SUMMARY OF THE ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING

Teleconference: 866-299-3188/9195415544# May 18, 2011; 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 May 18, 2011, from 1:00 to 3:00 p.m. EDT. 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.

AGENDA ITEMS:

1. OPENING REMARKS

Ms. Judy Morgan, Chair of ELAB, and Ms. Lara Autry, Designated Federal Officer (DFO) of ELAB, welcomed participants to the teleconference. Ms. Morgan called an official roll of the Board members and guests.

2. APPROVAL OF APRIL MINUTES

Ms. Morgan asked whether there were any changes to the April 2011 Board minutes; there were none. Mr. Dave Speis moved to accept the minutes, and Dr. Jeff Flowers seconded the motion. The Board unanimously approved the April minutes with no further discussion.

3. NEW DEVELOPMENTS/DISCUSSION

The Board discussed the proficiency testing (PT) issue and the letter to EPA that the Measurement and Technology Workgroup had developed. Mr. Jeff Lowry reminded the members that discussions started with Mr. Greg Carroll (EPA) in 2009, and at that time, a decision was made to send a questionnaire to Mr. Carroll's staff to share with the regions regarding the PT issue. As a result of the answers received from the questions, the Workgroup identified three topics of interest to discuss with Mr. Carroll, which are outlined on the second page of the letter. Mr. Lowry explained that the Workgroup is seeking input from the full Board regarding these topics.

Mr. Speis thought that the suggestions that were based on the regional input were good, although what he read in regard to state input did not agree with his personal experiences. He has not witnessed the regions reaching out to the state and laboratory communities to perform the activities that the regional questionnaire suggested. Mr. Lowry agreed that he had found some of the answers to be rather unexpected. Mr. Speis reiterated that he supported the recommendations in the letter. Ms. Morgan thought that the letter was well written and that the suggestions were sound. Dr. Flowers thought that editorial changes needed to be made to the letter. Also, he did not agree with the recommendations, because the Office of Water (OW) already has indicated that it will not adopt the two-PT standard. Mr. Lowry asked when OW had stated this. Dr. Flowers thought that Mr. Carroll had stated at several national-level meetings that OW would

ELAB Meeting 1 *May 18, 2011*

not adopt the two-PT standard¹, which will increase workloads, and by recommending that OW adopt The NELAC Institute (TNI) standards, ELAB essentially is recommending this. Dr. Reza Karimi noted that the issue was whether these are the right suggestions (i.e., there is a scientific basis for them), not whether they will be adopted.

Mr. Speis explained that the current suggestion was to adopt the TNI quality systems standards. Ms. Morgan thought that OW was looking to standardize the quality systems with the TNI standards and replace portions of the certification manual, with the office providing only technical requirements; it was not necessarily an adoption of the two-PT standard as much as it was the quality systems portion of the TNI standards. Mr. Speis agreed with this assessment. Ms. Morgan said that she did not think that Mr. Carroll intended to consider PT frequency; the goal is to have better quality standards, and the TNI quality systems standards would be an improvement for OW. PT frequency is not addressed by the current suggestion. Dr. Flowers thought that this needed to be made more clear in the letter. He asked whether the current recommendation is to adopt the quality systems component of TNI, with OW specifying the technology requirements of the program. Mr. Jack Farrell noted that this recommendation is consistent with the prior suggestions that ELAB has made to the Agency regarding quality systems standards.

Ms. Michelle Wade noted that the PT frequency issue was not addressed in the letter; Mr. John Phillips agreed. Ms. Silky Labie thought that if the letter suggests that EPA "adopt the quality systems portion of the TNI standards," this would be different from the PT portion and clarify the recommendation. Mr. Lowry read a portion of the letter that already included this language. Ms. Labie thought that the way it the letter was stated, the implication was that ELAB is suggesting that EPA adopt all of Volume 1, when it should only be Modules 2 through 7 (i.e., the quality systems standards). Dr. Flowers thought that there was a problem with at least one important accreditation body (AB), which has refused to use Module 1 of Volume 1. It was his understanding that the TNI standards needed to be revised to accommodate the AB; therefore, if EPA also adopted this module, it would disenfranchise this AB. Mr. Farrell suggested the following language: Any program or technical requirement specific to the drinking water program could still be contained within the Drinking Water Certification Manual. This language would provide the Agency with plenty of freedom. Mr. Speis said that ELAB sent a letter to EPA this year stating the same idea; the prior language could be used for the current issue. Mr. Lowry responded that he had used the prior language to create the letter to Mr. Carroll so that the message was consistent.

Mr. Farrell asked why, if the Board already has provided this recommendation to OW, ELAB was providing another recommendation. Mr. Lowry explained that many of the responses received from one of the survey questions precipitated the recommendation, which is slightly different from the quality system standards recommendation. Mr. Farrell asked, if ELAB is not recommending inclusion of Volume 1, why this is in a letter regarding the PT issue. Mr. Lowry explained that it addresses the question of what is a requirement versus guidance in terms of the PT issue.

Ms. Morgan thought that there had been a statement made regarding the regions relying on TNI requirements over the providers, which may be part of the relationship. Mr. Farrell reiterated that

¹ ELAB does not endorse the accuracy of this statement.

adding a sentence about allowing OW the freedom to designate the program and technical requirements in its Drinking Water Certification Manual would provide the needed clarification. Mr. Speis thought that the language was consistent with the quality systems component. The quality systems component of Volume 1 is completely separated from the PT issue in that it does not mention frequency. Dr. Flowers suggested that the letter recommend adoption of Modules 2 through 7, but Mr. Farrell was not comfortable explicitly excluding Module 1. Ms. Morgan suggested that OW adopt Volumes 2 through 6 "at a minimum" (Volume 7, regarding toxicity, does not apply). Mr. Speis was uncomfortable specifically stating this because ELAB had not stated this previously; he thought that the current language of the letter was adequate. Dr. Flowers thought that it would be a good change because it would provide clarity to the letter; in his opinion, clarity is more important than historical consistency.

In response to a question from Ms. Morgan regarding editorial changes to the letter, Ms. Wade pointed out that the signature block needed to be changed to Ms. Morgan's name. Ms. Morgan suggested that Mr. Lowry make the discussed clarifications and then send the letter out for Board approval via e-mail. Ms. Kristen LeBaron of The Scientific Consulting Group, Inc. will forward to Mr. Lowry via e-mail the language that Ms. Morgan and Mr. Farrell suggested during the meeting.

Mr. Farrell did not think that the value and purpose of PT had been defined. Ms. Morgan explained that the Measurement and Technology Workgroup has had significant conversations with the regions and OW, and the common denominator within these discussions is that PT is a tool to accompany an assessment. Mr. Farrell said that PTs are used for more than just acceptance results and numbers; PTs are tools that help the AB have confidence that the laboratory can continue to perform and meet requirements between the time periods in which the AB cannot perform an onsite assessment. He did not think that ELAB had officially concluded this or, if it had, expressed this conclusion. Mr. Lowry explained that the work regarding this issue was being performed in his Workgroup in terms of acceptance limits. Ms. Morgan did not think that ELAB needed to discuss the issue further as OW does not appear to see it as an issue. Dr. Karimi moved to approve the letter via e-mail once Mr. Lowry made the suggested changes. Ms. Wade and Mr. Phillips seconded the motion, which was passed unanimously.

The Board members next discussed how to market ELAB. Ms. Morgan explained that a small working group comprised of Mr. Speis, Dr. Michael Wichman, Ms. Patsy Root, and Ms. Morgan had volunteered to draft a letter to market the value and expertise of ELAB. The goal of the letter is to explain to the Agency the Board's role, highlight the combined expertise of the members, and emphasize that ELAB would like to be actively involved during the rulemaking process prior to rules being published in the Federal Register. The release of the letter will be coordinated with the release of the revised ELAB charter. The working group met via conference call and decided to improve the ELAB website to better feature the Board's accomplishments and its current involvement in the laboratory and regulatory communities. The current website does not fully indicate the expertise, involvement, and accomplishments of the Board. Mr. Speis explained that the letter still is being drafted, and when it and the revised charter are finalized, they will be forwarded to the Board members. Ms. Morgan stressed that Board member involvement in improving the ELAB website is critical. Input from the members regarding the content and design of the website is highly encouraged. The EPA website has improved considerably during the past year, and it would be beneficial for ELAB to improve its site as well. The ELAB logo also may be updated.

ELAB Meeting 3 May 18, 2011

Dr. Flowers stated that the Laboratory Management Workgroup completed the review of the key evaluation factor matrix; this review was sent to the Board members. The next step is to assign specific topic areas to the appropriate Workgroups so that they can be addressed; the full ELAB should decide which topics are important to pursue. Mr. Speis added that the intent is not to fill in all of the blocks on the spreadsheet—it is to provide the members with an idea of the topic areas and next steps. The first step in the process would be to obtain stakeholder input from the groups that the Board members represent (e.g., Mr. Speis represents the American Council of Independent Laboratories) and from this input develop a general idea of a good remedy for some of the issues that NELAC is facing. The issues can be consolidated, and ELAB can make a determination regarding whether it will make a recommendation to EPA if the Board determines that the Agency could help remedy some of the problems and challenges. Mr. Farrell asked for clarification regarding whether this effort was about implementation of a national accreditation system and not about the standards themselves. Dr. Flowers confirmed that this was the case and reiterated the assignment given by ELAB to the Workgroup. In response to a question from Ms. Morgan, Dr. Flowers responded that e-mail input from the Board members would be acceptable.

4. UPDATES

Dr. Jim Pletl provided an update regarding progress on the Sufficiently Sensitive Methods Rule. The Task Force held a conference call with EPA staff members on March 30, 2011, and during the April ELAB meeting, the Board members agreed to develop a thank-you letter and explain some of its concerns. The letter recommended to EPA that ELAB be included earlier in the rulemaking process and that the Board looked forward to working with the Agency in the future. ELAB also provided the requested data regarding the cost associated with the various technologies that may result from the rulemaking. Ms. Morgan sent the letter and data to Ms. Kathryn Kelley (EPA) and Mr. James Hanlon (EPA) on April 28, 2011. No response has been received to the electronic or hard copies that were sent. Ms. Morgan added that this effort was a driver for the ELAB marketing effort. As was highlighted in this case, Board involvement following publication limits the ability to affect change. Ms. Morgan hopes that the effort to reach out and reintroduce ELAB will be effective in allowing the Board to be actively involved during the proposal process and prior to publication in future EPA rulemaking efforts.

Dr. Flowers provided an update regarding the Methods Update Rule. He spoke with Mr. Lemuel Walker (EPA) and was informed that the Agency was narrowing the responses it had received. The Office of General Counsel (OGC) will review the effort to ensure that it is fair and equitable. The Agency is reviewing the proposed and final rule that will be brought forward and hopes to complete this by the end of June 2011. EPA is required to answer all questions (e.g., Why is quality assurance/control needed?). Although some of these questions may not be considered rational, OGC requires the office to respond to them. The goal is to publish the rule by late September or early October 2011.

Dr. Flowers had nothing to report regarding Improving EPA Regulations, which was a finite effort on the part of the Board.

Ms. Root provided an update regarding Recreational Water Quality Criteria Development. There will be a stakeholder meeting on June 14–15, 2001, in New Orleans, Louisiana. Ms. Root will

ELAB Meeting 4 May 18, 2011

not be able to attend, but she has contacts who will be presenting at the meeting. She is trying to determine whether they are presenting on implementation, and if so, Ms. Root will provide this information to the Board members during the June ELAB meeting.

Ms. Morgan explained that the Monitoring Workgroup did not meet in May, but there will be a June meeting prior to the full Board meeting. The Workgroup members will discuss the Recreational Water Quality Criteria Development issue to help inform the issue as it moves forward. Ms. Root suggested speaking to Dr. Julie Kinzelman (Racine Health Department). Dr. Flowers asked whether a method had been proposed. This may cause a good deal of problems, as the method would have to be very general. Ms. Root explained that two methods involving entorococci and *Bacteroides* were listed on the EPA website and have been through the ETV process, although they are not associated with a specific rule.

5. OTHER BUSINESS

Ms. Morgan brought the members' attention to the public comment received via the ELAB website from Mr. Ken Smith regarding Method 29 and asked the Board members whether they thought that this was an issue that ELAB could/should address. A member thought that there needed to be consistency, and this was perhaps an issue that the Board could address. Ms. Morgan wondered which organization would be appropriate to address because there are no true PT requirements. Because this is an air method, Ms. Morgan was unsure about the requirements; if this is an issue that the Agency can address, perhaps guidance could be issued. An ELAB member noted that EPA's Air Program is very particular in its requirements. Ms. Morgan remarked that the comment is that there is a discrepancy in how the PT provider is determining the concentrations for the PT, which causes different ranges for the results. Mr. Eddie Clemons suggested that Air Program staff could be consulted regarding this issue. Ms. Morgan agreed and thought that this issue could result in additional problems; there is a lack of consideration or requirement to report preparation methods, and some are more rigorous than others. This will be very challenging to investigate despite the fact that it probably is a relatively frequent occurrence. A Board member noted the need for information (e.g., stoichiometric) to be supplied to run the method properly. Dr. Richard Burrows said that there could be a difference between microwave and Method 50 for a real sample but was surprised that there is a difference in terms of PT.

Dr. Flowers asked to whom the data were being submitted. Mr. Clemons thought that it was the State of California; it is not EPA. Perhaps the commenter should address this with his PT provider. Dr. Flowers said it was appropriate for ELAB to advise EPA, not the State of California.

Ms. Morgan asked whether any Board members had similar experiences or experience with air issues. Mr. Speis thought that Mr. Lowry might be able to help in this area. Although this example may be specific to the State of California, the broader issue is how the ranges are being established, which is an issue appropriate for ELAB. Dr. Karimi wondered whether anything in the TNI Standards addressed this issue. Ms. Morgan was not aware of any. Dr. Karimi thought that the Board could adopt the topic from this angle. The Board discussed whether anything in Volumes 2, 3, or 4 might have relevant information. Mr. Speis was sure that this is an issue, but he was unsure whether it was appropriate for ELAB to adopt under the charter or if EPA even

ELAB Meeting 5 *May 18, 2011*

has any control. Ms. Morgan agreed that this needed to be determined. Mr. Clemons thought that perhaps it could be addressed by communicating with the PT organization within TNI because California conforms to these requirements. Ms. Labie stated that not all of California conforms, and other Board members agreed with her.

Mr. Farrell reported that he had glanced through Method 29, and it appears to focus on Parr Bombs or microwave. Dr. Karimi said that the claim is that the PT provider is not using this, so there will be discrepancies between the two methods. Is this a general problem or just this specific instance? Ms. Morgan noted that without any other complaints being received, it is difficult to determine how widespread the problem is and whether there are effects. A Board member explained that he has studied this extensively, including publishing on the subject, and there are many effects on sample preparation. The fundamentals are very different but have been ignored; this issue has been present for years but has not been addressed.

Mr. Farrell asked whether the commenter has spoken to the Air Program, and perhaps that could be ELAB's response because this sounds like a method compliance issue. It does not appear that Method 29 references 3050 or 3051. Dr. Flowers thought that the PT provider should be acting within the accepted method. A Board member thought the issue could be solved easily by the PT provider, which should not have transferred the problem to the laboratory. Ms. Morgan will contact the commenter to determine what actions he has taken. Depending on his response, the suggestions that the Board discussed will be implemented, unless the mandate was issued from EPA's Office of Air and Radiation. The Board members understand the issue, but there is more information that is needed before ELAB can determine how to act and whether it fits the charter.

6. REVIEW ACTION ITEMS

Ms. Morgan reported that the action items from the April 2011 Board meeting had been accomplished. Ms. LeBaron reviewed the action items identified during this meeting, which are listed in Attachment C. Mr. Farrell requested that discussion of the Board's face-to-face meeting in August be placed on the June meeting agenda; Ms. Morgan agreed that this needs to be discussed.

7. CLOSING REMARKS/ADJOURN

Ms. Morgan thanked everyone for their attendance and participation. Dr. Flowers introduced a motion to adjourn the meeting, which Mr. Phillips seconded. Following a unanimous vote, Ms. Morgan adjourned the meeting at 2:28 p.m.

ELAB Meeting 6 May 18, 2011

Attachment A

AGENDA ENVIRONMENTAL LABORATORY ADVISORY BOARD

Monthly Teleconference: 866-299-3188/9195415544# May 18, 2010; 1:00 – 3:00 p.m. (ET)

Opening Remarks Autry/Morgan

Approval of April Minutes Morgan

New Developments/Discussion

Measurement/Technology Workgroup – PT Frequency Issue Lowry

Attachments Provided

Marketing ELAB Morgan, et al.

Laboratory Management Workgroup – State of Accreditation Flowers

Updates (as available)

Sufficiently Sensitive Methods Pletl

Methods Update Rule (MUR) Flowers

Improving EPA's Regulations Flowers

Recreational Water Quality Criteria Development Root

Monitoring Workgroup Morgan

Other Business All

Review Action Items Morgan

Closing Remarks/Adjourn Autry/Morgan

ELAB Meeting 7 May 18, 2011

Attachment B

MEMBERSHIP LISTING AND GUESTS

ELAB TELECONFERENCE

April 20, 2010; 1:00 p.m. – 3:00 p.m. ET

Attendance (Y/N)	Name	Affiliation
Y	Ms. Judith (Judy) R. Morgan (Chair)	Environmental Science Corp. Representing: Commercial Environmental Laboratories
N	Ms. Aurora Shields (Vice-Chair)	City of Lawrence, Kansas Representing: Wastewater Laboratories
Y	Ms. Lara P. Autry, DFO	U.S. Environmental Protection Agency Representing: EPA
Y	Dr. Richard Burrows	Test America Inc. Representing: Commercial Laboratory Industry
Y	Mr. Eddie Clemons, II	Practical Quality Consulting Services Representing: Clients of QS Services
Y	Mr. John (Jack) E. Farrell, III	Analytical Excellence, Inc. Representing: The NELAC Institute (TNI)
Y	Dr. Jeff Flowers	City of Maitland, Florida Representing: Elected Officials of Local Government
Y	Dr. Reza Karimi	Battelle Memorial Institute Representing: Nonprofit Research and Development Organizations
Y	Dr. H. M. (Skip) Kingston	Duquesne University Representing: Government Consortiums, Native Americans, and Academia
Y	Ms. Sylvia (Silky) S. Labie	Environmental Laboratory Consulting & Technology, LLC Representing: Third Party Assessors
Y	Mr. Jeffrey (Jeff) C. Lowry	Environmental Resource Associates Representing: Proficiency Testing Providers
Y	Mr. John H. Phillips	Ford Motor Company Representing: Alliance of Auto Manufacturers
Y	Dr. James (Jim) Pletl	Hampton Roads Sanitation District Representing: Municipal Environmental Laboratories
Y	Ms. Patsy Root	IDEXX Laboratories, Inc. Representing: Laboratory Product Developers
Y	Mr. David (Dave) N. Speis	Accutest Laboratories Representing: American Council of Independent Laboratories (ACIL)
Y	Ms. Michelle L. Wade	Kansas Department of Health and the Environment Representing: Laboratory Accreditation Bodies
Y	Dr. Michael D. Wichman	University of Iowa Hygienic Laboratory Representing: Association of Public Health Laboratories (APHL)

Attendance (Y/N)	Name	Affiliation
Y	Ms. Kristen LeBaron (Contractor)	The Scientific Consulting Group, Inc. (SCG)

ELAB Meeting 9 *May 18, 2011*

Attachment C

ACTION ITEMS

- 1. Ms. LeBaron will finalize the April 2011 meeting minutes and send them to Ms. Autry via email.
- 2. Ms. LeBaron will forward to Mr. Lowry via e-mail the statements made by Ms. Morgan and Mr. Farrell regarding clarifications to the PT letter.
- 3. Mr. Lowry will make the clarifications to the PT letter and forward it via e-mail to the Board members for their approval.
- 4. ELAB members will consider content and design changes that should be made to the ELAB website.
- 5. ELAB members will poll the stakeholders that they represent and provide input regarding national accreditation to Dr. Flowers via e-mail.
- 6. Ms. Morgan will contact Mr. Smith regarding what action he has taken in terms of his Method 29 issues.
- 7. Discussion of the August 2011 face-to-face meeting will be added to the agenda for the June ELAB meeting.

Attachment D

I hereby certify that this is the final version of the minutes for the Environmental Laboratory Advisory Board Meeting held on May 18, 2011.

Signature Chair

Ms. Judith R. Morgan

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Print Name Chair