Flexible Approaches to Environmental Measurement

U.S. ENVIRONMENTAL PROTECTION AGENCY
FORUM ON ENVIRONMENTAL MEASUREMENTS

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Overview

- Background
  - Forum on Environmental Measurements
  - Original Performance Approach
  - "Flexible Approaches" Strategy
- Program Advancements
  - Office of Air Quality Planning and Standards
  - Office of Pesticide Programs
  - Office of Resource Conservation and Recovery
  - Office of Water

Background: Forum on Environmental Measurements (FEM)

- Formed by the EPA Science Policy Council (now the Science and Technology Policy Council) in April 2003.
- Mission: Promote consistency and consensus within EPA and provide an internal and external contact point for addressing measurement methodology, monitoring and laboratory science issues with multiprogram impact.
- Composition of Senior Agency Managers.

Background: Original Performance Approach

- "A set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner."
- Goals of the original performance approach were to:
  - Address the lengthy approval process for new methods and method modifications.
  - Lower the barrier to use of innovative technology while improving data quality.
  - Decrease the number of methods or method modifications that require EPA review or rulemaking before use.

Original Performance Approach: Concept for Implementation

- Instead of using prescriptive methods, the Agency would set data quality objectives (DQOs) for measurement in the regulation.
- Affected entity would select appropriate, cost effective methods/technology/procedures to meet DQOs.
- Regulation would require that method user document quality of measurement and meet DQOs along with data submission.

Challenges With Performance Approach Implementation

- After 10 years, EPA and its stakeholders concluded the Performance Approach warranted improvement; "one-size-fits-all" approach simply does not "fit all."
- Performance approach placed extra burdens on affected facilities/data collectors and regulators.
  - Affected facilities see extra burden in identifying methods and procedures to meet and demonstrate DQOs.
  - Affected facilities and data collectors not comfortable with lack of certainty with test method and procedures to demonstrate data quality.
  - Regulators (e.g., states) and other enforcement officials very concerned they lack expertise to determine if methods/ procedures chosen to meet DQOs are adequate.

Background: Development of Flexible Approaches

- In 2007, the FEM recognized the different needs of EPA's program offices.
- Acknowledged a single protocol for validation/quality assessment of measurements was not possible.
- New approach issued by the former Science Policy Council (now Science and Technology Policy Council) in February 2008.

Goals of Flexible Approaches

- Flexibility in choosing sampling and analytical methods/techniques.
- Development of new processes to validate that measurements meet quality requirements.
- Collaboration with stakeholders to develop validation processes for new measurement technology.
- Rapid assessment of new technologies, methods and procedures.

Intent of Flexible Approaches

- Make measurement requirements more flexible.
- Allow varying levels of specificity, according to the needs of the program.
- Reach stakeholders to describe and facilitate full implementation of Flexible Approaches to Environmental Measurement.

Office of Air Quality Planning & Standards (OAQPS) and Flexible Approaches

- Primary OAQPS programs requiring environmental measurements:
  - Stationary Source Program
    - Emission sources (industrial plants) conduct measurements to demonstrate compliance with emission standards
  - Ambient Air Monitoring Program
    - State and local agencies conduct ambient monitoring for National Ambient Air Quality Standards

Flexible Approaches in Air Program Regulating Stationary Sources

- Chosen approach—Promulgate test methods and performance specifications for continuous monitoring that provide flexibility by incorporating performance criteria.
  - "Performance-based method."
- Use of DQO infeasible in our long established compliance program—Need specified methods.
  - DQO approach relies on industry development and agency review of detailed Quality Assurance Project Plan.
  - Regulated industry wants certainty.
  - Enforcement officials concerned with lack of resources/expertise for review.

Flexible Approaches in Air Program Regulating Stationary Sources

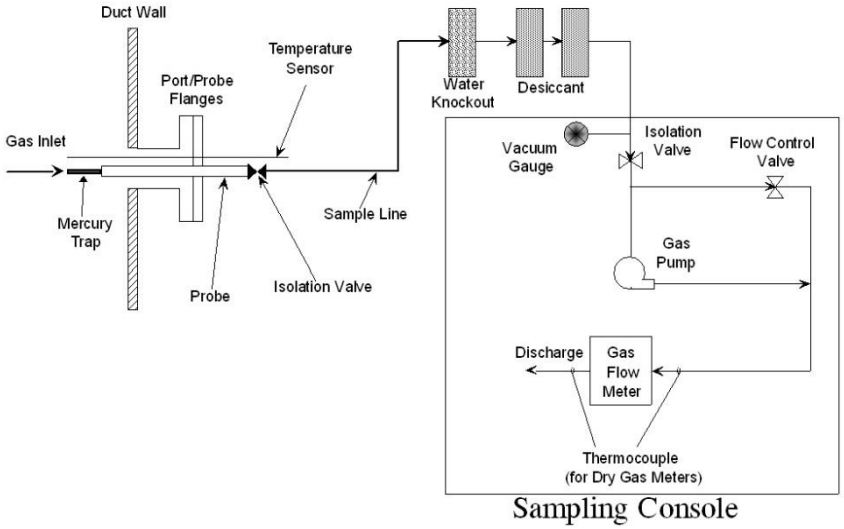
- Advantages of performance criteria within methods:
  - Provides regulated industry and their testers and laboratories with balance of flexibility and certainty.
  - Allows for advances in technology.
  - Provides information on data quality for each measurement program.
  - For responsible agencies, use of performance criteria coupled with specific procedures to demonstrate that performance simplifies:
    - Auditing.
    - Enforcement.
- Committed to using performance-based methods whenever possible.

Flexible Approaches in Air Program Regulating Stationary Sources

- What are performance-based methods?
  - Minimize prescriptive procedures.
  - Use specific quality check procedures and criteria to assess user-selected technologies and procedures.
  - Rely on reference materials (e.g., cal gases).

- Specify quality of measurement <u>within method or monitoring specification.</u>
  - Use performance criteria such as:
    - Bias (continuous monitor relative to reference method, cal gas check of entire instrumental measurement system).
    - Precision (e.g., relative deviation for paired samples).
    - Sensitivity.

Flexible Approaches in Air Program Regulating Stationary Sources



Sampling Console

- Method 30B—Mercury emissions using sorbent-trap
  - Specifies representative sample collection.
  - May use any sorbent, sample preparation and analytical technology that can meet performance criteria .
  - Key performance criteria using liquid and/or gaseous mercury standards.
    - Analytical bias study.
    - Spiking of field sample traps to assess for bias (with sample matrix).
    - Paired sample agreement for precision.

Flexible Approaches in Air Program Regulating Stationary Sources

- Performance Specification 18 for Continuous Monitoring of HCl Emissions:
  - Any instrumental technology that can meet performance criteria may be used.
  - Key performance criteria:
    - Interference test (gas standards).
    - 7-day calibration drift test (gas standards through system).
    - Linearity (gas standards through system).
    - Relative accuracy against reference method.
    - Level of detection (in actual gas matrix).
    - Temperature/pressure verification and beam intensity test (specific to cross-stack instruments).

Flexible Approaches in Air Program Regulating Stationary Sources

- Nimble alternative test method review process:
  - Delegated authority can approve/disapprove alternative by official letter.
  - Can issue broadly applicable approvals.
  - Published protocol (Method 301, 40 CFR 63) to validate method alternatives.
  - Reviews are timely.
  - Publish broad approvals on website and yearly in *Federal Register* notice.
- Additional information (including broad approvals) at www.epa.gov/emc

Flexible Approaches: Ambient Air Monitoring Program

- Federal Reference Methods (FRMs) are performance-based wherever possible; performance criteria are directly linked to program DQOs. For example:
  - PM-10 FRM specifies performance characteristics for the particle sampler.
  - PM-2.5 FRM has performance criteria for flow and temperature control and design characteristics for inlet and particle separator.

PM2.5 FRMs

2025

PQ200

Flexible Approaches: Ambient Air Monitoring Program

- Federal Equivalent Method (FEM) program allows for adoption of new methods/ technologies as alternatives to the FRM.
  - FEM requirements set forth a series of performance criteria to be met during the demonstration testing.
  - FEM performance criteria developed following DQO process.
- Extensive collaboration with stakeholders (state/local/tribal) to validate ambient air measurements and assess new technologies.
- Background information: www.epa.gov/amtic

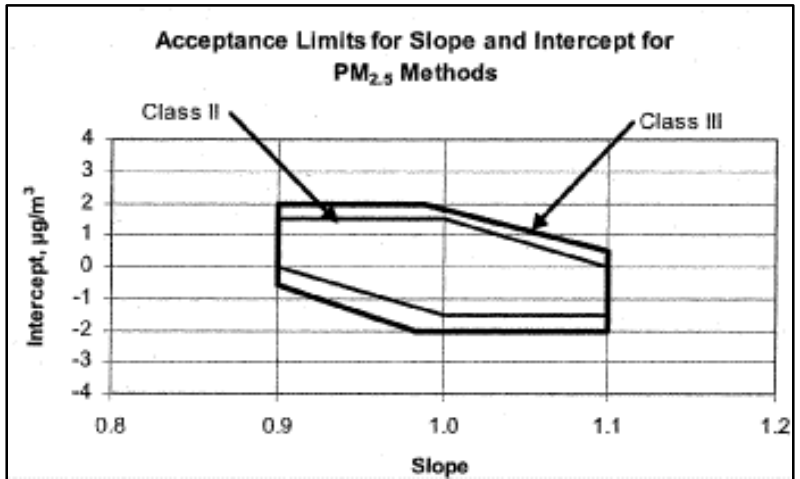
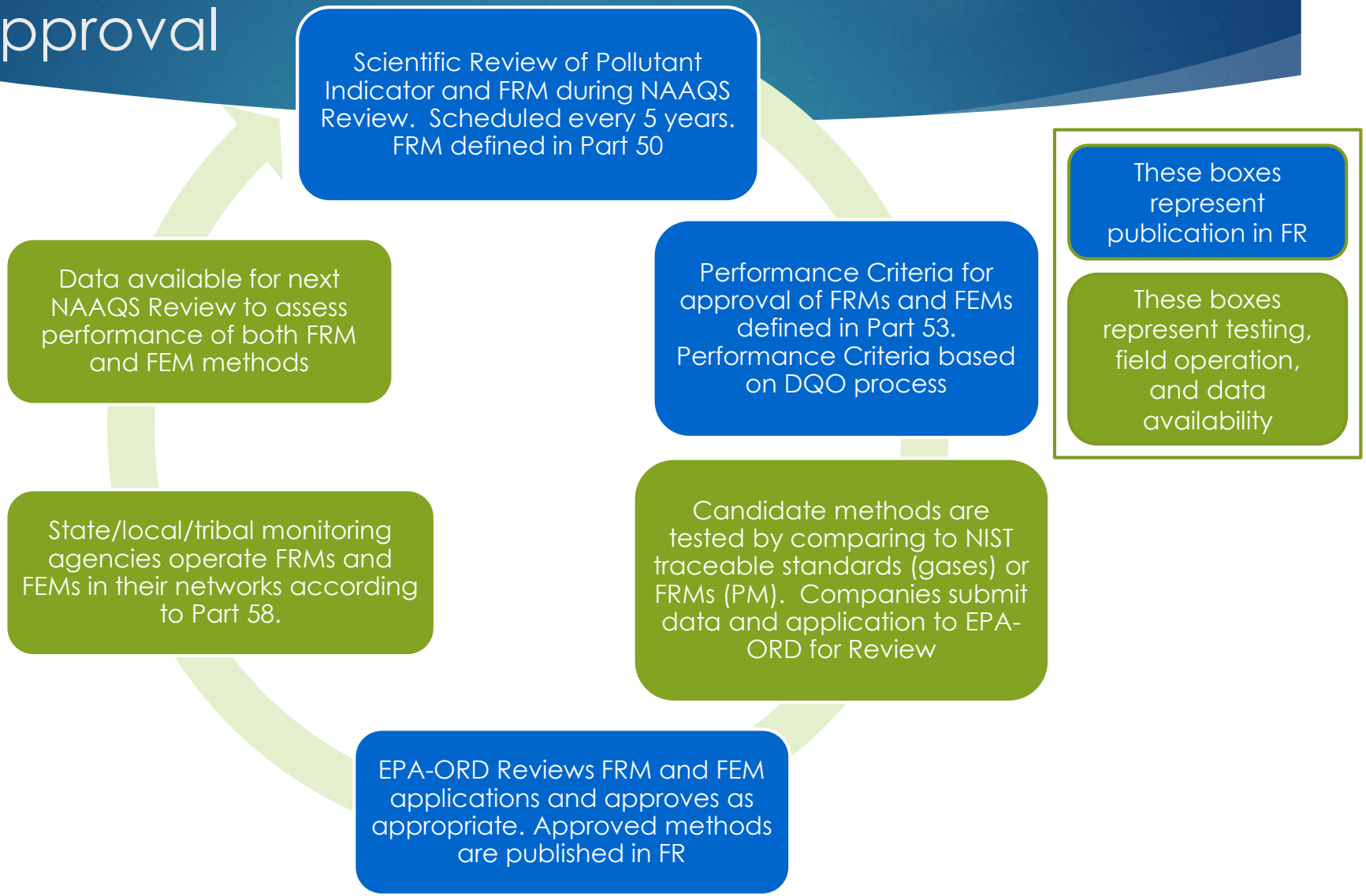


Figure C-2 to Subpart C of Part 53—Illustration of the Slope and Intercept Limits for Class II and Class III $PM_{2.5}$ Candidate Equivalent Methods

Flow Chart of Ambient Criteria Pollutant Method (FRM and FEM) Adoption and Approval



Ambient Air Monitoring Program Performance-Based Examples

1. Approval of **Very Sharp Cut Cyclone (VSCC)** in sampler as an approved FEM for $PM_{2.5}$. During NAAQS review, VSCC performance deemed appropriate to use as an alternative FRM.
2. Eleven **$PM_{2.5}$ continuous FEMs** have been approved since performance criteria promulgated in 2006.
3. New **Ozone (O_3) FRM using Nitric Oxide (NO)-Chemiluminescence** method in 2015.
   - Original O_3 FRM based on Ethylene (C_2H_4) chemiluminescence had become obsolete.
   - An O_3 FEM utilizing NO-Chemiluminescence Method was introduced in 2011.
   - New O_3 FRM was tested extensively against original FRM and widely used UV-FEMs.

WINS

VSCC

BAM 1020

SHARP

T265

Office of Pesticide Programs (OPP) and Flexible Approaches

- OPP has a flexible approach for meeting the data requirements for registering a product.
  - OPP does not require pesticide manufacturers to submit data using OPP prescribed analytical methods to register or reregister their product(s).
  - Instead, registrants can develop methods to determine pesticides and metabolites in various matrices and have an independent laboratory verification performed for the method.

OPP and Flexible Approaches

- These methods are reviewed by OPP as part of the data evaluation process.
- OPP sets the method acceptance criteria .
- OPP Guidelines provide the basic framework and criteria for the manufacturers to follow, including the specific formats, data and performance requirements for their methods.

OPP Fiscal Years (FYs) 2011 and 2012

- In 2011, OPP was in the process of finalizing a generic verification protocol, *Verification of Pesticide Application Spray Drift Reduction Technologies for Row and Field Crops*. The protocol was finalized in June 2016.
- The protocol provides a detailed method for conducting and reporting results from a verification test of pesticide application technologies for their potential to reduce spray drift.

OPP FYs 2011 and 2012

- This protocol describes the testing approach used to generate high-quality, peer-reviewed data for drift reduction technologies, including test design and quality assurance aspects.
- OPP, through its Environmental and Sustainable Technology Evaluations program, developed this protocol with input by external experts and stakeholders to provide the pesticide application technology industry with a standard method to voluntarily test their technologies for potential reductions in spray drift.
- EPA utilizes this test protocol as part of a program to accelerate acceptance and use of improved and cost-effective application technologies, which can significantly reduce spray drift and thereby provide benefits to applicators, the public and the environment.

OPP FY 2013

- OPP developed a new test protocol that will, for some pesticide products, reduce the time and costs involved in conducting the Storage Stability and Corrosion Characteristics guideline study protocols.
- The original studies took 1 year to complete. The new accelerated study takes only 14 days to conduct because it tests pesticides at an elevated temperature of 54°C.
- Because of the elevated temperature, registrants must consider the physical and chemical properties of their pesticide products and determine whether the new accelerated protocol or the 1-year study is appropriate.

OPP FY 2014

- OPP worked to revise and improve Guideline 860.1630 for the Multiresidue Method.
  - By 2014, the original procedures and methods were considered cumbersome and based on outdated technologies and methodologies.
  - Enlisted help from the U.S. Department of Agriculture, the U.S. Food and Drug Administration, and Canada's Pest Management Regulatory Agency.
  - The revised Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline for Multiresidue Methods was completed July 2014.
  - Designed as a living guideline that will keep up with rapid changes in technology and analytical instrumentation.

OPP FY 2015

- OPP updated the science policy document, *Use of an Alternate Testing Framework for Classification of Eye Irritation Potential of EPA Pesticide Products*.
- Document provides a framework for determining eye hazard classification and labeling for antimicrobial pesticide cleaning products using an alternative testing approach that does not rely on live animals.

OPP FY 2015

- Document provides a consideration on a case-by-case basis of the use of this framework of alternative tests for other types of pesticide products, including conventional, biochemical and other antimicrobial pesticides not within the scope of those with cleaning claims.
- OPP worked with the National Toxicology Program's National Interagency Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the validation of alternative methods to evaluate alternative eye irritation methods with a broader set of pesticide chemistries, including conventional pesticides.

OPP FY 2016

- OPP issued final guidance: *Process for Establishing & Implementing Alternative Approaches to Traditional* In Vivo *Acute Toxicity Studies for FIFRA Regulatory Use*.
- Guidance describes a process for evaluating and implementing alternative methods for the "six-pack studies":
  - Oral, dermal and inhalation acute systemic lethality studies; and
  - Eye irritation, dermal, and skin sensitization.

OPP FY 2016

- The guidance discusses the three major phases of the process and the implications for reporting information under FIFRA.
- Having such a process and a clear articulation of the related reporting requirements addresses a barrier that has previously been associated with adopting alternative methods. This guidance will help expand the acceptance of alternative methods for acute toxicity testing, thereby reducing animal use. Partnership with stakeholders is critical to making this a success.

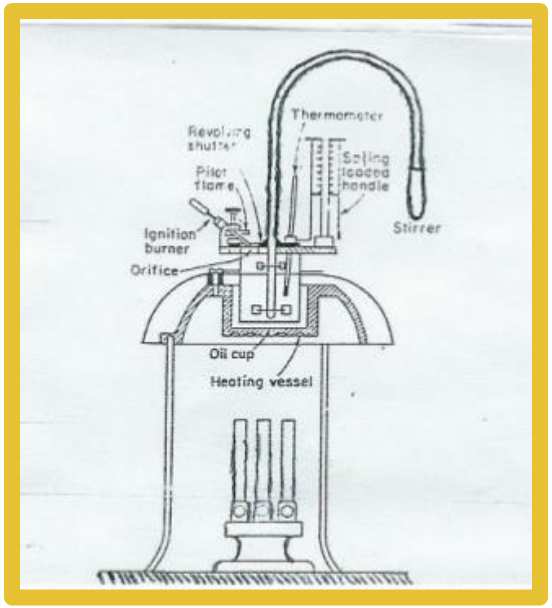
Office of Resource Conservation and Recovery (ORCR) and Flexible Approaches

- Solid waste analytical methods are found in *Test Methods for Evaluating Solid Waste, Physical/ Chemical Methods* (SW-846).
- On June 14, 2005, the Methods Innovation Rule (70 FR 34538) removed unnecessary requirements for uses of SW-846 methods other than Method Defined Parameters (MDPs).

www.epa.gov/hw-sw846/sw-846-compendium

ORCR and Flexible Approaches: Methods Innovation Rule

- Because of the variability and complexity of Resource Conservation and Recovery Act waste matrices, ORCR allows:
  - Method modifications to meet project-specific data quality needs for non-required existing methods.
  - Use of previous versions of methods when appropriate (e.g., existing permit, Sampling and Analysis Plans, Quality Assurance Project Plans).
  - Flexible method selection for preparation and determinative methods.
  - Method equivalency determination for required MDP methods through the "Equivalency Petition" process.



ORCR and Flexible Approaches: Streamlined Method Approval

- ORCR now has a streamlined SW-846 methods approval and availability process, published in 2016.
  - **Public Involvement**—methods still undergo public comment process.
  - **Easy Access**—methods published on SW-846 website (www.epa.gov/hw-sw846) not in *Federal Register*.
  - **Improved Communication**—method users can sign up for the SW-846 mailing list at www.epa.gov/hw-sw846/forms/contact-us-about-hazardous-waste-test-methods to receive notifications about SW-846 methods and guidance.
- The streamlined approach does not apply to MDPs.

ORCR and Flexible Approaches: SW-846 Program Update

- Finalized the Update V methods package (www.gpo.gov/fdsys/pkg/FR-2015-08-13/pdf/2015-20030.pdf) in August 2015:
  - ORCR Policy Statement.
  - 23 new and revised analytical procedures.
  - Five updated guidance chapters.
  - Initial Demonstration of Proficiency QC practice.
  - Relative Standard Error guidance.
  - Lower Limit of Quantitation guidance.
  - Blank Contamination Protocol guidance.

ORCR and Flexible Approaches: SW-846 Program Update

- Update VI phased release, 2017
  - Phase I—March 31, 2017
    - Method 1340—*In Vitro* Bioaccessibility Assay for Lead in Soil
  - Phase II – April 2017
    - Methods 8260D and 8270E—Volatile and Semivolatile Organic Compounds by GC/MS
  - Phase III – May 2017
    - Method 3050C—Acid Digestion of Sediments, Sludges, and Soils
  - Phase IV – May 2017
    - LEAF User Guide
    - LEAF Methods 1313, 1314, 1315, 1316

ORCR and Flexible Approaches: SW-846 Methods Team

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- LEAF Methods

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OGWDW and OST Flexible Approaches: Drinking Water and Wastewater Programs

- Office of Ground Water Drinking Water (OGWDW) and Office of Science and Technology (OST) incorporate substantial flexibility into Safe Drinking Water Act (SDWA) and Clean Water Act (CWA) compliance monitoring methods.
- The need for flexibility varies between both programs.
- Each program has developed unique approaches to provide method flexibility.

Flexibility to Modify CWA Methods—136.6

- Many approved methods provide analysts the flexibility to modify, without prior approval, of the modification.
- In 2007, EPA added 40 CFR Part 136.6 to describe additional (and to clarify existing) flexibility to modify any Part 136 chemical method without prior review. Embodies the spirit of the performance approach to method use.

Method Flexibility for Wastewater—136.6

- 40 CFR Part 136.6
  - Builds on the flexibility specified in section 9.2 of EPA's 1600-series chemical methods.
  - May modify methods to overcome matrix problems, automate methods, or otherwise improve method efficiency or accuracy without unnecessary delay.
  - Modifications are acceptable for compliance use, if the modification is documented to work.
    - Sample method performance should be comparable to that of the unmodified method.

Method Flexibility for Wastewater—136.6

- Potentially allowable changes include:
  - Automate manual methods.
  - Change calibration range (provided that the modified range covers relevant regulatory limits).
  - Change equipment operating parameters, such as changing the monitoring wavelength of a colorimeter.
  - Increase purge-and-trap sample volumes.
  - Use salts and inert surfactants to improve recovery.

Method Flexibility for Wastewater—136.6

- What is the meaning of "potentially" allowable changes in 136.6 text?
  - Changes must be tested in the appropriate application/ matrix.
  - Method performance must continue to meet method requirements.
  - Changes and testing are documented.

Method Flexibility for Wastewater—136.6

- What modifications are not within the allowable flexibility described in 136.6?
  - Changes to the determinative step (e.g., the detector), changes to the quality control, changes that significantly alter the chemistry of the method.
  - Some (not all) changes to methods that measure an MDP.

Method Flexibility for Wastewater—136.6

- Has 136.6 changed the CWA Alternate Test Procedure (ATP) program?
  - Yes, developers who submit a CWA method modification to the ATP program now must clearly explain why their modification falls outside the scope of 136.6.
  - The office will not review ATP submittals that omit this explanation or review methods that fall within the scope of 136.6.
  - Allows resources to be focused on novel methods instead of tweaks to existing methods.

Method Flexibility for Wastewater—136.6

- Do modified Part 136 methods that already have an ATP approval letter carry more weight than modified methods that will no longer have a letter because the modification falls within the scope of 136.6?
  - No, these methods may be used in the same situations as an older method that has an EPA letter.

OST Follow-Up Information

- OST updates with additional details about method flexibility: www.epa.gov/cwa-methods
  - Submit method questions using the "Contact Us" link at the above website.
- For questions regarding CWA method flexibility:
  - Adrian Hanley
  - Phone: 202-564-1564
  - E-mail: hanley.adrian@epa.gov

OGWDW Method Flexibility

- In OGWDW, method flexibility is incorporated during method development.
- The ability to incorporate flexibility varies based on the complexity of the chemistry in the method.
  - Complexity can result from several factors (e.g., sample matrix, target analytes, type of instrumentation.
  - Method performance must be evaluated after development before the method is deemed robust enough for drinking water compliance monitoring.
- Generally, allowed flexibilities are outlined within the method.

OGWDW Method Flexibility

- Example of method flexibilities:
  - Unless otherwise stated in liquid chromatography methods, the analyst may use any mobile phase, elution gradient, column or instrument manufacturer as long as the method QC criteria are met.
- Sometimes broader method allowances are permitted.
  - EPA Method 334.0 allows the use of any type of on-line chlorine analyzer as long as the method QC criteria are met.

OGWDW ATP Program

- OGWDW conducts evaluations under the SDWA ATP program for new or modified drinking water methods where the modifications are beyond the flexibility of the approved method.
- Methods are evaluated on a case-by-case basis.
- The ATP program evaluates methods but does not approve them.
  - Promulgation through notice-and-comment rulemaking.
  - Expedited method approval.

OGWDW ATP Process Highlights

- Submitted methods are evaluated individually by staff scientists with laboratory and method development experience.
- Open communication with ATP applicants is critical to the evaluation process.
- Validation studies are required as a part of the evaluation process to ensure valid and robust method performance.
- Drinking water methods must be demonstrated to be "equally effective" to the approved method in the regulation.

OGWDW Expedited Method Approval Process

- OGWDW established the "Expedited Method Approval" approach to speed the approval of alternative drinking water test methods; methods approved through this process are now added to Appendix A in 40 CFR Part 141, Subpart C.
  - ATP methods are acceptable for compliance monitoring and reporting.
  - State adoption of ATP methods is optional; however, if these methods are used, laboratory certification requirements extend to the use of methods approved through the expedited process.

OGWDW Follow-Up Information

- Drinking Water Methods
  - www.epa.gov/dwanalyticalmethods
  - Approved Methods
  - ATP Program
  - Expedited Method Approval
- For questions regarding drinking water method flexibility:
  - William A. Adams, Ph.D.
  - Phone: (513) 569-7656
  - E-mail: adams.william@epa.gov

Outreach

- Resources and information to be added to EPA's Environmental Measurement website: www.epa.gov/measurements.

- EPA welcomes internal or external (i.e., stakeholder) input for training material and additional educational resource needs.

Summary

- Since 1997, the Performance Approach has resulted in improvements, but the approach had limitations.
- Although the Flexible Approaches strategy does not eliminate EPA review or rulemaking for all methods, EPA program offices now have better tools to identify program-specific measurement requirements while offering flexibility.
- EPA programs are committed to helping stakeholders (particularly co-regulators and those who use analytical methods) interpret and implement the flexibility provided by the new strategy.

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Questions?