the SW-846 compendium.
Revised Methods	Methods included in SW–846 that have been updated to reflect changes from a previous version. Method revisions can be significant or non-significant. Significant revisions are those that broaden the method by adding to or changing the process and/or quality assurance practices. Examples of significant revisions include adding options for a sample processing step or adding or changing a quality control specification. Significant method revisions are designated as such by appending or incrementing the letter at the end of the method number. Minor/non-significant method revisions are editorial in nature or are otherwise minor and do not affect precision or bias. Examples of non-significant revisions include adding new performance data or updating format of an existing method. These method revisions are indicated by issuing a new date for the same method number and letter. Please note that previous versions of methods are not precluded from being used provided that the users

Method-Defined Parameters (MDPs)	demonstrate that it generates data that are appropriate for the intended use.
Draft Methods	New methods that are being evaluated for possible inclusion into SW–846. They represent the latest technological advancements in scientific methodology, but they have not completed technical review by EPA, nor have they been subject to public comment.
Superseded Methods	Superseded methods are earlier versions of SW–846 methods or other guidance that are no longer included in the SW–846 compendium because they have been replaced by newer versions. Revised versions of superseded methods should be viewed as the preferred method. Methods in this category are removed from the compendium but remain available on-line and are not precluded from use where required for existing projects or where an adequate justification for use exists. The term ‘‘Superseded’’ is documented in the method title as listed on EPA Web site for prior versions of final methods followed by the date it was superseded.
Withdrawn Methods	Withdrawn methods or other guidance are versions that EPA strongly recommends not be used (e.g., cyanide and sulfide reactivity guidance withdrawn on June 14, 2005). EPA has determined that such procedures or methods, for the use or technical objectives for which they were originally published, are technically inadequate and/or no longer meet such use or technical objectives. This does not mean, however, that there would be no situations under which the procedures or methods may be appropriate. In any situation in which a person may believe that the withdrawn method is appropriate, we strongly encourage consultation with applicable regulatory agencies at the state or federal level. The prospective user of the method will need to demonstrate the withdrawn method is appropriate. Any use of these methods, without any such consultation and demonstration, will be done at the user’s risk.

4.3.2 Contract Laboratory Program

The Contract Laboratory Program (CLP) supports EPA’s Superfund program created under the 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the 1986

Superfund Amendments and Reauthorization Act (SARA). The Superfund CLP's primary service is the provision of analytical data of known and documented quality to support the 10 EPA Regional Offices in their Superfund activities through national contracts. For additional information, please refer to EPA's CLP internet page at https://www.epa.gov/clp.

4.3.2.a Contract Laboratory Program Naming Convention

Superfund analytical contract Statements of Work are named relative to their intended purpose and incremented with each revision. Current analytical Statements of Work can be found on EPA's CLP website at https://www.epa.gov/clp.

4.3.2.b Contract Laboratory Program Method Terms

Term	*Explanation*
Superfund CLP Statements of Work	Superfund analytical contract documents that contain promulgated and published analytical methods with enhanced quality control requirements used for Superfund sample analysis under the Contract Laboratory Program (CLP).

4.4 Office of Water Programs

The Office of Water (OW) ensures drinking water is safe, and restores and maintains oceans, watersheds, and their aquatic ecosystems to protect human health, support economic and recreational activities, and provide healthy habitat for fish, plants, and wildlife. This office oversees the implementation of the following statutes: the Safe Drinking Water Act and the Clean Water Act.

4.4.1 Safe Drinking Water Act

The Safe Drinking Water Act (SDWA) was established in 1974 to assure that water supply systems serving the public meet minimum national standards for protection of public health (30). Pursuant to SDWA and its subsequent amendments, EPA promulgates National Primary Drinking Water Regulations (NPDWRs, 40 CFR Part 141), the enforceable health standards for regulated contaminants in drinking water. https://www.epa.gov/sdwa/drinking-water-regulations-and-contaminants. Under the SDWA program, EPA relies on analytical methods in two primary ways: 1) Drinking water compliance monitoring – as part of NPDWRs, EPA establishes analytical requirements for routinely monitoring regulated contaminants in drinking water, and 2) Unregulated Contaminant Monitoring Rule (UCMR) – in its UCMR rulemaking, EPA establishes requirements for public water systems to monitor unregulated contaminants in drinking water. In both instances, analytical methods are specifically identified to measure contaminant concentrations for their respective drinking water application. For additional information, please refer to the approved drinking water methods internet page at https://www.epa.gov/dwanalyticalmethods.

4.4.1.a Safe Drinking Water Act Methods Naming Convention

Generally, EPA-developed drinking water chemistry methods are assigned a three-digit method number: 100-400 series methods are applied to inorganic analyses, 500-series methods apply to organic analyses, and 900-series methods apply to radiochemical analyses. EPA microbiological methods most commonly are assigned a 1600-series designation and may also be developed by or in cooperation with Clean Water Act (CWA) programs. Drinking water methods developed outside of EPA but used for EPA purposes do not have a specific naming convention, but the developers are typically asked to provide a short method name (often numerical) to use for regulatory referencing.

4.4.1.b Safe Drinking Water Method Terms

Term	*Explanation*
Alternate Test Procedure (ATP)	Under the Alternate Test Procedures program, methods developed outside of EPA are evaluated and may subsequently be approved for analysis of one or more regulated contaminants as alternatives to those methods that are promulgated in the regulations. The OW organizations responsible for drinking water and wastewater have separate Alternate Test Procedure programs that evaluate methods

Alternate Test Procedure (ATP)	according to the requirements needed to support their programs.
Promulgated Method	Promulgated NPDWRs specify the methods that must be used to confirm compliance with regulatory requirements (such as maximum contaminant limits for drinking water contaminants). These methods are generally "incorporated by reference" into the promulgated rules that are published in the Federal Register (e.g., as an NPDWR or a "method update rule").
Approved Method for Regulated Contaminants	Regulated-contaminant methods approved by EPA are authorized for drinking water (DW) compliance monitoring. These methods are first addressed via Federal Register, and then codified in the *Code of Federal Regulations* at 40 CFR Part 141 (within the body of particular regulations and in Appendix A to Subpart C).
Other methods approved by EPA to support required monitoring for unregulated contaminants	SDWA 1996 Amendments specified establishment of monitoring for unregulated contaminants that may be present in drinking water. EPA promulgates the Unregulated Contaminant Monitoring Rule (UCMR) and specifies the use of particular methods to meet the statutory requirement.
EPA Published Method	A final, validated, peer-reviewed method that EPA has published. These methods may ultimately be specified and approved to support NPDWR or UCMR monitoring but the publication of a method, in and of itself, does not constitute approval for a particular purpose. Such approval is enacted through the aforementioned Federal Register notices and subsequent publication of the Code of Federal Regulations.
EPA Draft Method	EPA's draft methods are generally single-lab validated and are still going through multi-lab secondary validation, peer review, and final clearance. Draft methods may be made available to parties on an as-needed basis (e.g., those assisting in the validation/peer review process). EPA methods are not considered for NPDWR or UCMR monitoring until published as final.

Expedited Method Approval	Per SDWA section 1401(1), after the establishment of the original method requirements via an NPDWR promulgation, equally effective alternate methods may be approved by EPA to support NPDWR compliance monitoring through publication of a Federal Register notice. Under the "expedited method approval process," Appendix A to Subpart C of 40 CFR Part 141 was established as a repository for such methods.

4.4.2 Clean Water Act

The Clean Water Act (CWA) establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters. Under the CWA, EPA has implemented pollution control programs such as setting wastewater standards for industry. EPA has also developed national water quality criteria recommendations for pollutants in surface waters (22).

EPA Office of Water (OW) Engineering and Analysis Division publishes laboratory analytical methods (test procedures) that are used by industries and municipalities to analyze the chemical, physical and biological components of wastewater and other environmental samples required by the Clean Water Act. https://www.epa.gov/cwa-methods.

In addition to developing and approving methods for use in compliance monitoring, EPA may develop methods to support studies of specific industries (e.g., the Effluent Guidelines program) or for use in broad national surveys. If such studies or surveys lead to regulatory limits of new contaminants, EPA approves the applicable methods for nationwide or industry-specific use through rulemaking which includes an opportunity for public comment. For additional information, please refer to the Clean Water Act analytical methods internet page at https://www.epa.gov/cwa-methods.

4.4.2.a Clean Water Act Methods Naming Convention

The analytical methods promulgated under Clean Water Act section 304(h) are sometimes referred to as the "304(h)" or "Part 136" methods. The methods measure chemical and biological pollutants in media, such as wastewater, ambient water, sediment, and biosolids (sewage sludge).

4.4.2.b Clean Water Act Method Terms

Term	*Explanation*
Determinative Technique	Determinative technique refers to the analytical methodology employed for quantitatively measuring a contaminant (e.g., mass spectrometry or UV detection).
Alternate Test Procedures	The Clean Water Act Alternate Test Procedure (ATP) program is described at 40 CFR 136.4 and 136.5. This program provides a mechanism for submission and review of an application for nationwide use or limited use of an ATP for measurement of a pollutant as an alternative to the methods

Alternate Test Procedures	approved at 40 CFR Part 136. An ATP may fall into one of two categories: 1. A method using a determinative technique (e.g., a pollutant detector) different from that in an existing Part 136 method (for method validation and evaluation purposes this type of method is referred to as a new method), or 2. A modification to a Part 136 method that falls outside the scope of the modification flexibility described in the Part 136 method, or at 40 CFR 136.6 (for validation and evaluation purposes this type of method is referred to as an ATP).
Promulgated	Methods are promulgated in regulations to confirm compliance with regulatory requirements. Promulgation means the methods are made public by publishing them in the Federal Register as part of a rule (whether an industrial effluent guideline or a method update rule).
Approved Industry-Specific Methods	Industry-specific methods were developed to work in samples or for pollutants specific to certain industrial categories. For example, methods specific to the Pharmaceutical Manufacturing and Pesticide Chemicals Effluent Guidelines categories are listed in Tables I-F and I-G, respectively, at 40 CFR Part 136. Methods specific to other industrial categories are listed or incorporated by reference into the regulations at 40 CFR Parts 401 through 503. These include methods specific to the Pulp, Paper, and Paperboard category (40 CFR Part 430), and specific to Use or Disposal of Sewage Sludge (biosolids) (40 CFR Part 503). Industry-specific methods that are approved for compliance monitoring in the industry for which they are designated may be used for general use, if the same method is listed in Tables I-A to I-E, or I-H at 40 CFR 136.3.
Approved CWA Methods	CWA approved methods for wastewater monitoring are listed at 40 CFR Part 136. Approved methods are used for CWA compliance monitoring when required by the permit or permitting authority. These methods are sometimes referred to as "wastewater", "Part 136", or "304(h)" methods. Some approved methods may also be found at 40 CFR Parts 401 through 503 (Effluent Guidelines and Biosolids regulations).

Other CWA Methods	Optional methods for analyzing wastewater, ambient water and biosolids (not approved under 40 CFR Part 136). Although the chemical, microbiological and biosolids methods are not in EPA regulations, they may be of interest to regulated entities, permitting authorities, and the public. The presence of a method on the CWA website does not imply a regulatory requirement for its use. Other CWA Methods include both draft and final methods.
EPA Published	Published methods include both the approved and "Other CWA Methods." This means that EPA has written the method, the method has an EPA document ID number, and is posted on the CWA Methods website. (https://www.epa.gov/cwa-methods)
EPA Draft Method	Draft methods may be posted on the CWA website as "Other CWA Methods" after completion of at least a single-laboratory validation. Draft methods are not approved for CWA compliance monitoring until they have been proposed and promulgated through rulemaking.

4.5 Office of Research and Development Programs

The Office of Research and Development (ORD) is the scientific research arm of EPA. Its leading-edge research informs Agency decisions and supports the emerging needs of EPA stakeholders, including the Agency's state, tribal, and community partners. EPA's Research and Development Laboratories are responsible for conducting research, developing knowledge, assessments and scientific tools that underpin decisions about EPA's protective standards, risk assessments, and risk management decisions. For additional information, please refer to the regional laboratory internet page at https://www.epa.gov/labs/office-research-and-development-ord-laboratories.

The Research and Development Laboratories do not develop terminology to indicate the standing of a method, and therefore use the terminology developed by the Program Laboratories.

4.6 Regional Programs

EPA's regional laboratories provide scientific data in support of decisions by the EPA Regional Office's environmental programs, address the comprehensive needs of the regions, and inform immediate and near-term decisions on environmental conditions, emergency response, compliance, and enforcement. The Regional Laboratory Network applies scientific principles to support regulatory programs, monitoring programs, and special projects. EPA has 10 regional laboratories. Individual regional laboratories have specific capabilities and expertise due to unique geographic issues and needs. For

additional information, please refer to the regional laboratory internet page at https://www.epa.gov/labs/regional-laboratories.

The regional laboratories provide support for the Program Offices detailed above. As a result, the terminology utilized in the regional laboratories to indicate the standing of a method is based on the Program being supported. For example, when performing analytical work to support the Clean Water Act, the terminology for the standing of the methods is the same as those described in the table above for the Clean Water Act.

5. Appendices

5.1 Appendix A: Index

This table provides page number information for each term within this document, organized by the program to which the term is associated.

Term	*Associated Program(s)*	*Page Number*
Final Method/Guidance	OCSPP Chemical Safety and Pesticide Prevention Program OLEM SW-846 Program	Page 13 Page 17
Interim Method/Guidance	OCSPP Chemical Safety and Pesticide Prevention Program	Page 14
Method-Defined Parameters (MDPs)	OLEM SW-846 Program	Page 16
Methods Incorporated by Reference in RCRA	OLEM SW-846 Program	Page 15
Methods Promulgated in The Federal Register	OAR Stationary Source Program	Page 8
Methods Proposed in the Federal Register	OAR Stationary Source Program OLEM SW-846 Program	Page 8 Page 15
Multiresidue Analytical Methods	OCSPP Chemical Safety and Pesticide Prevention Program	Page 13
New/Modified Method	OCSPP Chemical Safety and Pesticide Prevention Program	Page 13
Non-Approved (analytical methods developed by EPA for analysis of unregulated contaminants)	OW Safe Drinking Water Program	Page 20
Non-Regulatory Methods	OAR Ambient Air Monitoring Program OLEM SW-846 Program	Page 11 Page 16
Other Methods	OAR Stationary Source Program OCSPP Chemical Safety and Pesticide Prevention Program OW Safe Drinking Water Program OW Clean Water Program	Page 9 Page 14 Page 20 Page 23
Product Label Enforcement Method	OCSPP Chemical Safety and Pesticide Prevention Program	Page 13
Promulgated Method	OW Safe Drinking Water Program OW Clean Water Program	Page 19 Page 22

Term	*Associated Program(s)*	*Page Number*
Published (or Final) Methods	OLEM SW-846 Program OW Safe Drinking Water Program OW Clean Water Program	Page 16 Page 20 Page 23
Recommended Method	OCSPP Chemical Safety and Pesticide Prevention Program	Page 13
Residue Analytical Methods	OCSPP Chemical Safety and Pesticide Prevention Program	Page 13
Revised Methods	OLEM SW-846 Program	Page 16
Source Category/Broadly Approved Alternative Methods	OAR Stationary Source Program	Page 9
Superfund CLP Statement of Work	OLEM Contract Laboratory Program	Page 18
Superseded Methods	OLEM SW-846 Program	Page 17
UCMR Program Approved Method	OW Safe Drinking Water Program	Page 20
Validated Methods	OLEM SW-846 Program	Page 15
Withdrawn Methods	OLEM SW-846 Program	Page 17

5.2 Appendix B: Acronyms

Acronym	Full Name
AA	Atomic Absorption
AMTIC	Ambient Monitoring Technology Information Center
AOAC	Association of Official Analytical Collaboration International
APHA	American Public Health Association
ASTM International	Formerly known as the "American Society for Testing and Materials"
ATP	Alternate Test Procedure
AWWA	American Water Works Association
CAA	Clean Air Act
CAS	Chemical Abstract Service
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CLP	Contract Laboratory Program
CTM	Conditional Test Method
CWA	Clean Water Act
DW	Drinking Water
EMC	Air Emission Measurement Center
EMF	Environmental Methods Forum
EMMC	Environmental Monitoring Management Council
EPA	Environmental Protection Agency
FEM	Federal Equivalent Method
FEM	Forum on Environmental Measurements
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FR	Federal Register
FRM	Federal Reference Method
GC	Gas Chromatograph
ICP	Inductively Coupled Plasma
IO	Inorganic
ISO	International Organization for Standardization
LEC	Laboratory Enterprise Council
MDPs	Method-defined Parameters
NAAQS	National Ambient Air Quality Standards
NPDWR	National Primary Drinking Water Regulations
OAR	Office of Air and Radiation
OCSPP	Office of Chemical Safety and Pollution Prevention
OLEM	Office of Land and Emergency Management
OPP	Office of Pesticide Programs

OPPT	Office of Pollution Prevention and Toxics
ORCR	Office of Resource Conservation and Recovery
ORD	Office of Research and Development
OW	Office of Water
PPA	Pollution Prevention Act
QA	Quality Assurance
QC	Quality Control
RCRA	Resource Conservation and Recovery Act
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act
SIP	State Implementation Plans
SOP	Standard Operating Procedure
TO	Toxic Organic
TSCA	Toxic Substances Control Act
TTR	Total Toxic Residue
UCMR	Unregulated Contaminant Monitoring Rule
UV	Ultraviolet Index
VCSB	Voluntary Consensus Standards Bodies
VOC	Volatile Organic Compounds
WEF	Water Environment Federation

4.3 Appendix C: Statutes

This section summarizes EPA's interpretation of the Statues that influence environmental analysis method development.

1. **Office of Air and Radiation (OAR)**
    i. Clean Air Act of 1970 (CAA): regulates air emissions from stationary and mobile sources. This law authorized EPA to establish National Ambient Air Quality Standards (NAAQS) to protect public health and welfare from specified widespread pollutants as well as to regulate emissions of hazardous air pollutants. The Act was amended in 1977 and 1990 primarily to set new goals (dates) for achieving attainment of the NAAQS since many areas of the country had failed to meet the deadlines and to establish the use of technology-based standards to control major and area sources of hazardous air pollutants (23).
2. **Office of Chemical Safety and Pollution Prevention (OCSPP)**
    i. Toxic Substances Control Act of 1976 (TSCA): provides EPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides (24).
    ii. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by EPA. Before EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment (25).''
    iii. Federal Food, Drug, and Cosmetic Act (FFDCA): authorized EPA to set tolerances, or maximum residue limits, for pesticide residues on foods. In the absence of a tolerance for a pesticide residue, a food containing such a residue is subject to seizure by the government. Once a tolerance is established, the residue level in the tolerance is the trigger for enforcement actions. That is, if residues are found above that level, the commodity will be subject to seizure (26).
    iv. Pollution Prevention Act of 1990 (PPA): focused industry, government, and public attention on reducing the amount of pollution through cost-effective changes in production, operation, and raw materials use. Opportunities for source reduction are often not realized because of existing regulations, and the industrial resources required for compliance, focus on treatment and disposal (27).
3. **Office of Land and Emergency Management (OLEM)**
    i. The Resource Conservation and Recovery Act of 1976 (RCRA): governs the disposal of solid and hazardous waste. Congress passed RCRA on October 21, 1976, to address the increasing problems the nation faced from a growing volume of municipal and industrial waste.
        - The United States Environmental Protection Agency's (EPA) Office of Resource Conservation and Recovery (ORCR) provides analytical and sampling methods to

assist the regulated and regulatory community and others in implementing the Resource Conservation and Recovery Act (RCRA). These methods are published in the Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW–846) and are available on the ORCR Web site (www.epa.gov./epawaste/hazard/testmethods/index.htm). With the exception of those particular methods which are promulgated in the regulations to implement RCRA (see 40 CFR 260.11), the remaining methods are considered guidance, and users may select any scientifically appropriate method when conducting analyses to comply with the RCRA regulatory program (19).

- SW-846 Compendium consists of three main parts—chapters, methods, and supporting documents. Most methods are intended as guidance, except for method defined parameters (MDPs) that are mandated by the RCRA regulations. The chapters provide insight on how to successfully use the test methods (28).

ii. Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), or Superfund: established to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other emergency releases of pollutants and contaminants into the environment (29).

iii. The Superfund Amendments and Reauthorization Act of 1986 (SARA): reauthorized CERCLA to continue cleanup activities around the country. Several site-specific amendments, definitions clarifications, and technical requirements were added to the legislation, including additional enforcement authorities (30).

4. Office of Water (OW)

i. Safe Drinking Water Act of 1974 (SDWA): authorizes EPA to establish minimum standards to protect the quality of drinking water in the U.S. and requires all owners or operators of public water systems to comply with these primary (health-related) standards (31).

ii. Clean Water Act of 1972 (CWA): establishes the basic structure for regulating discharges of pollutants into the waters of the U.S. and regulating quality standards for surface waters. Pursuant to the CWA, EPA developed national water quality criteria recommendations for pollutants in surface waters (22).

5.4 Appendix D: Environmental Monitoring Management Council (EMMC) Methods Format

For full text of EMMC format, please visit https://www3.epa.gov/ttn/emc/guidlnd/gd-045.pdf.

1.0 Scope and Application

Use a tabular format whenever possible for:

- Analyte list(s)
- Chemical Abstract Service (CAS) numbers
- Matrices
- Method Sensitivity (expressed as mass and as concentration with a specific sample size)

Include a list of analytes (by common name) and their CAS registry numbers, the matrices to which the method applies, a generic description of method sensitivity (expressed both as the mass of analyte that can be quantified and as the concentration for a specific sample volume or size), and the data quality objectives which the method is designed to meet. Much of this material may be presented in a tabular format.

2.0 Summary of Method

Sample volume requirements

- Extraction
- Digestion
- Concentration, and other preparation steps employed
- Analytical instrumentation and detector system(s), and
- Techniques used for quantitative determinations

Summarize the method in a few paragraphs. The purpose of the summary is to provide a succinct overview of the technique to aid the reviewer or data user in evaluating the method and the data. List sample volume, extraction, digestion, concentration, other preparation steps employed, the analytical instrumentation and detector system(s), and the techniques used for quantitative determinations.

3.0 Definitions of Method

Include the definitions of all method-specific terms here. For extensive lists of definitions, this section may simply refer to a glossary attached at the end of the method document.

4.0 Interferences

This section should discuss any known interferences, especially those that are specific to the performance-based method. If known interferences in the reference method are not interferences in the performance-based method, this should be clearly stated.

5.0 Safety

- Above and beyond good laboratory practices
- Disclaimer statement (look at ASTM disclaimer)
- Special precautions
- Specific toxicity of target analytes or reagents
- Not appropriate for general safety statements

This section should discuss only those safety issues specific to the method and beyond the scope of routine laboratory practices. Target analytes or reagents that pose specific toxicity or safety issues should be addressed in this section.

6.0 Equipment and Supplies

Use generic language wherever possible. However, for specific equipment such as GC (gas chromatograph) columns, do not assume equivalency of equipment that was not specifically evaluated and clearly state what equipment and supplies were tested.

7.0 Reagents and Standards

Provide sufficient details on the concentration and preparation of reagents and standards to allow the work to be duplicated but avoid lengthy discussions of common procedures.

8.0 Sample Collection, Preservation and Storage

- Provide information on sample collection, preservation, shipment, and storage conditions
- Holding times, if evaluated

If effects of holding time were specifically evaluated, provide reference to relevant data, otherwise, do not establish specific holding times.

9.0 Quality Control

Describe specific quality control steps, including such procedures as method blanks, laboratory control samples, QC check samples, instrument checks, etc., defining all terms in Section 3.0. Include frequencies for each such QC operation.

10.0 Calibration and Standardization

Discuss initial calibration procedures here. Indicate frequency of such calibrations, refer to performance specifications, and indicate corrective actions that must be taken when performance specifications are not met. This Section may also include procedures for calibration verification or continuing calibration, or these steps may be included in Section 11.0.

11.0 Procedure

Provide a general description of the sample processing and instrumental analysis steps. Discuss those steps that are essential to the process and avoid unnecessarily restrictive instructions.

12.0 Data Analysis and Calculations

Describe qualitative and quantitative aspects of the method. List identification criteria used. Provide equations used to derive final sample results from typical instrument data. Provide discussion of estimating detection limits, if appropriate.

13.0 Method Performance

A precision/bias statement should be incorporated in the Section, including:

- detection limits
- source/limitations of data

Provide detailed description of method performance, including data on precision, bias, detection limits (including the method by which they were determined and matrices to which they apply), statistical procedures used to develop performance specification, etc. Where performance is tested relative to the reference method, provide a side-by-side comparison of performance versus reference method specifications.

14.0 Pollution Prevention

Describe aspects of this method that minimize or prevent pollution that may be attributable to the reference method.

15.0 Waste Management

Cite how waste and samples are minimized and properly disposed.

16.0 References

- Source documents
- Publications

17.0 Tables, Diagrams, Flowcharts and Validation Data

Additional information may be presented at the end of the method. Lengthy tables may be included here and referred to elsewhere in the text by number. Diagrams should only include new or unusual equipment or aspects of the method.

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