U.S. Environmental Protection Agency
Forum on Environmental Measurements

FLEXIBLE APPROACHES TO ENVIRONMENTAL MEASUREMENT WEBINAR SERIES – QUESTION/ANSWER SUMMARY

September 23, 2010; 1:00 – 3:00 pm (ET)

The following is a summary of the Webinar participants' comments and questions and the speakers' responses.

- Art Clark of Region 1 asked whether the two water programs might be able to have methods approved in the same expedited fashion that the air program uses. Steve Wendelken responded that this would not be possible without legislative action because the two programs operate under different laws. The Safe Drinking Water Act and the Clean Water Act do not permit the quicker options that are available to the air program. In general, flexible approaches have to be consistent with what is allowed by legislation. There are important programmatic differences between different EPA programs. In some instances, opportunities for flexibility can be created through regulation, but in this particular case, legislative action would be needed. Robin Segall added that in some programs, results from laboratories across the country must be compared with one another; the need to maintain comparability restricts the opportunities for flexibility. For example, obtaining approvals for alternative methods to be used in the ambient air program takes longer than it does for the stationary source program because results from the former program have to be compared across the country and those for the latter do not.
- William Hall from the New Hampshire Environmental Laboratory Accreditation Program (ELAP) said that he had sent in questions on the Methods Information Communication Exchange (MICE) hotline and had not received replies. Kim Kirkland said that her team had reviewed this issue but had no way of knowing whether a call had not been answered. She provided her e-mail address and suggested that the participant contact her for follow-up. Jim Michael commented that he has also heard at other meetings that responses are not always provided in a timely manner. He said that if people encounter this problem, they should let him or Kim know so that they can take the necessary steps to rectify it. The contractor typically tries to communicate up to three times with the person asking the question; if they do not hear back, they assume the question has been answered.
- Kathleen Foley of Region 2 asked Betsy Grim whether EPA will evaluate methods of analysis of polyfluorinated compounds that are already in use in other countries rather than developing new methods. Betsy replied that this question would need to be referred to Joe Ferrario in the environmental chemistry branch and volunteered to contact him.
- Jill Russell from the Texas Commission for Environmental Quality (TCEQ) observed that flexibility may appear to be attractive, but states have standards and criteria that must be met. She asked (1) how flexibility can be meaningful when laboratories must adhere to state standards and (2) whether laboratories that must run tests on thousands of samples a day actually tweak their instruments to provide different aspects of the method, or whether they

just run the samples through and report the numbers in a way that creates the appearance of flexibility. Jim Michael responded to the first question by noting that under some programs, states can be and sometimes are more stringent than the federal government. In such instances, opportunities for flexibility may be limited. In response to the second question, Steve Wendelken noted that Standard Operating Procedures (SOPs) and a good auditing program should prevent improper actions of the type that Jill had described. Kim Kirkland noted that performance criteria are not the same as QA/QC acceptance criteria; SOPs should be based on what the individual laboratory can achieve. It is important to understand the question that is being asked and the analyte of concern and to pick a suitable method to provide data that can answer the question.

- Ann Marie Allen from the Massachusetts Department of Environmental Protection noted that with regard to drinking water methods, it would be helpful to know more about the chemistry of the method and the reasons for doing things in the prescribed way. For example, certain steps in a process may be designed to overcome particular types of interference; if it is known that this type of interference is not present in a particular matrix, can these steps be skipped? Steve Wendelken responded that flexibility of this type would be specified in the method. More generally, for methods developed in 2003 or later, there exists a method development report that explains the development of the method, the rationale for each of the steps in the method, and whether or not particular parts of the method can be changed. Steve offered to assist anyone who needs to find the method development report for a specific method. Kim Kirkland noted that when new methods are developed, all of the supporting information is placed in the docket. The Notice of Availability explains how to obtain access to this information. The docket system was recently updated and is now easier to use.

October 7, 2010; 1:00 – 3:00 pm (ET)

The following is a summary of the Webinar participants' comments and questions and the speakers' responses.

- Donalea Dinsmore from Wisconsin asked Robin Segall about the Federal Equivalent Method for particulates. She and her colleagues have been told that they must use the exact instrument configuration in the Federal Equivalent Method approval without any modification; this can require expensive upgrades of equipment without any improvement in performance. She asked whether this was the intent of the Federal Equivalent Method. Robin responded that this topic was outside of her area of expertise and offered to obtain information from colleagues with greater knowledge of the subject. Donalea also commented that in the air program, every time a change is made in a method, it is necessary to obtain an entirely new method number, which leads to a cumbersome methods list. Identical methods using equipment from different vendors or even different model numbers of equipment from the same vendor have different method numbers. Donalea asked for guidance on when a new method number for a federal equivalent method is needed. Robin explained that the strictness of these requirements is partly driven by the extremely tight data quality objectives used in the ambient monitoring program to ensure the comparability of data. She offered to have someone with specific knowledge of these requirements contact Donalea directly to provide further information.

- Stephanie Dryer from Minnesota asked Steve Wendelken whether, in the Clean Water Program, programs and program partners are working together on procedures for reviewing method flexibility, or whether coordination is expected to occur through regional alternate test procedure (ATP) coordinators. Steve replied that the current preference is not to review any changes that are covered under the flexibility in 40 CFR Part 136 (136.6). He noted that some of the guidance that has been provided is confusing. Whether changes need to be reviewed depends on whether they are outside the scope of 136.6. Stephanie said that the issue of greatest concern to her involved obtaining data from the developer of a technology or method. Steve referred her to Lem Walker for further information.
- Mark McDermid of Wisconsin asked whether the information just presented included all of the situations where flexible monitoring is used or whether the situations described were merely examples. He asked whether there are other forms of flexibility and other opportunities for flexibility in various EPA programs. Steve replied that the development of flexibility is an evolutionary process. Opportunities are sought to make things as easy as possible. As new and emerging technologies come into use, situations may change. The current situation with regard to flexibility is not static or permanent. Lara Autry added that the current Administration's emphasis on technology innovation provides an impetus to create as much flexibility as possible. It is likely that increased flexibility will be seen in the years to come. However, in some instances, the laws that EPA administers do not leave much room for flexibility, and therefore some procedures cannot be made more flexible unless Congress changes the Agency's statutory authority.
- Sharon Robinson of the New Jersey Department of Health asked about the availability of slides from this Webinar and contact information for the speakers. Lara explained that after the series of four Webinars concludes, she will post the slides and related information on the FEM Web Site and send out an e-mail to inform Webinar participants of their availability.
- Scott Syers of Illinois asked why no representative from the wastewater program was included among the seminar speakers. Steve Wendelken explained that it had proved to be convenient to have him cover both of the water-related programs, with the understanding that he would relay Webinar participants' specific questions about wastewater issues to experts from the wastewater program if he could not answer them himself.

October 14, 2010; 1:00 – 3:00 pm (ET)

The following is a summary of the Webinar participants' comments and questions and the speakers' responses.

- John Smith, from Texas, commented that the greatest need of his group is training and assistance with evaluating Fourier Transform Infrared Spectroscopy (FTIR) reports. His group also is facing technology challenges because they are still accepting paper reports and have no good way of evaluating electronic reports. Robin Segall responded that this problem is recognized. This topic will be addressed in a workshop on emission measurement for state and regional personnel to be held in Research Triangle Park, NC, in December; that workshop should provide a better sense of the particulars of the issues involved. Robin will report to management that FTIR reports still are a key concern.

- John also noted that the use of ASTM methods is creating cost concerns. His office is not accustomed to budgeting for ASTM methods, but these methods increasingly are being used, at a cost of $40 to $50 per paper copy. Robin said that the Agency recognizes that the cost of ASTM methods is an issue. The National Technology Transfer and Advancement Act tells EPA to use ASTM methods when possible. Lara Autry added that she had just received a position paper recently written by the American National Standards Institute that specifically pertains to the incorporation of voluntary standards into government regulations and addresses the topics of retaining copyright protection and charging for the use of the methods. This paper raises the same issues that John raised but from the point of view of the voluntary organizations. Lara has forwarded this position paper to EPA attorneys and will inform John of ongoing developments on this topic. Robin added that accessing ASTM methods may be more efficient if an organization's library subscribes to them. John will investigate whether this would be possible for his library.
- Sherm Garrison of Region 3 (Maryland) noted that state legislative auditors often are inflexible about changes in processes from one program to another and asked whether the same situation exists at the federal level. Lara replied that her experience in working with the laboratory accreditation community indicates that there can be considerable differences among individual auditors. Efforts are being made to train people more effectively so that they are prepared to deal with increasing flexibility in programs, to develop templates and standards, and to achieve as much consistency as possible.

November 10, 2010; 1:00 – 3:00 pm (ET)

The following is a summary of the Webinar participants' comments and questions and the speakers' responses.

- Ron Mills of the California Environmental Laboratory Accreditation Program (ELAP) noted that Steve Wendelken had mentioned that expedited method approvals would take 9 to 12 months. Ron asked how the new, improved process differs from the previous one and how it helps to achieve the goal more quickly. Steve replied that the 9 to 12 months refers to the time for the actual approval process. A method can come in either through the Alternate Test Procedure (ATP) program or through another procedure for standard methods. After the ATP program reviews the method's technical content and recommends it for approval, the approval process begins. Previously, the only way to obtain approval was through proposal and promulgation, which is a multi-year process. Now, once the reviewer has determined that the method is ready for approval, it goes into the expedited methods queue, and as soon as there are enough methods in the queue, an action will begin. What is different here is that the signature authority has been delegated down from the Administrator to the Assistant Administrator level, which has cut years from the process. No legislative approval is required. Once the approval is signed, a notice is placed in the *Federal Register*, and the method is added to Appendix A of the regulation when it is re-published. A method approved in this way has the same legal status as one approved by the conventional process.
- Scott Hudson from Oregon commented that on a regional level, the ATP process for the Clean Water Act often has been site-specific, for one particular permittee. A laboratory may have to apply for separate approvals to use the same method for each of several permittees.

He asked whether this might be changed to a more method-specific approach. Steve replied that a broad regional approval is possible and offered to follow up with Lem Walker to obtain further information on this topic.

- Gina Grepo-Grove, the ATP coordinator for Region 10, commented that in her region, permits are performance based. If different facilities are using the same method, but with different modifications, supporting documentation must be submitted to demonstrate comparability.
- Jack Herbert asked Robin Segall where to look for guidance and rules when a proposal comes in for modification. Robin referred him to the Emission Measurement Center Web Site shown during the Webinar, www.epa.gov/ttn/emc, which has a guidance document on what an alternative test method approval request must contain. The regulatory provisions that address alternative test method approvals are in 40 CFR Part 63.7(f) and 40 CFR Part 60.8. In each of the Parts—60, 61, and 63—there are provisions that lay out how a facility owner or others can request an alternative test method. Jack asked whether these are the traditional procedures for obtaining alternative test method approval and Robin replied that they are; the procedures have not been changed except for the interpretation of whether or not broad approvals are possible. It has been decided and explained in a Federal Register Notice that as long as the processes and procedures in 40 CFR Parts 60, 61, and 63 are followed, broad approvals as facility-specific approvals are acceptable.
- Jack also raised the issue of audit samples, noting that the rules emphasize their importance but also state that audit samples are not required unless there are two commercial providers. There may be many methods for which there is only one provider or none, and EPA therefore would not require audit samples. Jack asked whether a state could require audit samples even if EPA does not or whether states could require proficiency samples as an alternative. Robin replied that states have the option of being more stringent than the federal program and therefore could require samples even if EPA does not, regardless of whether the emissions limit in question is federally mandated or state mandated. Jack pointed out that one rationale for not requiring audit samples unless there are two providers is that a single provider could charge a very high price. In practice, however, the prices charged in instances where a company is the sole provider of a test have been comparable to those charged in instances where competition is present.
- Cindy Gagnon of the Louisiana Department of Environmental Quality posed questions about the SW-846 manual. Is it the intention of EPA to change the guidance and to what extent? A chemist from the Office of Resource Conservation and Recovery replied that it depends on the matrix because measures are performance based. If laboratories intend to lower their limit, they have to demonstrate why they lowered it to a particular level. Normally, if a laboratory can meet or exceed a recommended level, the level should not be lowered without a good explanation. Cindy clarified that she was asking about standards, not the matrix. States may require a matrix spike. If laboratory control sample duplicates are required, it is much easier to pass than with a matrix spike. The chemist said that the laboratory control sample is another requirement. If a matrix spike is low, then matrix interference is present. The nature of the sample determines whether the acceptance criteria can be widened. Thus, decisions need to be made on a case-by-case basis. Cindy clarified that she was asking how much discretion states have when the guidance says that something “must” be done. Kim Kirkland replied that states have the authority to set parameters, as set out in their sample analysis plan or quality control project plan. Many of the methods were developed in the

early 1980s, when requirements were more specific, and the word "must" frequently was used. Today, as we review and revise our methods, we will address the use of the words "must" and "should" on a case-by-case basis and will remove the word "must", if and when it is appropriate to do so. In some cases, the use of the word "must" will be retained to ensure the accuracy of the method. Methods that are not required by the regulation can be modified, and quality assurance/quality control information may be adjusted, but the appropriateness of such changes must be demonstrated. Information on typical expected results should not be interpreted as requirements. Kim offered to discuss these issues further or provide written information if Cindy or others want to contact her individually.

- Richard Hepburn of the Alaska Department of Environmental Conservation pointed out the difficulties his jurisdiction faces when attempting to transport water and wastewater samples for some types of analyses to laboratories within the requisite time. This is particularly a problem for chlorine, where the method requires measurements within 15 minutes, which is not feasible in Alaska. The only other option is hand-held meters, but their lower limits of detectability are inadequate to meet some standards such as the aquatic life water quality regulations. Richard asked how much flexibility there is for the use of these types of instruments. Steve asked Richard to clarify whether he was discussing wastewater or ambient water. Richard clarified that he was discussing water at the point of effluent discharge into ambient water and noted that even with laboratory methods; the lower limit of detectability is barely adequate. Steve said that he would contact someone who could answer Richard's question by e-mail.

February 15, 2011; 1:00 – 3:00 pm (ET)

The following is a summary of the Webinar participants' comments and questions and the speakers' responses.

- Webinar participant Charles Simon asked how alternative performance methods could be verified when a current method is flawed for a particular application. Mr. Simon, who runs an emissions measurement laboratory for volatile organic compounds (VOCs) from stationary sources, said he is challenged by a specific situation. EPA Method 25 for measuring emissions was last updated in 1989, and he is trying to apply it to National Emission Standard for Hazardous Air Pollutants (NESHAP) Subpart Y emitted during marine fueling operations that have either a flare or an enclosed vapor combustion unit. Mr. Simon finds that Method 25 does not perform well when trying to measure gasoline or other VOCs at the 5 milliliter level. He has found that Method 25 does not handle anything above one-fifth that concentration. He would like to know how alternative methods can be verified given the difficulty of comparing it to a "base method." Mr. Simon said EPA's efforts to develop more accurate and applicable approaches for Method 25 ran out of funding, but that he has finished this research and presented it at professional conferences. His question is how verification would be carried out on the performance of an alternate method if the standard method is inherently flawed for a given application.

- EPA's Robin Segall replied that Method 25 is indeed one of the older, more prescriptive methods to count carbon and measure control efficiency. Ms. Segall encouraged Mr. Simon to gather information on developing alternative methods through EPA's guidelines available on the Office of Air and Radiation (OAR) TTN Web Site www.epa.gov/ttn/. Alternately, he could contact her via e-mail with the information to support the new alternative. She noted that as long as changes do not alter the ability to "show compliance," then EPA can pursue discussions on alternatives. The key is that any alternatives must be adequate to "determine compliance" and not change the regulation according to the mandates under 40 CFR Parts 60, 61, and 63 that EPA's Office of Air and Radiation (OAR) must follow.

February 23, 2011; 1:00 – 3:00 pm (ET)

The following is a summary of the Webinar participants' comments and questions and the speakers' responses.

- Webinar participant Al Verstoff, an independent consultant, asked if EPA's Office of Mobile Sources is participating in the "Flexible Approaches to Environmental Measurement" program. EPA's Robin Segall replied that she is unsure about recent developments but that the Office of Transportation and Air Quality (OTAQ) – its new name – did participate in efforts to field performance-based fuel tests in the 1990s and has worked to approve alternatives when it could not offer flexibility in its fuel measurement methods. EPA's Lara Autry added that in the 1990s OTAQ released a rule to develop performance-based criteria for measurements but is not aware of any more recent actions.
- Webinar participant John Phillips from the Ford Motor Company asked whether all EPA offices except the pesticide program and the Office of Resource Conservation and Recovery (ORCR) have "reference methods." Lara replied that the pesticide program has no reference methods per se but is making an effort to improve their measurement program. Kim Kirtland of ORCR said her office has some reference methods that allow you to go back to confirm a result generated by using a flexible or alternative method. ORCR reviews a number of methods depending on the analyte of concern. ORCR has a variety of approaches to the complex mix of analytes, matrices, and action levels it must evaluate, approaches that other countries have adopted. Robin stated that the reference method construct involves having a method-defined parameter where the only way you know that something has been measured correctly is by using the method. You would need a reference method to compare alternatives to those method-defined parameter methods. For other situations where reference materials can be used as a benchmark for testing whether a testing organization "got the right answer," reference methods are not as important. Mr. Phillips asked about a scenario where his organization uses a method that is not a reference method and the EPA or the state environmental agency measures the same media using the reference method. In such a scenario, if Ford got a different result, could Ford defend their finding in court using a flexible approach? Robin responded by saying it depends on the specific case. Some of these programs are

established with federal reference methods such as ambient air monitoring. EPA would probably say that your method needs to match the reference method in those cases. Mr. Phillips said Agency methods tend to have deference in court cases and so Ford tends to stick to reference methods as they are more defensible, reducing the value of the flexible and alternative measurements program. Robin said the Agency does have many older, quite prescriptive methods but is working to modernize them.

- Bob Schaffer of British Petroleum noted that he chairs the American Petroleum Institute's Test Method Working Group that is collaborating with OTAQ on a generic, alternative, Performance-Based Measurement (PBM) approach. Although developing this generic approach is still in progress, industry has had to file individual petitions with the Agency to make alternative measurements. In general, for the four programs presented in the Webinar, Mr. Schaffer asked how long it has taken to develop and approve PBM approaches. Greg Carroll of the Office of Water noted that his organization builds flexibility into its methods so they are a "continuing work in progress." After several years of attorney review, the technical and policy development and approval process has been about 1 ½ years to establish, secure management vetting, publish for public comment, and then finalize the administrative process. Robin said that the stationary source part of the air program has used the performance approach in its instrumental methods and performance specifications for continuous emissions monitoring for over 20 years. However, she acknowledged that it is not an instant process and that there are still a number of prescriptive methods that will need to be updated as resources allow. Kim said ORCR accepts flexible approaches more readily to keep up with technology and the interests of stakeholders. Lara said that the pesticide program in the 1990s provided some flexibility but has identified some programs, like antimicrobial testing, where more flexibility is warranted and work has continued on that for more than 2 years.
- Don Simmons of Iowa asked when the presentations given during the webinar will be made available to the public. Lara said they will be posted on the FEM Web Site on March 7, 2011.
- Gail with the environmental laboratory in the State of Montana asked about the 200.8 DRC method for water quality and when revisions to the method will be complete. Greg said his counterparts in the EPA Office of Research and Development are very close to completing the modifications to 200.8 and finalization is expected in the fall of 2011.

March 3, 2011; 1:00 – 3:00 pm (ET)

The following is a summary of the Webinar participants' comments and questions as well as the speakers' responses.

- Julie Gish, Columbia Analytical Laboratory, asked whether procedures under SW-846 Methods that include the word "must" are inflexible and mandated criteria. Kim Kirkland responded that this was correct, and that her office was drafting a new policy statement that will clarify some of these issues. The Office of Resource Conservation and Recovery (ORCR) is promoting the use of the most recent version of procedures because newer technology may exist. If the QA/QC criteria are changed, ORCR will outline those

changes in redline so users can determine if the change is technical or non-technical. She had a discussion with some people in the Office of Enforcement and Compliance Assurance (OECA) to ensure that they were not having any problem with methods that are considered guidance. OECA responded that most people follow the method to the letter. There may be some times when modifications are needed, but OECA did not believe that users would modify the methods inappropriately.

- Gayle Gliechauf, Thermo Fisher Scientific, noted that auditors have trouble in determining method flexibility. Steve Wendelken agreed that was a problem and that auditors have the authority not to accept a modification. That is one reason that the Office of Water is attempting to put the flexibility into the method itself so that it becomes clear within the method what is acceptable for flexibility and what is not, for example, "you may use any chromatography column mobile phase." It is difficult to write performance criteria that will be compatible with all of the technologies that may come along in the future. Auditors are becoming more comfortable with flexibility within a method than with a laboratory that makes a change based on the CFR's allowance of flexibility. Many auditors are not experienced analytical chemists, and when flexibilities are allowed, a skilled analytical chemist is needed to determine whether a process is acceptable or not. Ms. Gliechauf asked for advice for a laboratory that is trying to have flexibility and is running into an auditor that is uncomfortable with that. Steve responded that the laboratory should contact him. Sometimes his office is able to resolve these situations, and may have an interpretation of the language that the auditor has not considered. Sometimes the answer, however, will be "no, that is not an area in which we can allow flexibility." Mr. Gliechauf noted that in the case of clean water analysis (waste water), the states have more authority. Steve replied that this was because of the permitting process, and waste water has a different regulatory paradigm than drinking water. The drinking water program can do well with prescriptive methods, but a program like the Clean Water Act that has many matrices issues inherently needs some extra flexibility. That is what is happening with 136.6, but it is difficult because the confusion factor with post guidance is significant. Ms. Gliechauf expressed an interest in the future of 136.6 because her customers are reluctant to use it. Steve noted that as the performance-based measurement system (PBMS) evolved, his office received feedback that it was a good idea for wastewater, but not for the drinking water program.
- Eileen Wong, Los Angeles Department of Water and Power (LADWP) water quality laboratory, asked about the older methods that do not have flexibility built into them; do these have to be followed word by word? Steve responded that currently they did have to be followed, but that the office was examining the feasibility of creating a method update rule to amend old methods. There are limited resources, however, and the office's approach has been to incorporate flexibilities in anything new and if the resources become available, to fix some past methods. This may not happen in a timely manner, but laboratories may contact the Technical Support Center (TSC) if there is an issue that needs to be addressed quickly. If there is an older method that contains a step or procedure that is significantly outdated, the office has the ability to approve alternate methodologies that may avoid that step. Another participant from the LADWP water quality laboratory noted that the organization was a drinking water laboratory, and California is a primacy state, so the laboratory answers to EPA, a regulatory agency in the state of California, and the Environmental Laboratory Advisory Board (ELAB)

accreditation group. How will the laboratory let state regulators and auditors know that it has the "ok" from EPA to make a method change? Steve answered that the primacy agency, the state, would be authority on what the laboratory could do. Generally, if EPA approves a process, the primacy agency tends to concur with it, but they always reserve the right to be more restrictive. With minor changes, EPA can write an "acceptable version letter" that acknowledges to the primacy agency that the change that EPA has examined is so minor that the method is comparable to the old method. Usually, the states will accept that. The participant responded that an example would be chromium-6 in drinking water. EPA recently extended the allowed holding time to 5 days. The auditor, however, said that he had to look into this case. Steve replied that chromium-6 is not a regulated entity, so EPA has no authority to prescribe anything for it; that holding time is just a recommendation, but the state is free to say that there is a shorter holding time.

- Kim Kirkland noted that some of EPA's earlier methods that have not been updated since the early 1980s might use the terms "must" and "should" interchangeably. EPA has an ongoing project called the Fourth Edition, and is trying to remove all those methods that are not used anymore, consolidate the SW-846, and examine the instances in which "must" and "should" are used interchangeably.
- Cliff Baker, Continental Analytical, asked about the status of the proposed changes for the Clean Water Act published Thursday, September 23, 2010, in *Federal Register*. His company is interested particularly in the collision cell. Steve said he did not know the status because he works in the drinking water area, but knows that it is still moving along. He suggested that Mr. Baker visit the Water Science EPA Web page and see if there is anything posted there, or contact Lem Walker using the contact information on the slide.
- Roy at Corning asked if any audit sampling was available. Lara responded that the program that was being developed with the NELAC institute recently was completed, and the proficiency testing providers under that program may state whether audit samples are available on their Web sites. Robin Segall said she could forward an e-mail to Candace Sorrell, who is the expert on the topic.