#### SUMMARY OF THE ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING Teleconference February 21, 2007; 1:00 – 3:00 PM EDT

The Environmental Laboratory Advisory Board (ELAB) meeting was held via regular teleconference on February 21, 2007 from 1:00 - 3:00 PM EDT. The agenda for this meeting is provided as Attachment A. A list of participants is given in Attachment B. Action items are included in Attachment C. The official signature of the Chair or Vice-Chair is included in Attachment D.

### INTRODUCTION

Ms. Lara Autry (USEPA/ORD) welcomed Board members. Ms. Autry then handed the meeting over to the ELAB chair, Mr. Robert Wyeth (Severn Trent Laboratories), who took a roll call of the Board. There were no guests that participated in the call.

## AGENDA ITEMS

### APPROVAL OF OR CHANGES TO PREVIOUS MEETING/CALL MINUTES

Minutes from January 17, 2007 meeting –Mr. Wyeth asked members if they had any comments or corrections to the minutes. There were no changes or comments to the minutes.

Minutes from the Face-to-Face meeting – Versar noted that the summary of the meeting had been sent to Mr. Wyeth. Mr. Wyeth will review the minutes and send them to ELAB members.

Minutes from Open forum - Mr. Wyeth noted that the he had received the minutes written by Ms. Autry. Ms. Autry indicated that she had sent the minutes to all members. Mr. Wyeth will review the open forum minutes.

### WORK GROUP CORRESPONDENCE TO FEM

### Performance Approach

Mr. Wyeth asked Ms. Autry to summarize ELAB's role in regards to providing information on Performance Approach to the FEM. Ms. Autry noted that the FEM will hold a half-day session on Performance Approach in early April. The FEM would like to hear ELAB's thoughts and opinions regarding the Performance Approach. ELAB can present to the FEM existing materials on Performance Approach or prepare a new document citing these other materials. She noted that at the face-to-face meeting ELAB members identified some areas related to Performance Approach that should be addressed. The areas where divided up among the three ELAB workgroups and people volunteered to cover certain topics. She noted that she had sent an e-mail on February 6 noting the writing assignments.

Mr. Lowery noted that his workgroup wrote a short paragraph on the subject. This paragraph can be included in a letter to the FEM with references to existing background materials. Ms. Autry noted that a 2-3-page document with supporting background materials should be fine.

Ms. Morgan asked how ELAB will promote the Performance Approach; whether it is Performance Approach in regards to modifications to existing methods or development of new methods. Mr. Wyeth noted that ELAB should be talking about both approaches. It was noted that the data quality proof needed for a modified method is similar to the one needed for new methods. Mr. Wyeth noted that a few years

ago he and other ELAB members wrote a document on PBMS implementation for NELAC that discusses this issue of what is required for a new method versus a modified method. Ms. Morgan noted that she believes that new methods require more documentation and proof compared to a modified method. She also stated that the real concern with formulating new methods is giving laboratories the latitude to do whatever they want since some labs are not good even though they are certified. It was noted that it is the job of the Accrediting Authorities to determine that the labs are able to do their jobs. Ms. Morgan noted that no all laboratories are audited by Accrediting Authorities. It was suggested that this issue be discussed in the letter. It should be emphasized in the letter that any lab doing work under a regulation needs to be accredited.

Mr. Wyeth indicated that the ELAB letter should discuss the advantages and limitations of Performance Approach. Performance approach can be a solution to the problem of labs not been accredited. He stated that he believes that if a lab is going to use a performance approach the lab would need to have even more documentation that what is required for normal accreditation. Ms. Morgan noted that there is still the problem of who is going to check that the labs have proper documentation. Mr. Wyeth suggested that ELAB make a recommendation in the letter for the use of third-party auditors in states that do not have an accreditation program.

Mr. Jordan noted that Rock Vitale had sent some information on Performance approach and timely regulatory approval. It says that regulators would need to assemble a significant number of technical reviewers to review requests for new methods and methods modifications. Mr. Wyeth indicated that ELAB may need to address the issue of managing the cost in the letter to the FEM. He noted that labs need to understand that Performance approach will have an impact in the cost of accreditation. It was noted that it is important to take a look at anything that increases the cost of doing business for environmental labs. With accreditation, the cost of doing business has increased over the years and that is why some states do not want to participate in the accreditation program. Thus, it is important to make sure that every data item ELAB is asking for is required and would provide the information that is needed. It was noted that some PTs don't have any value added service.

Regarding review of internal processes, it was noted that it would be useful to look at how international organizations deal with this issue from an ISO viewpoint. Mr. Wyeth indicated that European countries use ISO and are more performance oriented than the U.S. It was noted that most of the ISO documentation allows for use of any methods but certain data quality objectives need to be met. As long as the data quality objectives are met the data is acceptable. Data are not generally qualified under that system; data either passes or not.

Mr. Scot Cocanour noted that based on his Internet research, Canada, countries of the European Union and Asia do not concern themselves with the minutiae of methodology detail. Organizations in these countries are data quality objective oriented. It was suggested that this issue be communicated in the letter to the FEM on performance approach. If the American system is to be viewed as synonym to the systems in other countries, the NELAC program needs to be in conformance with what other countries are doing. It was noted that the NELAC standards is not ISO compliant.

Ms. Morgan asked about round robin as it relates to Performance Approach. She noted that round robin is generally performed when formulating or bringing a new method to the market. Mr. Wyeth noted that ASTM performs round robin for verification of methods and the end result is a prescriptive method. There is also the issue of a lab not wanting to give away potential trade secrets for producing sound data points. Ms. Morgan asked whether proprietary methods are something that should be promoted. It was noted that once a method is audited by a regulator is not longer proprietary. However, if a lab states that information is business confidential the government has the obligation to make sure the information is

kept confidential. One member noted that trying to extend the Performance approach to cover proprietary information at the beginning is a mistake since it will create confusion.

Mr. Wyeth asked ELAB members whether the letter should include discussion on new methods and technologies. It was agreed that the letter should discuss only modifications to existing methods. Ms. Autry suggested that ELAB write a report to cover all these issues instead of just a letter. The letter can be just used to transmit the document. Mr. Wyeth agreed that this is a good suggestion.

Mr. Wyeth asked if there were other topics the group wanted to discuss. With regards to usability and data quality objectives, it was noted that a lot of existing methods can not meet what people assume the data quality objectives really are. For some methods for volatiles it is not possible to get the expected recoveries. An advantage of Performance Approach over the existing system is that the lab needs to demonstrate that the defined data quality objectives have been met. It was noted that in his write-up, Mr. Dechant's recommendation is that EPA needs to define the basic validation statistics needed to support the quality assessment. Mr. Wyeth asked whether this means that for all types of measurements EPA is expected to provide some level of reference criteria for precision, for example. It was noted that for the radiochemistry methods there are PT tables that basically serve as minimum DQOs. Mr. Dechant noted that from the Q9 and usability prospective, it is important to have guidelines on how to set up and evaluate if a modified method performs as the established methods and if the methods does what the analysts needs it to do. Mr. Wyeth indicated that if the DQOs are set up properly it may not be necessary to evaluate if the modified method performs as the established method. Mr. Dechant noted that there may be different types of DQOs: one DQO may be to have  $\pm 5\%$  bias and 30% precision; another DQO may be to meet the NPDES permit. He believes most DQOs will fall in the second category. When a DQO references a regulatory method, the analyst needs to prove that his procedure is comparable. He noted that the question is how the permit writer is going to define what is needed for a Performance Approach prospective. For this reason, EPA needs to provide at least general guidance to permit writers. Mr. Dechant noted that one of the issues with Performance approach is that data users will have to understand chemistry. He indicated that it may be necessary to phase in the implementation of Performance Approach. Mr. Wyeth indicated that this is something that should be mentioned in the letter to the FEM.

Regarding the liability/responsible party issue, Mr. Wyeth noted that if Performance approach is applied properly it can reduce liability because there would be more confidence on the data. In the Performance approach it would be known if the data quality objectives were met. Currently, it is only assumed that data quality objectives are met. Mr. Jordan indicated that he will draft some language to discuss the issue of liability/responsible party.

Ms. Morgan noted that the burden of proof for validation of method modifications should mimic the typical method validation requirements needed for a new method. For validation of method modifications it will be necessary to do comparison studies and performance testing. The value and the validity of a particular change need to be documented. Mr. Wyeth noted that the requirements may be more elaborate than just running the MDL and doing comparability studies as it is done now. This will increase the costs of doing business. Ms. Morgan noted that the process can be made as simple or as complicated as one wants to, but it is a matter of deciding what is reasonable and acceptable. One member asked if a comparability study is really needed. Ms. Morgan noted even if one assumes that a method has been demonstrated to work with different matrices it is important to show that the modified method also works for the matrices.

Regarding the issue of implications, it was noted that Mr. Joe Pardue and members of his workgroup have already written some language on the issue. Mr. Wyeth asked that this information be shared with the rest of ELAB members.

It was agreed that the workgroups will produce a first draft of their write-ups by March 8.

## WORK GROUP REPORTS

This topic will be discussed at the next meeting.

## PENDING AND NEW BUSINESS

## TNI update(s)

Ms. Morgan noted that her workgroup met with Ms. Lynn Bradley at the TNI meeting and discussed method acceptability. According to Ms. Morgan, Ms. Bradley suggested that ELAB write a letter or make a comment to the FEM about having Regional representatives at these meetings. It was noted that the workgroup should continue communicating with Ms. Bradley regarding the methods compendium. Mr. Wyeth asked whether a statement indicating that ELAB supports and encourages the continued participation of the Regions should be included in a letter to EPA if there is a follow-up to the Dr. Gray's letter. Ms. Autry noted that TNI will discuss the issue of Regional involvement in its presentation to the FEM in April. If ELAB supports that message then ELAB can also include a statement about this if there is a follow up letter to Dr. Grey. ELAB can also express its support for Regional involvement in its presentation to the FEM.

Ms. Autry also noted that TNI had a very successful meeting in Denver. There is a little bit of frustration that there are still a lot of things to do for full transition but for the most part people were very impressed with what has been done so far. She noted that it is very encouraging that TNI plans to ask the FEM for a formal member of the Agency to be a liaison member of the board.

# **Open Forum and Denver Face-to-Face**

**ACTION:** Mr. Wyeth will review the minutes from the open forum and face-to-face meetings. He will send the minutes from the face-to-face meeting to all ELAB members.

### Web Site Work Group

This topic will be discussed at the next meeting.

### Letter to Dr. George Gray

Mr. Wyeth noted that the letter has been sent to Dr. Grey.

### FAC on Detection and Quantification

Ms. Autry noted that the FAC has not met recently. The group is done with the data collection.

### Issues Spreadsheet

Mr. Wyeth asked ELAB members to continue to record the completion dates on the issues.

### **COMMENTS AND/OR ADDITIONAL ISSUES**

There were no comments and/or additional issues.

# ADJOURNMENT

Mr. Wyeth adjourned the Board meeting at 3:00 p.m. EST.

#### AGENDA ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING

# February 21, 2007; 1:00 – 3:00 PM EDT Conference Call Call in number: 1-866-299-3188; code 9195415544#

	Торіс	Individual	
		Responsible	
1	Opening Remarks	DFO	
2	Role Call for ELAB Member	Chair	
	Introduction of Guests		
3	Approval of or changes to Previous Meeting/Call Minutes	Chair	
	• January 17, 2007		
	Denver Face-to-Face and Open Forum		
4	Work Group Correspondence to FEM/Response form EPA	Chair	
	Performance Approach	DFO	
5	Work Group Reports – Definitions and assignments	Chair	
	Monitoring Work Group	Morgan	
	Laboratory Management Work Group	Flowers	
	Letters reference NELAP		
	Measurement and Technology Work Group	Lowry	
	PA document		
6	Pending and New Business		
	• TNI update(s)	DFO	
	Open Forum Issues	Chair	
	Web Site Work Group	Banfer/DFO	
	• FAC on Detection and Quantification	Pletl/Thomey	
	Issues Spreadsheet	All	
	1. Corrections and/or updates to spreadsheet		
	2. New issues		
7	Comments and/or Additional Issues All		
8	Open Discussion and Comments from Guests All		
9	Adjourn/Closing Remarks Chair/DFO		

Attendance (Y/N)	Name	Affiliation
· · · ·	Mr. Robert (Bob) K. Wyeth (Chair)	Severn Trent Laboratories
Y		Representing: ACIL
Y	Ms. Lara P. Autry, DFO	US Environmental Protection Agency
ĭ		Representing: EPA
V	Mr. Gerald (Gary) Dechant	Analytical Quality Associates, Inc.
Y		Representing: DOE Analy. Mgmt. Pgm.
N	Mr. Paul Banfer	EISC (Environnemental Info. Sys. Corp.)
Ν		Representing: Information Systems
V	Mr. James (Jimmy) Jordan	Bechtel Jacobs, Inc.
Y		Representing: Large Go's Contractors
NT	Ms. Nan Thomey	Environmental Chemistry, Inc.
Ν		Representing: Small Laboratories
NT	Mr. Rock Vitale	Environmental Standards, Inc.
Ν		Representing: Third Party Assessors
37	Mr. Eddie Clemons	Golden Specialty Laboratory
Y		Representing: INELA
	Mr. Scot Cocanour	Promium
Y		Representing: Lab. Customers of Information
		Technology
37	Dr. Jeff Flowers	Flowers Chemical Laboratories, Inc.
Y		Representing: Elected Officials for Local Gvt
	Dr. Reza Karimi	Southwest Research Institute
Ν		Representing: Non-profit Research and
		Development Organizations with Academia
V	Mr. Jeff Lowry	Environmental Resource Associates
Y		Representing: Proficiency Testing Providers
37	Ms. Judy Morgan	Environmental Science Corp.
Y		Representing: Commercial Env. Lab.
N7	Mr. Joe Pardue	Parallax, Inc.
Y		Representing: Clients of QS Services
Ŋ	Dr. Jim Pletl	Hampton Roads Sanitation District
Ν		Representing: Municipal Env. Lab.
<b>X</b> 7	Dr. Albrecht Schwalm	Oglala Lakota College
Y		Representing: Academic & Indian Nations

## MEMBERSHIP LISTING AND GUESTS ELAB MEETING February 21, 2007; 1:00 – 3:00 PM EDT

# Attachment C

# **ACTION ITEMS**

- 1. Mr. Wyeth will review the minutes from the face-to-face meeting and send them to ELAB members. Mr. Wyeth will also review the open forum minutes.
- 2. Workgroups will produce a first draft of their write-ups by March 8.
- 3. ELAB will continue to communicate with Ms. Bradley regarding the methods compendium.

Attachment D

I hereby certify that these are the final version of minutes for the Environmental Laboratory Advisor Board Meeting held on February 21, 2007.

atkoyth

Signature Chairman

Robert K. Wyeth

Print Name Chairman