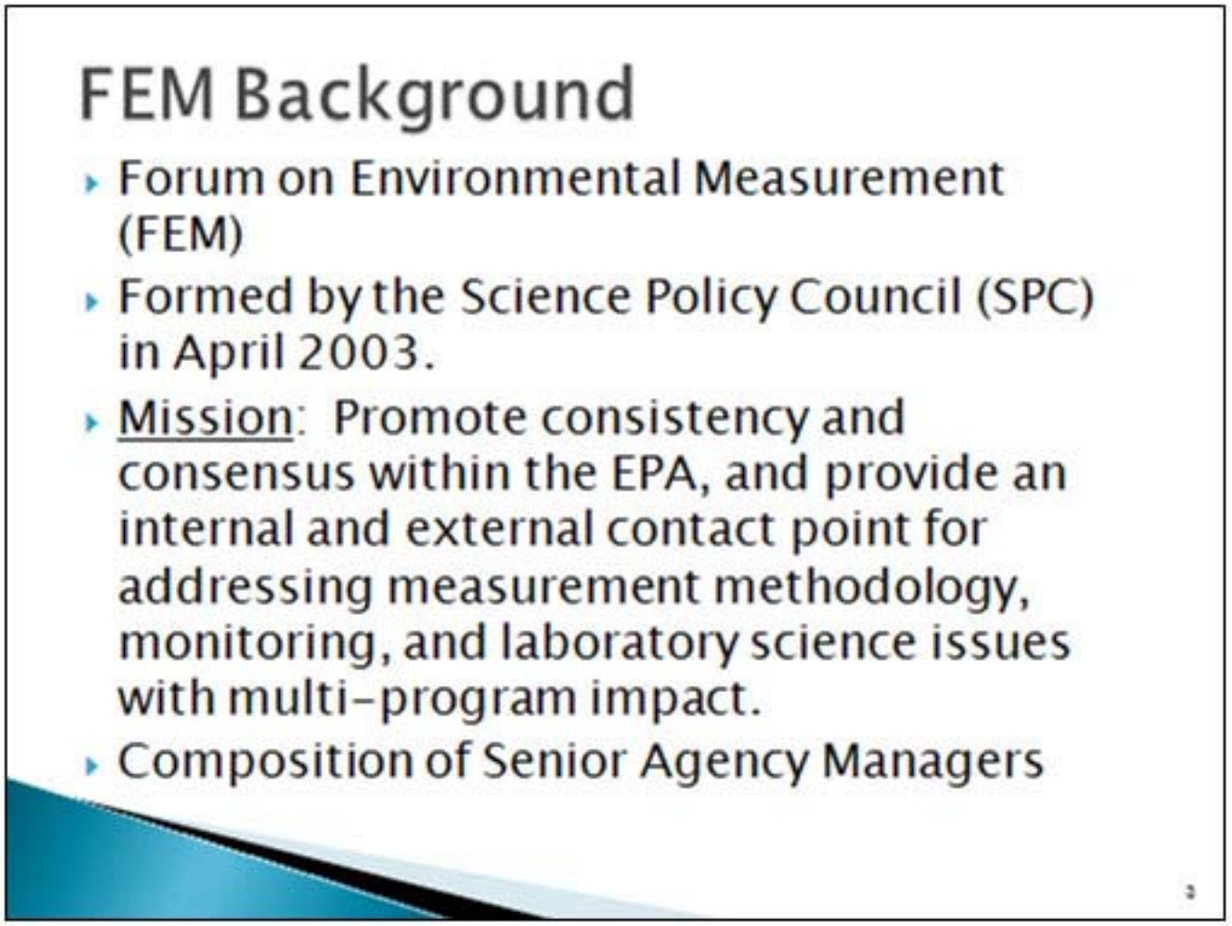
Welcome and general announcements.

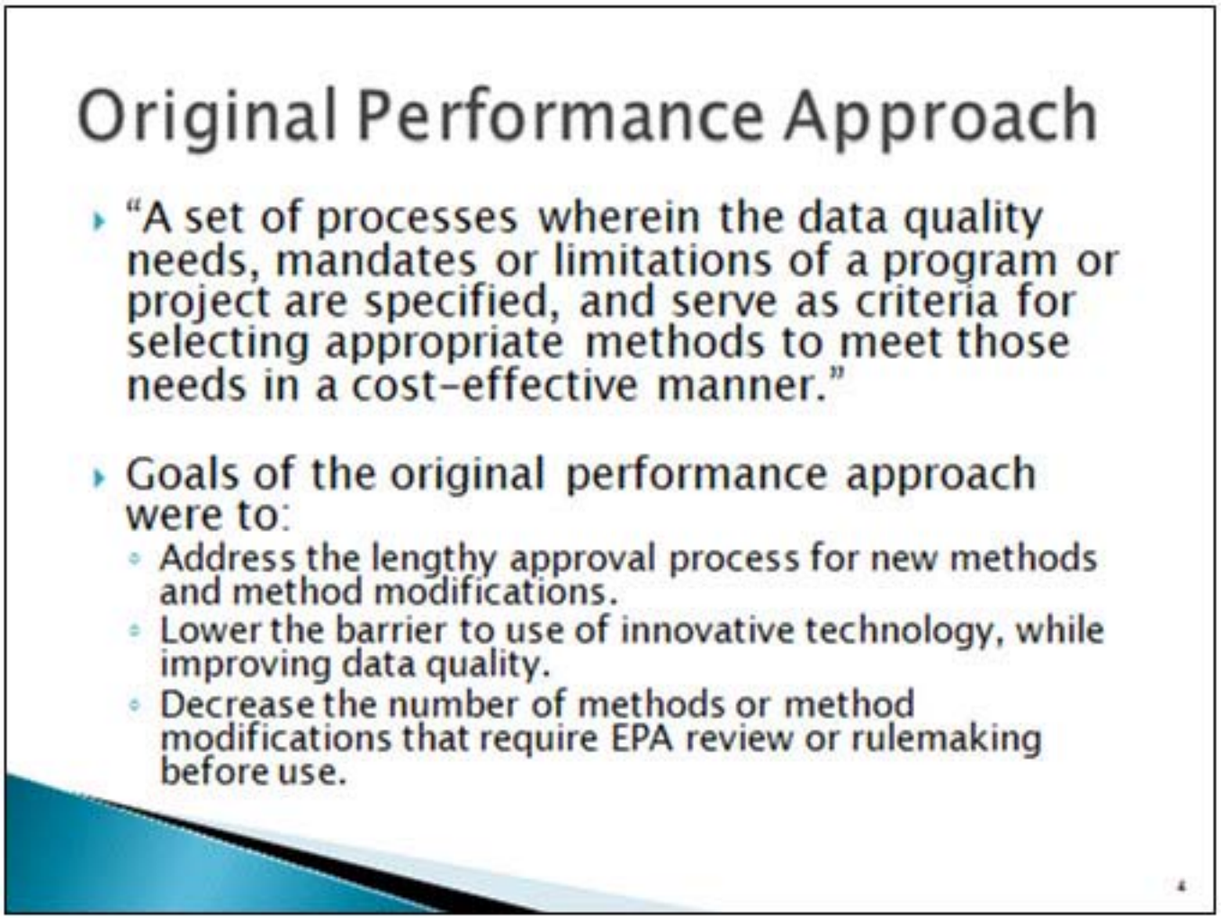
Once we cover the background material, each of our program offices will have an expert talking about their respective program efforts to embrace greater flexibility into their programs.



The Forum on Environmental Measurements (or FEM) was established to promote consistency and consensus within the Agency on measurement issues in addition to enhancing EPA's measurement programs by recommending to the Agency's Science Policy Council, which is now the Science Technology Policy Council (STPC), basic principles to guide the Agency's measurement community in:

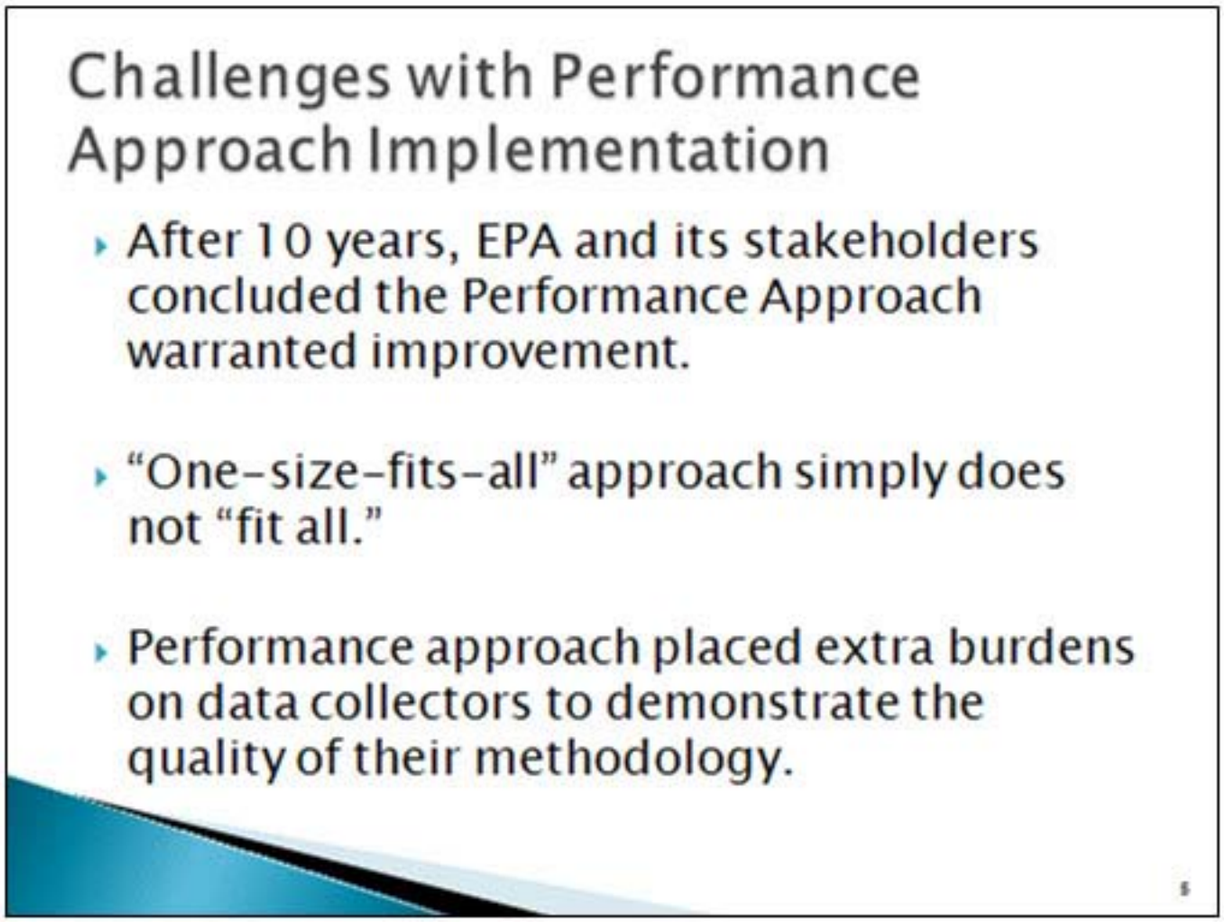
- Validating and disseminating methods for sample collection and for biological, chemical, radiological and toxicological analysis;
- Developing scientifically rigorous, statistically sound and representative measurements;
- Employing a quality systems approach that ensures that the data gathered and used by the Agency are of known and documented quality; and
- Investigating innovative monitoring and sensor technologies.

The FEM serves as the central point for addressing measurement issues and policies with multi-program impact.

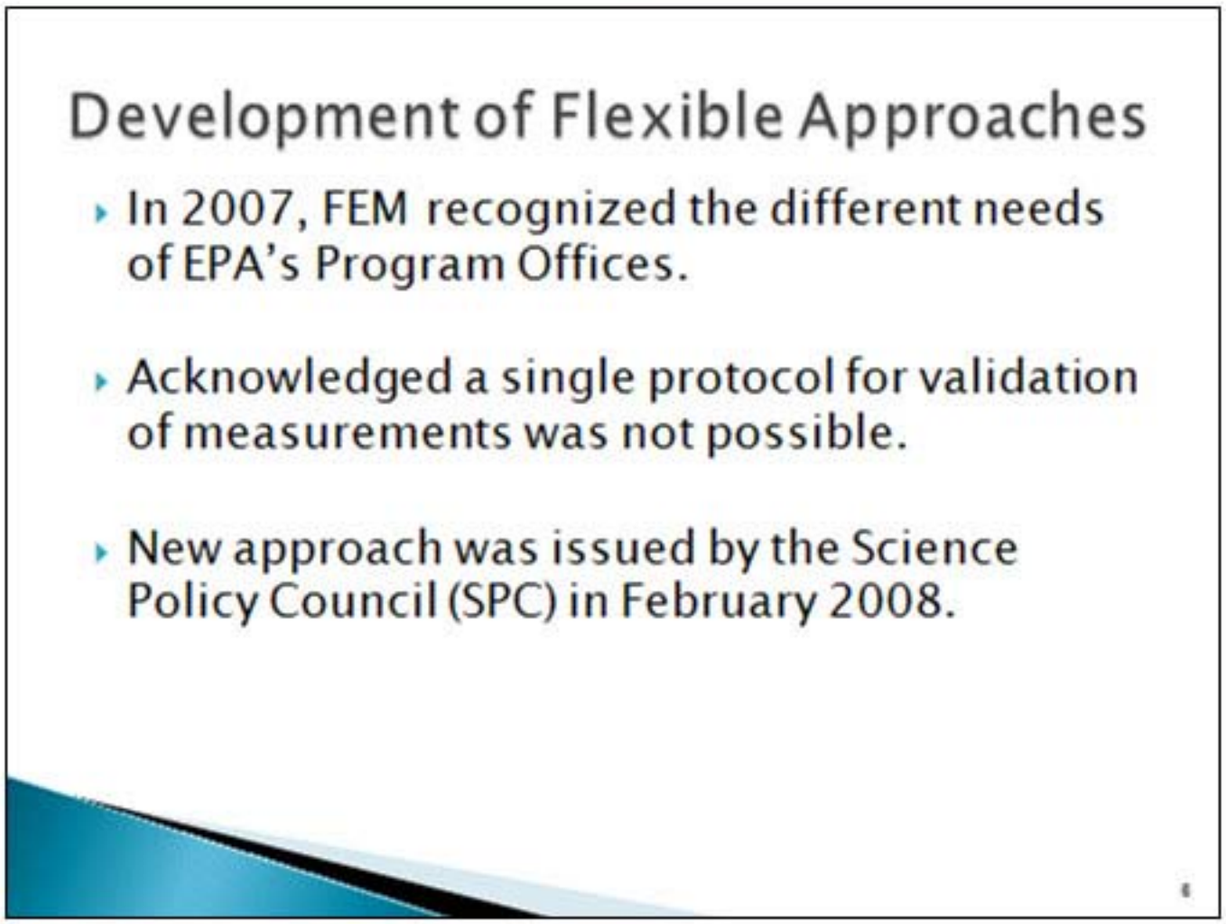


Performance Based Measurement Systems (PBMS) of "the original performance approach" was announced via a federal register notice in September 1997. In that notice, PBMS was defined as "a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner." All of the Agency's program offices took a different approach to implementation. Some of the targeted goals each program, however, were expected to achieve were:

- Address the lengthy approval process for new methods and method modifications;
- Lower the barrier to use of innovative technology, while improving data quality; and
- Decrease the number of methods or method modifications that require EPA review or rulemaking before use.



After 10 years, the FEM pulled together its membership with the expert program representatives for the performance approach to examine why more had not been accomplished. Unfortunately, the original PBMS framework had been set-up to be 'one-size-fits-all' and our individual program offices are anything but 'one-size', so it did not 'fit-all'! Original efforts were placing extra burdens on data collectors to demonstrate the quality of their methodology instead of making it easier. Many States and the EPA's Regional Programs were greatly concerned about having the necessary staff and technical expertise to review all the variations that might suddenly be submitted, as well.



Assuring the quality of environmental measurements is essential to implementation of EPA's environmental programs, both regulatory and voluntary. In a 1997 Notice of Intent, the Agency outlined a "Performance Based Measurement System" concept that would "have the overall effect of improving data quality and encouraging advancement of analytical technologies." Ten years later, EPA has revisited the 1997 concept, gauged Agency progress towards achieving its goals, and redefined steps needed to ensure continued progress.

The Agency now believes that while it may be possible to specify performance criteria in a manner that is independent of methods, techniques, or instruments, the development of a single protocol for the validation of these measurements that could be applied to all measurements, including measurements made with techniques yet to be invented, is simply not possible. Accordingly, EPA is introducing flexible approaches in environmental measurement which capture that Agency's experience of the past ten years and sets the stage for future progress.

This new approach approved by the former Science Policy Council on February 15, 2008 is posted on the FEM website (http://www.epa.gov/fem).

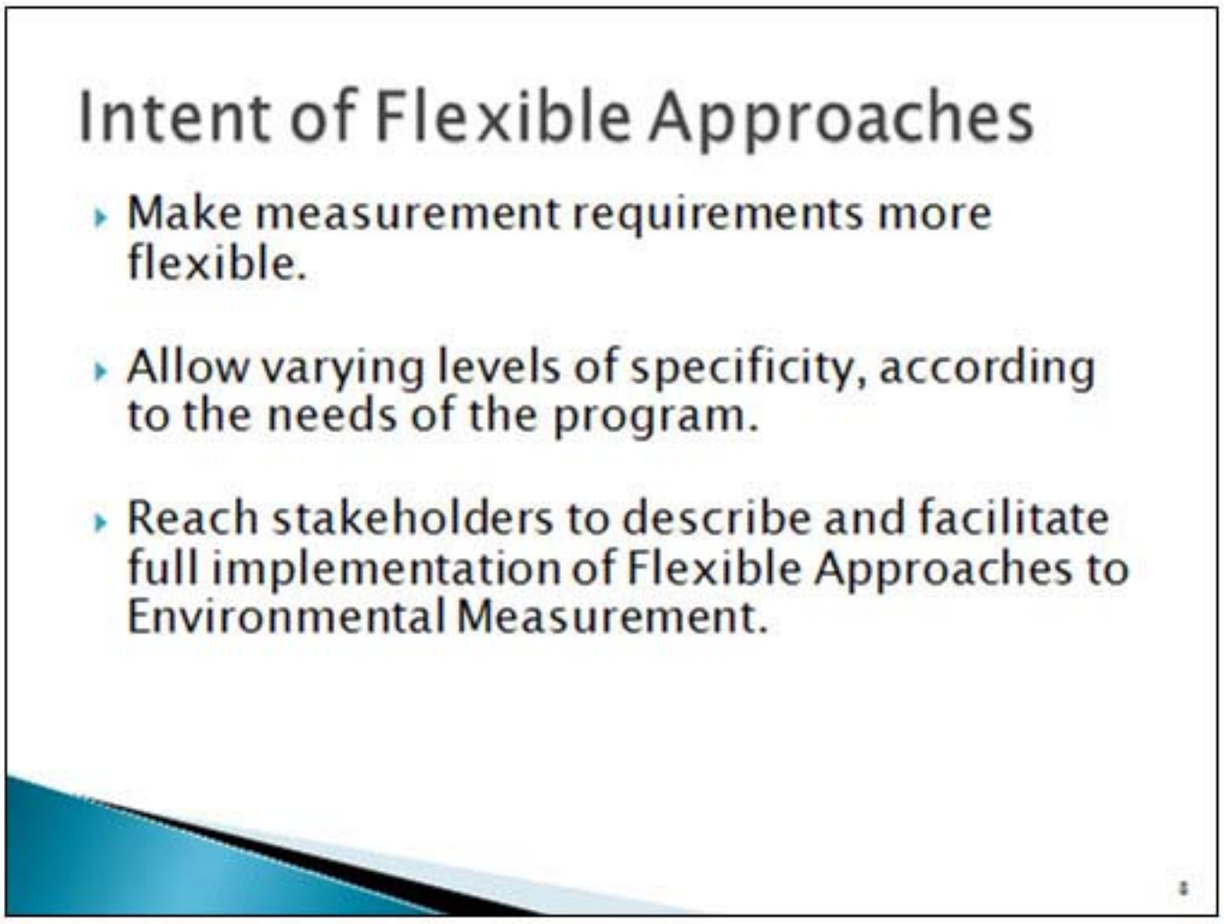
Some quick highlights of the four goals of Flexible Approaches to Environmental Measurement:

• Increased emphasis on flexibility in choosing sampling and analytical approaches to meet regulatory requirements for measurements. This is an effort to acknowledge many measurement quality requirements that appear throughout regulations are more specific than absolutely necessary, and we intend to make these requirements more flexible as time and resources allow.

• Development of processes for validations that confirm that measurements meet quality requirements. EPA intends to develop processes for validation that allow for an appropriate choice of specificity. For some applications, this may continue to be the use of defined procedures with ongoing quality control, while other applications may place emphasis on greater flexibility and include verification that the requirements for a specific use are achieved.

•Increased collaboration with stakeholders to develop validation processes for new measurement technology. The Agency anticipates that development of validation processes for application of new technology will require collaboration with stakeholders to ensure timely development of these processes.

•Rapid assessment of new or modified technologies, methods and procedures. The Agency is committed to rapid assessment of proposed alternatives to these requirements and to timely approval of these alternatives when approval is sought.



The decision to implement flexible approaches to environmental measurement is consistent with the goals of the performance approach which are:

- adapting and incorporating new measurement methods and technologies,
- improving data quality, and
- adopting new technology in a timely manner.

Turn over Robin Segall to talk about the Air Programs.

OAQPS is part of OAR.

Have two primary programs requiring environmental measurement.

Under stationary source program, we regulate stationary sources of air pollution such as refineries & chemical plants, steel mills, pulp & paper mills, stationary engines, and electric utilities. The affected facilities conduct measurements to demonstrate compliance with emissions standards.

For ambient air monitoring program, state & local agencies must monitor their ambient air to show compliance with the National Ambient Air quality Standards of NAAQS for PM, sulfur dioxide, nitrogen oxides, VOC, lead, and ozone. Though we do not set NAAQS for them, we also have program for monitoring inorganic and organic air toxics.

OAQPS and Flexible Approaches: Stationary Source Program

- Promulgate validated methods, performance-based wherever possible
  - Specify quality of measurement within test method or monitoring specifications using performance criteria such as:
    - Bias (e.g., accuracy relative to reference method for continuous monitors, system bias checks using reference gases for instrumental methods)
    - Precision (e.g., relative deviation for paired samples)
    - Sensitivity
  - Also specify procedures for verifying performance
  - Flexibility to use any technology that meets performance criteria

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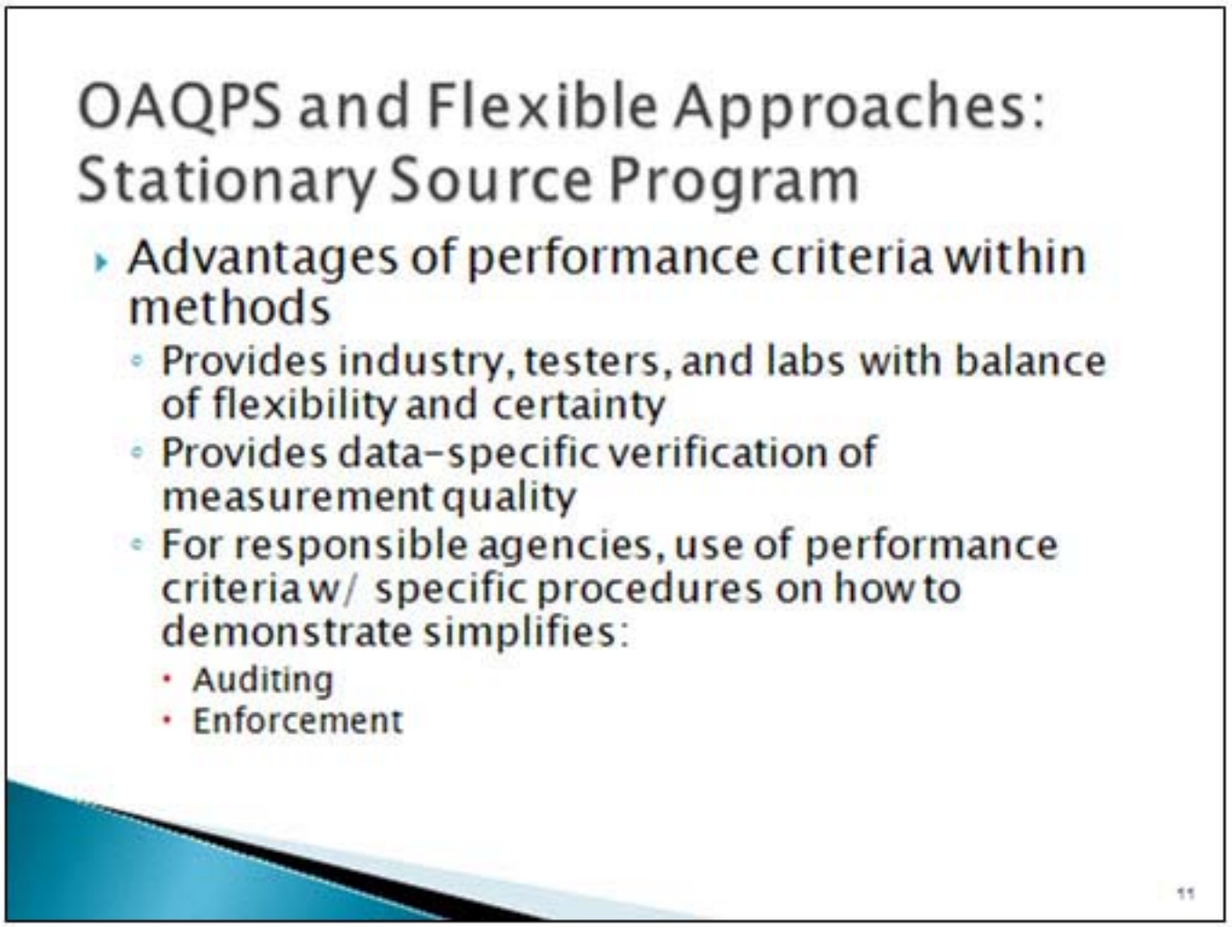
•Though some of older methods are prescriptive, going forward we are promulgating performance-based methods and monitoring performance specifications (PS), wherever possible. Aim of these methods and monitoring PS is to allow use of any appropriate technology that can meet the performance criteria. Our Performance-based methods and PS incorporate performance criteria along with procedures describing how to measure performance against those criteria. This is consistent with Goal 1.

•Generally, use performance criteria to assess bias, precision, sensitivity, and specificity.

•For example, for our instrumental methods (e.g., 40 CFR 60, Appendix A, Methods 3A, 6C, 7E, 10, 25, 30A, which make real-time measurements of pollutants in the field) our performance criteria are:

- •Calibration error
- •'Dynamic' spike recovery (add analyte spike to stack matrix through entire measurement system to assess bias), or System bias check (calibrate through entire measurement system to assess bias).
- •Instrument drift test to ensure stability over measurement period.

•Top picture is short term, manual sampling system used to measure pollutants such as PM, metals, HCl. Bottom picture shows a continuous emissions monitoring system.



OAQPS has found significant advantages to the approach where the measurement performance criteria along with procedures for their demonstration are specified within the method. First, it provides flexibility to the regulated community, labs, and others to adopt new or more cost effective technologies while providing regulated facilities and their testers certainty on measurement requirements. Second, it provides data-specific verification of measurement. And, third, it provides the enforcement folks (States, local and EPA headquarters and Regions) structure to facilitate auditing and enforcement.

OAQPS and Flexible Approaches: Stationary Source Program

- Example of performance criteria within method
- Method 30A – Instrumental method for mercury emissions from stacks
  - Specifies representative sample collection
  - Any instrument that can meet performance criteria can be used
  - Key performance criteria using mercury gas standards
    - Linearity (through system)
    - Spiking of stack gas to confirm no interference or bias
    - Final calibration to check for drift

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•Provide a couple of examples of recently promulgated performance-based methods, both for mercury.

•The first is an instrumental method, Method 30A (40 CFR 60, Appendix A). Sample is withdrawn from stack (see probe on left in picture), conditioned and goes into instrument (blue in picture) for analysis.

•Sample collection must be relatively prescriptive to ensure a representative sample.

•Any instrument that can meet performance criteria can be used. In this case, atomic fluorescence and atomic absorption instruments have thus far been used.

•The key performance criteria and procedures utilize NIST-traceable elemental and oxidized mercury gas standards and include an multipoint calibration to confirm linearity across the measurement range, 'dynamic' spiking of the stack gas matrix to confirm no bias or interferences, and a final calibration to assess instrument drift.

OAQPS and Flexible Approaches: Stationary Source Program

- Another example of performance criteria within method
- Method 30B – Sorbent-based method for mercury emissions from stacks
  - Specifies representative sample collection
  - Any sorbent, sample prep, and analytical approach that meets performance criteria can be used
  - Key performance criteria using liquid and/or gaseous mercury standards
    - Analytical bias study
    - Spiking of field sample tubes for bias
    - Paired sample agreement for precision

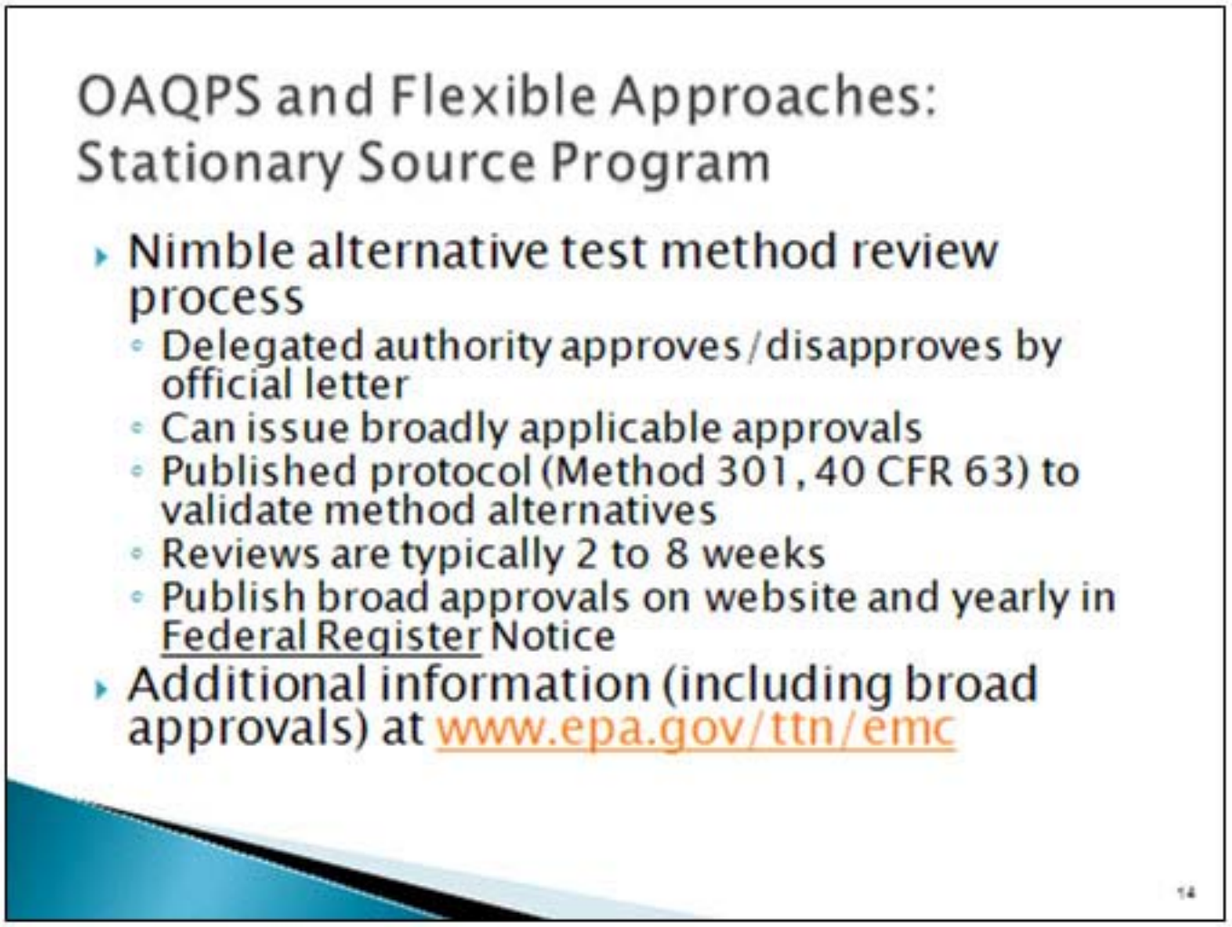
•Second example of new performance-based method is also for mercury, but uses more classic, integrated sample collection and analysis techniques. It is Method 30B (40 CFR 60, Appendix A) for gaseous mercury emissions. It uses a sorbent (see sorbent in tubes pictured) for sample collection coupled with an instrumental analysis. Tubes are installed in probe held by tester(?) in picture. Box is for sample gas withdrawal and gas volume measurement.

•Again, the performance criteria are within the method along w/ specific procedures on how to demonstrate that you meet the criteria.

•Sample collection is relatively prescriptive to ensure a representative sample, except that any sorbent may be used as long as meets criteria in an analytical bias study.

•Sample prep and analysis are totally flexible as long as the performance criteria can be met.

•The key performance criteria and procedures utilize NIST traceable liquid and gaseous mercury standards and include an analytical bias study, recovery of spikes that are subjected to the field sampling (bias), and paired sampling system agreement (precision). The method also requires the tester to demonstrate adequate sensitivity for the intended application.



•For cases where the required method or portion of a method is not performance-based, the regulated community has the option under the General Provisions to 40 CFR Parts 60, 61, and 63 (in specific, 60.8(b), 61.13(h), 63.7(e), and 63.7(f)) to submit a request for alternatives to or modifications of methods. The review and approval process for this is quite nimble. As long as the proper supporting information is supplied in the request, we typically review and issue an approval/disapproval via official letter in 2 to 8 weeks.

•The delegated authority also allows for approval of broadly applicable alternatives/modifications (e.g., applicable to an entire source category as opposed to a single facility or applicable to any application of a particular method). Publish broad approvals on EPA website and in yearly FR Notices.

•We have a promulgated protocol, Method 301 (40 CFR 63, Appendix A), for use by requestors to field validate alternative methods or major modifications.

•Promulgated performance-based methods, Method 301 field validation protocol, broadly applicable alternative methods and other background information are available on EPA Emission Measurement Center Website at: www.epa.gov/ttn/emc.

OAQPS and Flexible Approaches: Ambient Monitoring Program

- New Federal Reference Methods or FRM , are performance-based wherever possible; performance criteria are directly linked to program data quality objectives or DQO
  - 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

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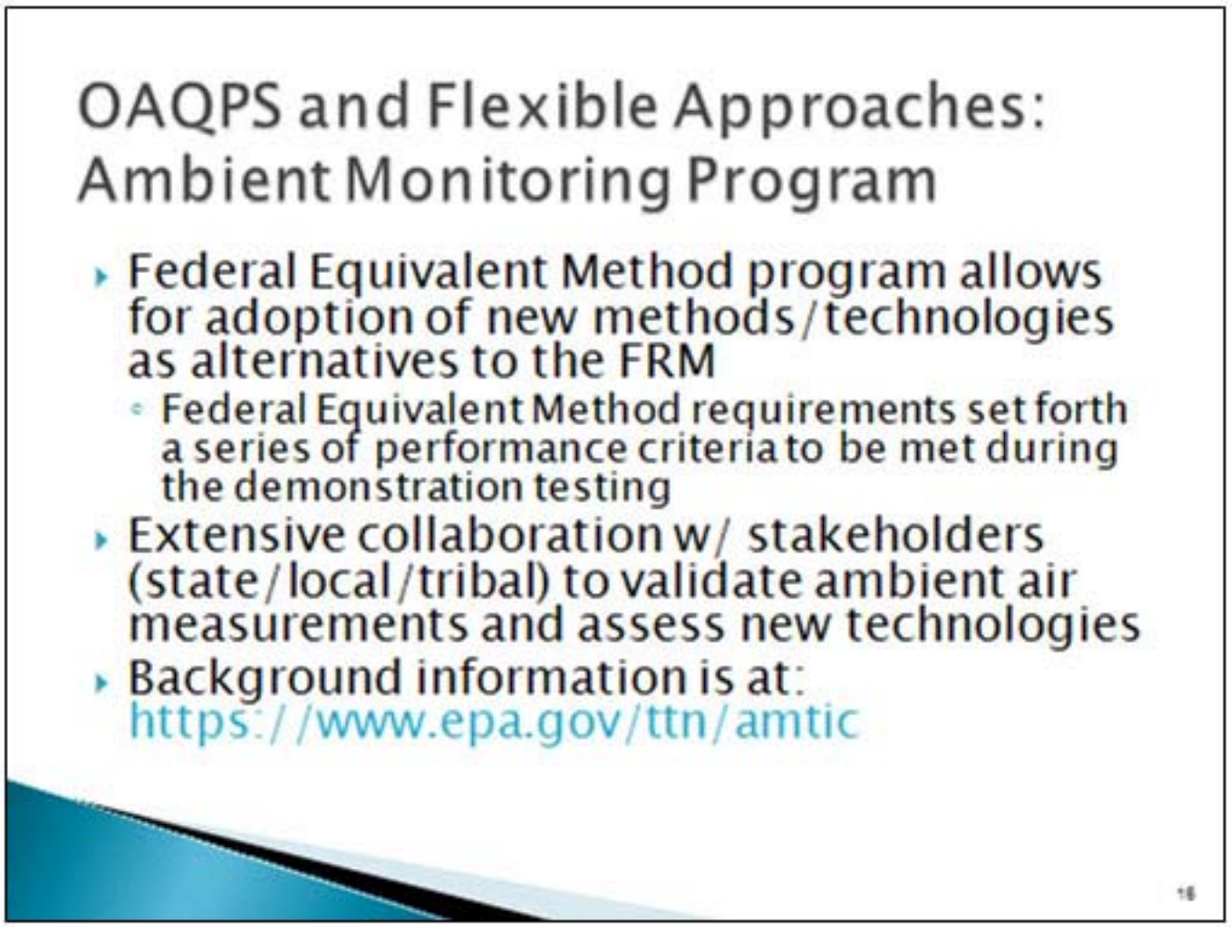
•For our ambient monitoring program, pollutants in ambient air are measured by State, local, and Tribal programs in order to show compliance with the National Ambient Air Quality Standards or NAAQS for criteria pollutants (PM, SO2, NOx, CO, O3, and lead) in 40 CFR Part 50. Criteria pollutant Federal Reference Methods (FRM) are promulgated by EPA and are also in 40 CFR Part 50.

•Though there are no national standards for ambient air toxics, there are programs for their measurement and EPA has published methods for air toxics in the ambient air in the Inorganic (IO) or Toxic Organic (TO) compound compendiums at http://www.epa.gov/ttnamti1/airtox.html.

•Historically, criteria pollutant FRMs have been relatively prescriptive, but newer methods are performance-based wherever possible with performance criteria in the methods linked to program DQO. FRM may also be a combination of both design and performance criteria. For instance, the PM2.5 FRM has both design characteristics including the inlet, second stage separator, and filter cassette, and performance specifications such as the flow control and temperature control systems.

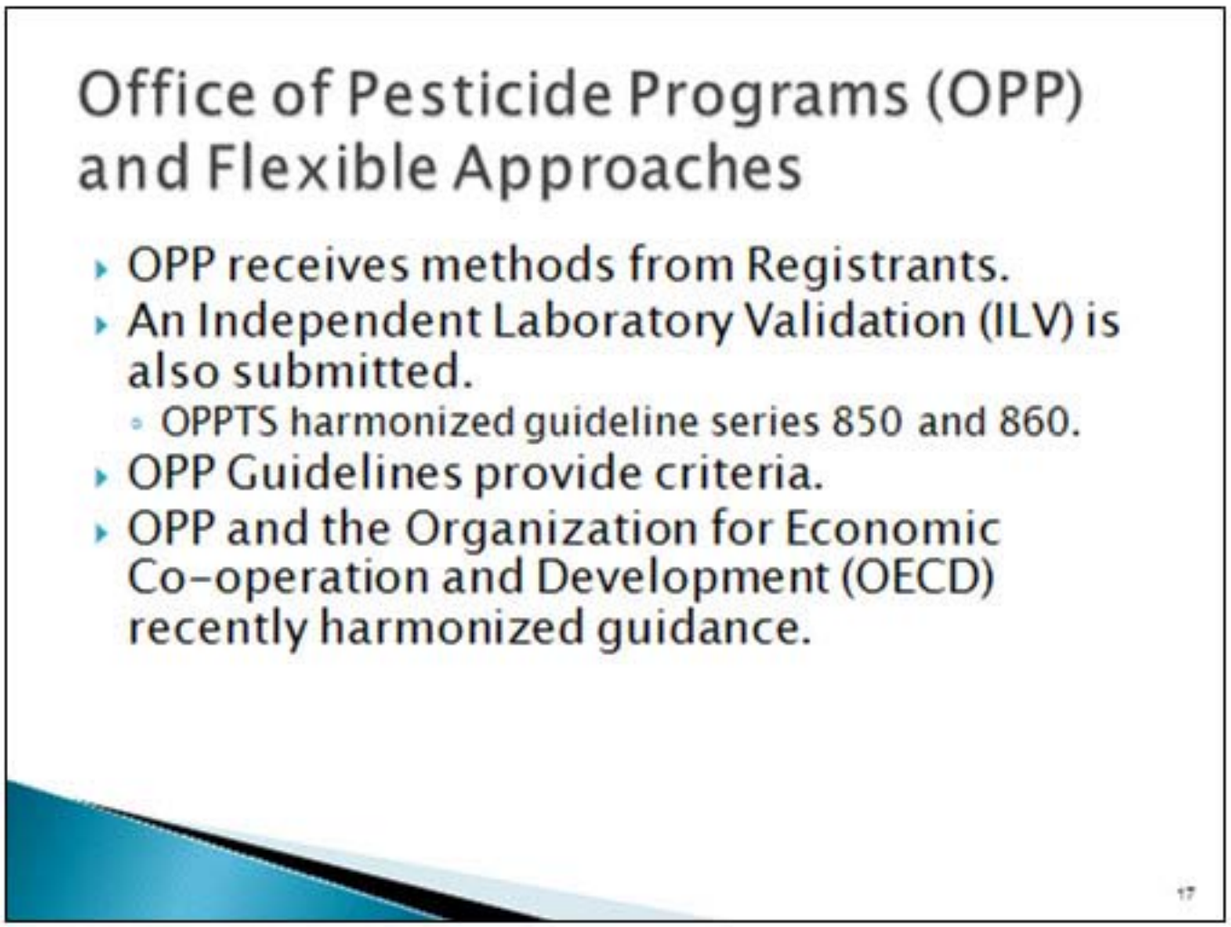


•FRM's provide benchmark for evaluation of candidate Federal Equivalent Methods (40 CFR Part 53) which may be used as alternatives to the FRMs. Federal Equivalent Method requirements in 40 CFR Part 53 set forth a series of performance criteria to be met during the demonstration testing of candidate Federal Equivalent Methods. Typically, performance criteria for equivalency determination are determined through DQO process so data resulting from a FEM will meet or exceed quality needed to compare to the National Ambient Air Quality Standards. We recently took a major step forward to encourage development of new methods for the PM mass program by publishing performance criteria for both filter-based and continuous Federal Equivalent Method for PM10-2.5 and PM2.5 (71 FR 61236, October 17, 2006).

•Because the results must be directly comparable from state to state across the entire US, we must keep tight controls on the DQO.

•Collaborate extensively w/ state/local/tribal agencies to assess and validate ambient monitoring technologies

•Promulgated performance-based Federal Reference Methods, Federal Equivalency Method demonstration procedures and application process (40 CFR 53), and other background information are available on Ambient Monitoring Technical Information Center Website at: www.epa.gov/ttn/amtic



For pesticide registration, the Office of Pesticide Programs has adopted and fully supports a performance approach for submissions of methods by registrants. OPP does not require pesticide manufacturers to submit prescribed analytical methods in order to register their product. Registrants develop methods to determine pesticides and metabolites in various matrices. Registrants also submit an Independent Laboratory Validation (ILV) for their methods as described in the OPPTS harmonized guideline series 850 and 860. These methods are reviewed by OPP as part of the data evaluation involved in registering pesticides. For methods, OPP sets the criteria (acceptance criteria) and these include precision, accuracy, and detection limits. OPP Guidelines provide the basic framework and criteria for the manufacturers to follow, including the specific formats, data and performance requirements for their methods. We have recently harmonized this guidance with the OECD.

OPP and Flexible Approaches

- OPP has other sources of methods besides registrants:
  - OPP's own labs;
  - The IR-4 program;
  - The Pesticide Data (PDP); and
  - States.

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OPP, however, has other sources of methods besides the registrants. These include OPP's own labs, the IR-4 program which is a program for minor use of pesticides, the PDP (Pesticide Data Program) which is a USDA program and the States.

OPP and Flexible Approaches

- There is one area that requires attention:
  - OPP Antimicrobial Testing Program.
    - The analysis is used for enforcement purposes.
    - OPP has been evaluating a new process.

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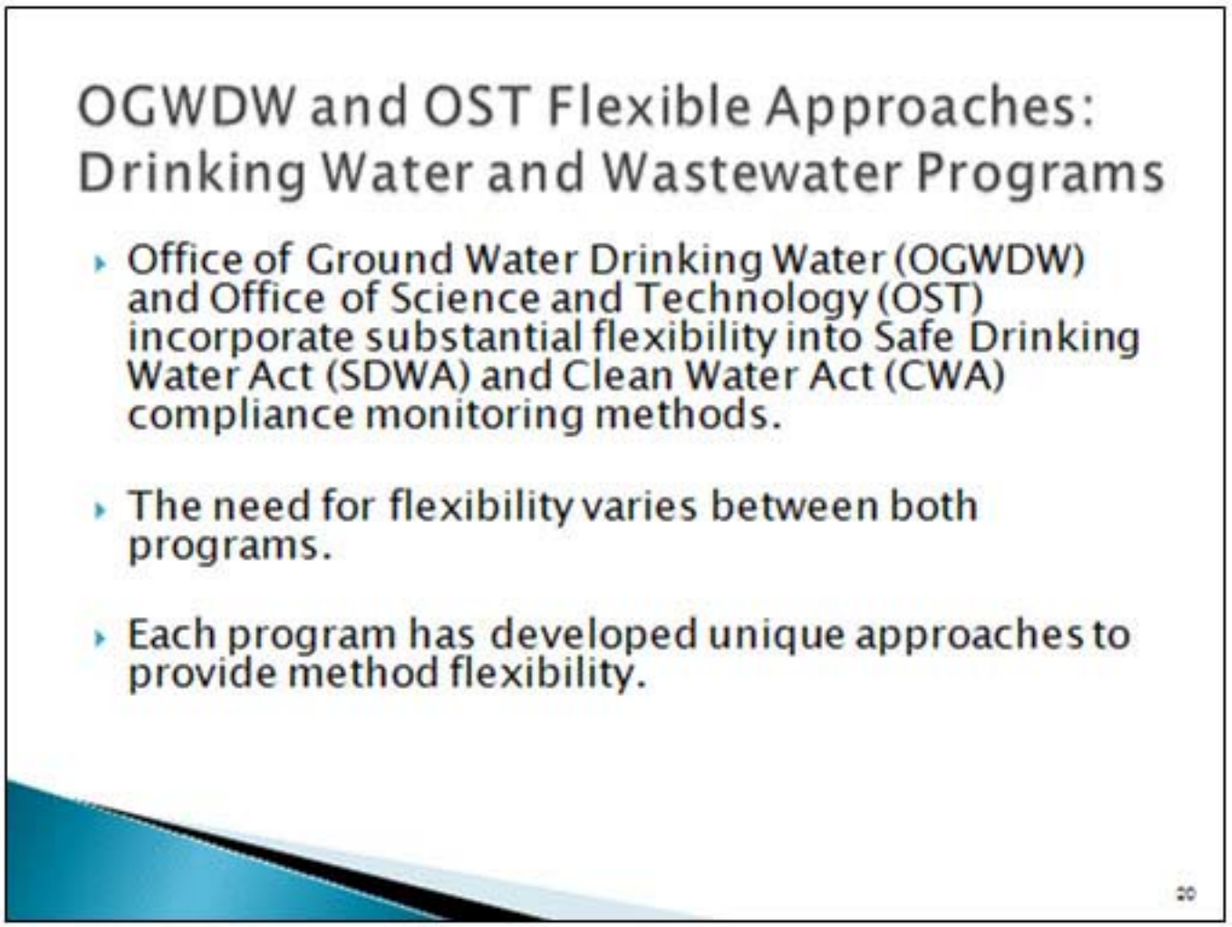
The area of the program that continues to require attention and needs to move to a more flexible approach is the support to the Antimicrobial Testing Program. The OPP Analytical Chemistry Branch (ACB) and its state partners conduct formulation chemistry analysis in support of the Antimicrobial Testing Program. The results from this testing may be used by OECA for enforcement purposes. Historically, OECA has required analysis using the exact method submitted by the registrant, in addition to analysis the ACB (or one of the participating state laboratories) may have done using an established laboratory in-house method. This has sometimes presented a problem for the laboratories participating in the ATP program. Analysis has had to be repeated using registrant's methods which, depending on the time or the original registration, can be sometimes antiquated or have used obsolete technology. OPP has made progress evaluating new processes. At the time of our first report, OPP and OECA had agreed that ACB and the state partner laboratories could use established methods for the analysis of antimicrobial products containing Quaternary Ammonium active ingredients. We have now done multi-lab validations on methods for the Quaternary ammonium compounds, lactic acid and citric acid. These methods will be published on the Web. In addition, we are in the process of doing an AOAC International collaborative study on a method. Additional new efforts include SOPs which have been written for (1) extracting antimicrobial towelettes, (2) (draft SOP) for a method for sodium hypochlorite and (2) (draft SOP) for a method for samples containing hydrogen peroxide and peracetic acid.



•OGWDW and OST incorporate the maximum flexibility practical in Safe Drinking Water Act (SDWA) and Clean Water Act (CWA) compliance monitoring methods, while assuring the quality of analytical results.

•OGWDW and OST collaborate with ORD-, Regional-, commercial-, and utility laboratories; voluntary consensus standard bodies (such as ASTM International and Standard Methods); instrument manufacturers, and universities to develop and evaluate analytical methods.

•OST amended 40 CFR Part 136 (136.6) to add explicit authority to modify, without EPA approval, many steps in an approved CWA method provided all performance requirements in the approved method are met.

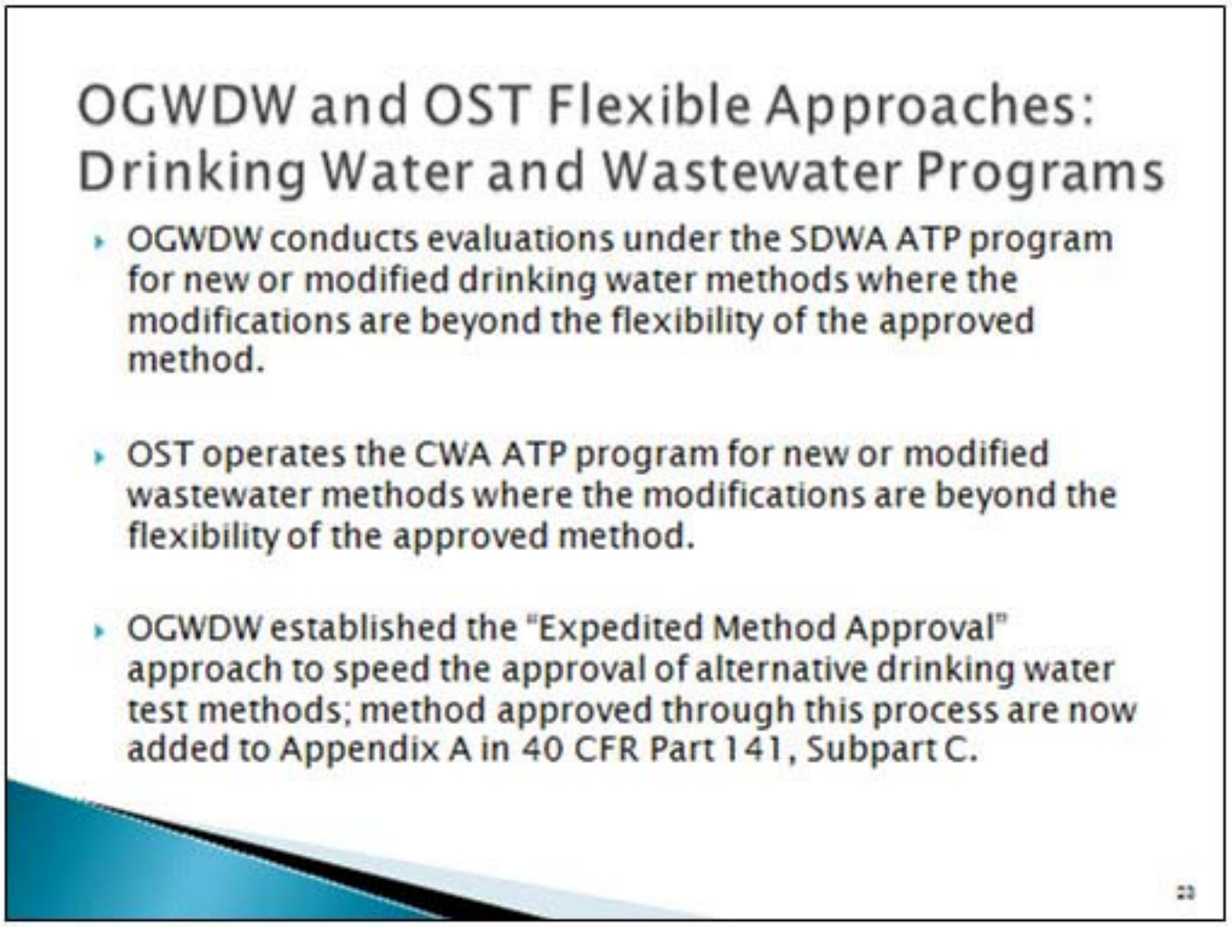
•OST regularly updates their methods website http://www.epa.gov/waterscience/methods/ with answers to questions about method flexibility, and add new examples of allowed and not allowed modifications to CWA methods.

In OGWDW Method Flexibility is Being Incorporated During Method Development

- The ability to incorporate flexibility varies based on the complexity of the chemistry in the method.
- In recent perchlorate methods the analyst may use any column, LC, IC or mass spectrometer as long as the method QC criteria are met.
- Method 334.0 allows the use of any amperometric chlorine probe as long as the method QC criteria are met.

In OST the Focus has Been on Allowing the End User to Modify Approved Methods

- OST amended 40 CFR Part 136 (136.6) to allow many modifications to CWA methods, without EPA approval, provided performance requirements are met.
- OST updates with additional details about method flexibility.
  http://www.epa.gov/waterscience/methods
- The CWA allows for regional or single laboratory approvals of modified methods, but the SDWA does not.



•For wastewater method modifications that do not fall within the flexibility of the approved method or the modifications allowed by 136.6, or for new methods that lack a corresponding approved method to compare performance against, OST operates the CWA Alternate Test Procedures (ATP) program.

•For drinking water method modifications that go beyond the flexibility of the approved method, or for new methods, OGWDW conducts evaluations under the SDWAATP program.

•OGWDW developed and implemented the "Expedited Method Approval" approach, based on SDWA-specific authority, for approving alternative drinking water test methods, and created Appendix A to Subpart C in 40 CFR Part 141 to house those methods . The new approach does not require rulemaking, and provides much faster approval of new measurement techniques, thereby creating greater flexibility in the selection of analytical methods.

•OST maintains a CWA methods team email OSTCWAMethods@epa.gov from which any team member may read and respond to inquiries.

•OGWDW addresses method-related direct inquiries, as well referrals from the Safe Drinking Water Hotline (http://www.epa.gov/safewater/hotline/index.html, 1-800-426-4791). The Hotline's Question/Answer Database allows users to find an answer or ask a question about the SDWA-based programs.

OGWDW and OST Flexible Approaches: Drinking Water and Wastewater Programs

- For questions regarding drinking water method flexibility:

  Steven C. Wendelken, Ph.D.
  Phone: (513) 569-7491
  wendelken.steve@epa.gov

- For questions regarding CWA method flexibility:

  Lemuel Walker, Ph.D.
  Phone: (202) 566-1077
  walker.lemuel@epa.gov

ORCR and Flexible Approaches:
RCRA Methods Program

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

1) Published in the early 1980"s, SW-846 officially know as as "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" was EPA's official compendium of analytical and sampling methods that were evaluated and approved for use in complying with the RCRA regulations. SW-846 was initially intended to serve as a guidance manual for generally appropriate and reliable analytical methods for RCRA-related testing and monitoring. However, as time went on EPA published regulations which required the use of SW-846 methods in general.
2) Subsequently, members of the regulated community made it clear to EPA that they would like the opportunity to use other reliable methods, and EPA also had concurrently decided that some of the SW-846 requirements were not necessary.
3) In response to the public's concerns, EPA on June 14, 2005 promulgated the Methods Innovation Rule (MIR) (70 FR 34538). This rule revised certain RCRA regulations to remove unnecessary required uses of SW-846 methods other than the Method Defined Parameters (MDPs) which are required (e.g., the Toxicity Characteristic Leaching Procedure (TCLP), Paint Filter LiquidsTest). This rule provided greater flexibility by allowing the use of alternate test procedures other than SW-846 that are considered "appropriate" as long as they fall within EPA's mission to safeguard human health and the environment and meet the goals, data quality objectives, and quality control parameters of the project. Further more, this rule was important step forward in implementing the use of a performance-based approach.

ORCR and Flexible Approaches:
RCRA Methods Program

- ORCR incorporates a flexible approach for determination of waste and materials under the Resource Conservation and Recovery Act (RCRA) given the variability and complexity of RCRA waste matrices.
- ORCR allows:
  - method modifications in order to meet project-specific data quality needs for non-required existing methods
  - use of previous versions of methods when appropriate (e.g., existing permit, SAPs, QAPPs).
  - method selection for preparation and determinative methods.
  - method equivalency determination for required methods through the "Equivalency Petition" process.

1) With the MIR in place, ORCR incorporated a flexible approach to meet the goals of making a determination of a hazardous waste under RCRA. This approach became necessary, due to the variability and complexity of RCRA waste matrices, and EPA found the Performance Based Measurement System (PBMS)/Flexible Approach is necessary in most cases when dealing with these complex matrices. Guidance for choosing an alternate method can be found in Chapter 2 of SW-846.

2) ORCR allows modifications for non-required existing methods, if the modifications at a minimum meets the performance requirements intended for an existing method and achievethe desired data quality objectives. Method modifications can be as simple as changing the acid strength in a metals digestion. Of course this depends on the method's data quality objectives.

3) ORCR's flexible approach still allows the use of previous versions of methods when appropriate, for example for existing permits, ongoing enforcement actions, previously approved SAP's and QAPP's.

4) ORCR guidance allows for the selection of instrumentation to perform an analysis. For example, in the determination of metal analytes, the analysis might select an ICP or Flame AA instrument. However, the selection of the instrumentation still must meet the project needs.

5) Finally, the regulations in 260.21 (a) provides that any person seeking to add a testing or analytical method may petition for a regulatory amendment. To be successful the person must demonstrate to the satisfaction of the Administrator that the proposed method is equal to or superior to the corresponding method prescribed in the regulations (i.e., 27 MDP's). This known as the "Equivalency Petition" process.

ORCR and Flexible Approaches:
RCRA Methods Program

- ORCR now has a streamlined SW-846 methods approval and availability process based on the MIR publication.
- Method "updates" are published on the EPA SW-846 Methods Team homepage (http://www.epa.gov/waste/hazard/testmethods/sw846/online/index.htm) and in the Federal Register.
- ORCR collaborates with stakeholders in the development and validation of SW-846 methods, and informs the public about analytical policies, new and revised methods via annual national meetings, communications and correspondence.
- ORCR staff addresses technical, regulatory and policy questions regarding method inquiries from the states, public, academia, regions, industry and interest groups.
- ORCR provides a hotline known as the Methods Information Communication Exchange (MICE).
  to answer technical questions.

Phone: (703) 818-3238
E-mail: mice@techlawinc.com

1) ORCR has streamlined the approval and availability process for issuing methods in SW-846 with the publishing of MIR, and announces the availability of method "updates" on the EPA Methods Team homepage (http://www.epa.gov/waste/hazard/testmethods/sw846/online/index.htm) and in the Federal Register. EPA/ORCR also takes comments on new and revised methods and evaluates comments before finalizing each method.

2) ORCR engages in a dialogue with interested parties (e.g., FACA committees, interest groups, the public, industry, academia, and others) regarding methods in SW-846, and informs the public via communications and correspondence (e.g., Fact Sheets, Q's and A's, Desk Statements, teleconferences, memoranda or face-to-face meetings).

3) In addition, ORCR staff addresses many technical, regulatory and policy questions regarding method inquiries. These inquiries are received from the states, public, academia, Regions, industry and interest groups.

4) Finaly, ORCR provides a hotline known as the Methods Information Communication Exchange (MICE), staffed by an EPA contractor to answer technical questions in regards to the use and flexibility of methods in SW-846. For more information see: http://www.epa.gov/waste/hazard/testmethods/mice.htm (need to put on slide)

Outreach

- Resources and information to be added to the FEM website: http://www.epa.gov/fem.

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

Make sure to remind folks about the federal register notices, website, and contacting Us via the website.

Summary

- Since 1997, 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 Offices now have better tools to identify program-specific measurement requirements while offering flexibility.
- EPA programs are committed to helping our stakeholders (particularly co-regulators and those who use analytical methods) interpret and implement the flexibility provided by the new strategy.

Recap the points above.

Leave-up this slide of contact information, while taking questions.