

**SUMMARY OF THE
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
Monthly Teleconference Meeting: 866-299-3188/9195415544#
June 21, 2017; 1:00 – 3:00 p.m. EDT**

The U.S. Environmental Protection Agency's (EPA) Environmental Laboratory Advisory Board (ELAB or Board) teleconference was held on June 21, 2017. The agenda for this meeting is provided as Attachment A, a list of the participants is provided as Attachment B, and action items from the teleconference are included as Attachment C. The official certification of the minutes by the Chair or Vice-Chair is included as Attachment D.

ROLL CALL/INTRODUCTION

Dr. Henry Leibovitz, Chair of ELAB, and Ms. Lara Phelps, Designated Federal Official (DFO) of ELAB, welcomed participants and guests to the teleconference. Ms. Sally Paustian called the roll of the Board members and guests.

APPROVAL OF PREVIOUS MINUTES

Dr. Leibovitz asked for any comments about the May minutes; Ms. Kristen LeBaron will update the affiliation for Mr. Brad Meadows. Dr. Mahesh Pujari moved to accept the May 2017 minutes with the updated contact information; Mr. Meadows seconded the motion. The Board members voted unanimously to approve the May 2017 minutes with Mr. Meadows' updated affiliation.

OPENING REMARKS AND UPDATES FROM THE DFO

Ms. Phelps explained that the Board's charter has been reapproved by the General Services Administration for an additional 2 years; the approval will become official when it is filed on July 10, 2017.

FLEXIBLE APPROACHES FOR ENVIRONMENTAL MEASUREMENTS WEBINAR

Forum on Environmental Measurements (FEM) members provided to ELAB the webinar that they are presenting as part of a series to various audiences within and outside of the Agency.

Background

Ms. Phelps provided background on the effort, explaining that the performance-based measurement systems (PBMS) of the original performance approach were announced in the *Federal Register* in September 1997. In that notice, PBMS were 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." Each of the Agency's program offices took a different approach to implementation but were expected to achieve the following goals: address the lengthy approval process for new methods and method modifications, lower the barrier to the 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.

Instead of using prescriptive methods in implementation of the original performance approach, the Agency would set data quality objectives (DQOs) for measurement in the regulation, and affected entities would select appropriate, cost-effective methods, technology and/or procedures to meet these DQOs. Regulations would require that the method user document the quality of measurement and achievement of the DQOs and provide this information when submitting data. After 10 years, the FEM members, in conjunction with the expert program representatives for the performance approach, examined the results of the approach and determined that improvement was needed. The original PBMS framework had been set up as a “one size fits all” approach, which did not meet the needs of the individual program offices.

In 2007, the FEM recognized the different needs of the Agency’s programs and acknowledged that a single protocol for validation and quality assessment of measurements was not possible. A new approach was issued by the former Science Policy Council (now Science and Technology Policy Council) in February 2008. The four goals of Flexible Approaches to Environmental Measurement are (1) flexibility in choosing sampling and analytical methods/techniques; (2) development of new processes to validate that measurements meet quality requirements; (3) collaboration with stakeholders to develop validation processes for new measurement technology; and (4) rapid assessment of new technologies, methods and procedures. The intent of implementing flexible approaches is to make measurement requirements more flexible, allow varying levels of specificity according to the needs of each program, and reach stakeholders to describe and facilitate full implementation of Flexible Approaches to Environmental Measurement.

Office of Air Quality Planning and Standards (OAQPS) Program Advancements

Ms. Robin Segall (EPA) and Mr. Tim Hanley (EPA) presented about OAQPS program advances. The primary OAQPS programs requiring environmental measurements are the Stationary Source Program and the Ambient Air Monitoring Program. Under the Stationary Source Program, emission sources (e.g., industrial plants) conduct measurements to demonstrate compliance with emission standards. Under the Ambient Air Monitoring Program, state and local agencies conduct ambient monitoring for National Ambient Air Quality Standards. OAQPS has chosen an approach to promulgate test methods and performance specifications for continuous monitoring that provides flexibility by incorporating performance criteria (i.e., performance-based methods). The office found that the DQO approach was not feasible for the long-established compliance program for stationary sources because the regulated industry wants certainty in the required method.

Including performance criteria within methods provides the regulated industry and its testers and laboratories with a balance of flexibility and certainty, allows for advances in technology, provides information on data quality for each measurement program, and simplifies auditing and enforcement. Therefore, OAQPS is committed to using performance-based methods whenever possible. Performance-based methods minimize prescriptive procedures, use specific quality check procedures and criteria to assess user-selected technologies and procedures, and rely on reference materials (e.g., cal gases). Thus, the quality of the measurement is detailed within the method or performance specification. For example, performance criteria are used to assess bias, precision and sensitivity. Representative examples include Method 30B for mercury emissions

and Performance Specification 18 (40 CFR 60, Appendix B) for continuous monitoring of hydrochloric acid emissions.

OAQPS has established a nimble Alternative Test Method review process in which a delegated authority can approve or disapprove alternatives by official letter and can issue broadly applicable approvals. The office published the protocol to validate method alternatives (Method 301, 40 CFR 63) and publishes broad approvals on its website and in annual *Federal Register* notices.

For the Ambient Air Monitoring Program, Federal Reference Methods (FRMs) are performance-based wherever possible, and performance criteria are linked directly to program DQOs. The Federal Equivalent Method program, which sets forth a series of performance criteria to be met during the demonstration testing, allows for adoption of new methods and technologies as alternatives to the FRM. OAQPS collaborates extensively with state, local and tribal stakeholders to validate ambient air measurements and assess new technologies. The office has developed a flow chart of ambient air criteria method adoption and approval. Examples of how defining the acceptable performance of methods has led to an innovation or a new ambient air monitoring method include OAQPS approval of the Very Sharp Cut Cyclone sampler and a new ozone FRM using nitric oxide chemiluminescence. Additionally, 11 fine particulate matter continuous Federal Equivalent Methods have been approved since the performance criteria were promulgated in 2006.

Mr. Jeff Loewe asked about the timeframe for the office to evaluate the change in wind technology, including the testing and approval processes. Mr. T. Hanley responded that it took several years. The company's research and development took 2 years for approval as an equivalent method. The bulk of the dataset that EPA used to evaluate the technology against other methods was obtained during the following 3-year period when the company sold the technology to various users. The change to the FRM then was finalized in less than 1 year.

Office of Resource Conservation and Recovery (ORCR) Program Advancements

Ms. Christina Langlois-Miller (EPA) explained that 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). 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, flexible method selection for preparation and determinative methods, and method equivalency determination for required MDP methods through the "Equivalency Petition" process.

ORCR now has a streamlined SW-846 methods approval and availability process, published in 2016, that provides public involvement, easy access and improved communication. The streamlined approach does not apply to MDPs. ORCR also finalized the Update V methods package in August 2015. It includes an ORCR Policy Statement, 23 new and revised analytical procedures, and five updated guidance chapters. The update describes the Initial Demonstration of Proficiency Quality Control (QC) Practice and provides guidance on relative standard error,

lower limit of quantitation and blank contamination protocol. Update VI will have a phased release throughout the first half of 2017.

Dr. Leibovitz asked whether the revised methods had been implemented in regional programs with Quality Assurance Project Plans (QAPPs) in place and whether the QAPPs must be updated. Ms. Langlois-Miller thought that the QAPPs would need to be updated to incorporate the new method if significant changes had been made. Any QAPP revision requirements ultimately are the state's decision.

Mr. Meadows asked whether the Agency has a particular position on the use of the newer, evolving methods (i.e., is there a strong recommendation that laboratories use the newer methods?). Ms. Langlois-Miller indicated that EPA strongly advises use of the newer methods when possible on its website, but she was not aware if the Agency has a signed policy stating as such. Mr. Meadows noted that the state of California is following old methods; endorsement of use of the new methods by EPA would help the state move forward. Dr. Pujari commented that the state is moving toward new methods.

Ms. Deb Waller explained that the state of New Jersey only will be accepting use of the latest approved SW-846 methods within the next year.

Office of Water (OW) Program Advancements

Mr. Adrian Hanley (EPA) and Mr. Will Adams (EPA) presented about OW's program advancements. The Office of Science and Technology (OST) and Office of Ground Water and Drinking Water (OGWDW) incorporate substantial flexibility into Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) compliance monitoring methods. Because the need for flexibility varies between the programs, each program has developed unique approaches to provide method flexibility.

Many approved methods provide analysts the flexibility to make a modification without obtaining prior approval. 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. This embodies the spirit of the performance approach to method use. 40 CFR Part 136.6 builds on the flexibility specified in section 9.2 of EPA's 1600-series chemical methods. Wastewater methods may be modified 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 as effective, and the sample method performance should be comparable to that of the unmodified method. Examples of potentially allowable changes include automation of manual methods, changes to calibration range or equipment operating parameters, increasing purge-and-trap sample volumes, or using salts and inert surfactants to improve recovery. These changes, however, must be tested in the appropriate application/matrix, method performance must continue to meet method requirements, and changes and testing must be documented. Modifications not allowed are changes to the determinative step (e.g., the detector), changes to QC, changes that significantly alter the chemistry of the method, and some changes to methods that measure a method-defined parameter.

Part 136.6 has changed the CWA Alternate Test Procedure (ATP) Program in that developers who submit a CWA method modification to the ATP Program now must clearly explain why

their modifications fall 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 Part 136.6. This allows resources to be focused on novel methods instead of tweaks to existing methods. Modified Part 136 methods that already have an ATP approval letter may be used in the same situations as modified methods that will no longer have a letter because the modification falls within the scope of Part 136.6.

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, which 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. For example, 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. For example, 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 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. These methods are evaluated on a case-by-case basis, and the ATP program evaluates methods but does not approve them. Promulgation is through notice-and-comment rulemaking with expedited method approval. Submitted methods are evaluated individually by staff scientists with laboratory and method development experience, and 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 established the “Expedited Method Approval” approach to speed the approval of alternative drinking water test methods; methods approved through this process now are 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.

Dr. Leibovitz asked how important it is to capture the flexibility in the names of the methods. Some methods may be different but have the same name. Mr. A. Hanley explained that it is necessary to save all documentation, and this documentation should indicate the allowed modification that was used; this should address this issue.

Dr. Kitty Kong asked whether the sample preservation and holding time requirements are included in the flexible approaches. Mr. A. Hanley said that they are not included for wastewater methods. Mr. Adams confirmed that it is the same for drinking water.

Ms. Sharon Mertens asked whether the programs actively communicate with EPA regions and states to promote the innovative approaches that have been submitted to the programs. Mr. A.

Hanley explained that an ATP coordinator within each region responds to these types of inquiries from the regions. The office meets with the states a few times a year.

Mr. Mike Delaney asked about the status of the Methods Update Rule. Mr. A. Hanley indicated that it has been resubmitted and awaiting administrative signatures. He does not believe that it is a high priority at this time.

Office of Pesticide Programs (OPP) Program Advancements

In the absence of the OPP representative, Ms. Phelps explained that OPP has a flexible approach for meeting the data requirements for registering a product. The office 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. These methods are reviewed by OPP as part of the data evaluation process, and the office sets the method acceptance criteria. OPP guidelines provide the basic framework and criteria for the manufacturers to follow, including the specific format, data and performance requirements for their methods.

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*, which was finalized in June 2016. This 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. It also 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 from 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.

In 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 new accelerated study takes only 14 days to conduct, rather than 1 year, because it tests pesticides at an elevated temperature. 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.

In 2014, OPP worked to revise and improve Guideline 860.1630 for the Multiresidue Method because the original procedures and methods were considered cumbersome and based on outdated technologies and methodologies. With 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 Guideline for Multiresidue Methods* was completed in July 2014. It was designed as a living guideline that will keep up with rapid changes in technology and analytical instrumentation.

In 2015, OPP updated the science policy document, *Use of an Alternate Testing Framework for Classification of Eye Irritation Potential of EPA Pesticide Products*, which 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. The 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.

In 2016, OPP issued the final guidance, *Process for Establishing & Implementing Alternative Approaches to Traditional In Vivo Acute Toxicity Studies for FIFRA Regulatory Use*, which 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. 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.

Summary

Resources and information about this webinar and flexible approaches will be added to EPA's Environmental Measurement website at www.epa.gov/measurements. The Agency welcomes internal or external input for training material and additional educational resource needs.

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, Agency 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.

Ms. Mertens asked how many more webinars were scheduled. Ms. Phelps responded that the webinar will be presented two additional times in July; the session on July 10 will be open to the general public and those who have not yet attended a session. She also will present the information on the second day of the National Environmental Monitoring Conference (NEMC) in August. Representatives from a variety of organizations (EPA headquarters and regions, tribal nations, states, etc.) and from the public and private sectors have attended the previous webinars. When the webinar series is complete, the FEM members involved in the effort will review any feedback received. It also is important that this information remain available as staff retire.

Dr. Dallas Wait asked whether the slides would be made available. Ms. Phelps explained that they would be published on the EPA Environmental Measurement website at the conclusion of the series.

TASK GROUP UPDATES ON CURRENT TOPICS

The following open topics are on hold with no current updates: methods harmonization, selected ion monitoring and whole effluent toxicity testing.

Drinking Water Certification Officer's Course

Ms. Mertens reported that she understands that progress has been made toward addressing the concerns brought forth in January. She has been unable to obtain the details on these changes. She has been attempting to meet with Ms. Aaren Alger (Pennsylvania Department of Environmental Protection) to discuss the changes. It may not be necessary for ELAB to develop a letter depending on how the concerns have been addressed.

Cyanide Methodology

Dr. Delaney explained that he had revised the letter to EPA regarding cyanide methodology recommendations and provided the final letter to the Board. He requested a motion to approve the letter and submit it to the Agency. Dr. Leibovitz moved to approve the letter and attachment on cyanide methodology and submit the letter to EPA. Ms. Waller seconded the motion. The Board unanimously approved the motion. Dr. Delaney will provide a final cyanide presentation at the NEMC. Ms. LeBaron will format and finalize the letter and provide it to Dr. Leibovitz, who will send it to EPA.

In-Line and On-Line Monitoring

Mr. Michael Flournoy is awaiting a response from EPA.

Interagency Data Quality Task Force

The Interagency Data Quality Task Force held an internal meeting to discuss ELAB's letter; Ms. Phelps was unable to attend but is awaiting a report on the proceedings. She expects that the group will follow up with the Board.

NEW TOPICS/ISSUES FOR CONSIDERATION

Gas Chromatography/Mass Spectrometry Spectral Libraries

The gas chromatography/mass spectrometry discussion was deferred until the next meeting because of time constraints.

Additional Topics/Issues for Consideration

No additional topics were brought forth.

WRAP-UP/SUMMARY OF ACTION ITEMS

Ms. Paustian reviewed the action items identified during the meeting, which are included as Attachment C.

CLOSING REMARKS/ADJOURNMENT

The meeting was adjourned at 2:45 p.m.

Attachment A

**AGENDA
ENVIRONMENTAL LABORATORY ADVISORY BOARD
Monthly Teleconference Meeting: 866-299-3188/9195415544#
June 21, 2017; 1:00 – 3:00 p.m. EDT**

Call to Order/Roll Call/Introduction of Guests	Leibovitz/LeBaron
Approval of Prior Minutes	Leibovitz
Opening Remarks and Updates From the DFO	Phelps
Updates on Current Topics	

Drinking Water Certification Officer’s Course: Mertens
Cyanide Methodology: Delaney
In-Line and On-Line Monitoring: Flournoy

Open topics with no current updates:

*Interagency Data Quality Task Force/Data Quality Objective Process
Methods Harmonization
Selected Ion Monitoring
Whole Effluent Toxicity Testing*

New Topics/Issues for Consideration	Leibovitz
-------------------------------------	-----------

Gas Chromatography/Mass Spectrometry (GC/MS) Spectral Libraries

Continue discussion on request to ELAB to address existing inconsistencies across EPA methods (624, 625, 8270) regarding the requirements for GC/MS spectral library sources.

Wrap-Up/Summary of Action Items	Leibovitz/LeBaron
Closing Remarks/Adjournment	Phelps/Leibovitz

Attachment B

PARTICIPANTS LIST
Board Members

Attendance (Y/N)	Name	Affiliation
Y	Dr. Henry Leibovitz (Chair)	Rhode Island State Health Laboratories Representing: Association of Public Health Laboratories
Y	Dr. Michael (Mike) Delaney (Vice-Chair)	Massachusetts Water Resources Authority (MWRA) Representing: MWRA
Y	Ms. Lara Phelps (DFO)	U.S. Environmental Protection Agency Representing: EPA
Y	Dr. Kim Anderson	Oregon State University Representing: Academia—Oregon State University
N	Ms. Ann Bailey	EcoChem, Inc. Representing: EcoChem, Inc.
N	Dr. Brian Buckley	Rutgers Environmental and Occupational Health Sciences Institute Representing: Academia and Laboratory—Rutgers
Y	Ms. Patricia (Patty) Carvajal	San Antonio River Authority Representing: Watershed/Restoration
Y	Mr. Michael Flournoy	Eurofins Environment Testing USA Representing: American Council of Independent Laboratories
N	Dr. Keri Hornbuckle	The University of Iowa Representing: Academia—The University of Iowa
Y	Dr. Deyuan (Kitty) Kong	Chevron Energy Technology Company Representing: Chevron
Y	Mr. Jeff Loewe	NiSource, Inc. Representing: Industry—NiSource, Inc.
Y	Mr. Brad Meadows	Babcock Laboratories, Inc. Representing: Commercial Laboratory—Babcock Laboratories, Inc.
Y	Ms. Sharon Mertens	Milwaukee Metropolitan Sewerage District Representing: The NELAC Institute
Y	Dr. Mahesh Pujari	City of Los Angeles Representing: National Association of Clean Water Agencies
N	Mr. Elan Rieser	Con Edison Representing: Utility Water Act Group
Y	Dr. A. Dallas Wait	Gradient Representing: Consumer Products Industry
Y	Ms. Debra (Deb) Waller	New Jersey Department of Environmental Protection (NJDEP) Representing: State Government—NJDEP

PARTICIPANTS LIST (CONT.)
Contractors and Guests

Attendance (Y/N)	Name	Affiliation
Y	Ms. Sally Paustian (Contractor)	The Scientific Consulting Group, Inc. (SCG)
Y	Mr. Will Adams (Guest)	U.S. Environmental Protection Agency
Y	Mr. Adrian Hanley (Guest)	U.S. Environmental Protection Agency
Y	Mr. Tim Hanley (Guest)	U.S. Environmental Protection Agency
Y	Ms. Christina Langlois-Miller (Guest)	U.S. Environmental Protection Agency
Y	Mr. Joe Lapcevich (Guest)	First Energy
Y	Ms. Robin Segall (Guest)	U.S. Environmental Protection Agency

Attachment C

ACTION ITEMS

1. Ms. LeBaron will finalize the May meeting minutes and send them via email to Ms. Phelps.
2. Ms. LeBaron will format and finalize the cyanide methodology letter and provide it to Dr. Leibovitz.
3. *Outstanding action item from November 2016:* The Board will determine whether it will form a Task Group to review the Independent Laboratories Institute's document regarding the addition of microwave and interference-resolving technologies to Method 200.8.

Attachment D

I hereby certify that this is the final version of the minutes for the Environmental Laboratory Advisory Board Meeting held on June 21, 2017.



Signature, Chair

Dr. Henry Leibovitz

Print Name, Chair