

**SUMMARY OF THE
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING**

Teleconference: 866-299-3188/9195415544#

February 15, 2012; 1:00 – 3:00 p.m. EST

The U.S. Environmental Protection Agency's (EPA) Environmental Laboratory Advisory Board (ELAB or Board) teleconference was held on February 15, 2012, from 1:00 to 3:00 p.m. EST. 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 JANUARY MINUTES

Ms. Morgan thought that clarification was needed regarding Ms. Aaren Alger's comment on page 7 about the potential requirement of National Environmental Laboratory Accreditation Program (NELAP) accreditation being a disservice to states. Mr. Dave Speis moved to accept the minutes pending clarification from Ms. Alger, and Mr. John Phillips seconded the motion. The Board unanimously approved the January minutes pending clarification from Ms. Alger regarding her statement.

3. GENERAL WORKGROUP ACTIVITY

Monitoring Workgroup

Ms. Patsy Root explained that the *Federal Register* notice regarding the Agency's Recreational Water Quality Criteria development had been released. When the Monitoring Workgroup had expressed its desire to provide input regarding the criteria development to Ms. Grace Rubio's (EPA) group, Ms. Denise Hawkins (EPA) said that it would be appropriate for ELAB to comment following publication of the *Federal Register* notice. The Monitoring Workgroup met via teleconference the day prior and discussed the parts of the guidance that would be of particular interest to ELAB. The Workgroup focused on implementation at the state level, as this is guidance that states will adopt into their regulations for beach monitoring and eventually for determination of total maximum daily load, National Pollutant Discharge Elimination System levels and so forth. The Workgroup developed six appropriate "talking points" as the basis for ELAB's comments, which only have been released within the Workgroup. Ms. Morgan added that the public comment period closes on February 21, 2012. Ms. Morgan will send the six talking points via e-mail to all of the Board members so that those not present could review them. Ms. Root introduced the talking points to ELAB:

1. How will laboratory technicians be trained consistently on the equipment and materials?
2. How will laboratory auditors be technically trained for laboratory certification and accreditation programs?
3. What is the timeline for implementation and validation of qPCR?
4. Who will act as proficiency testing (PT) providers and who will assess these PT providers? What mechanism will be used to accredit or certify them?
5. Will EPA support the states in implementation? If so, how?
6. The language regarding culture methods is too broad, and EPA-promulgated methods under 40 CFR 136.3 are the only ones that should be allowed.

Mr. Jack Farrell asked for clarification about whether ELAB would be asking EPA questions to which the Agency was expected to respond or whether the Board would be making comments and recommendations. Ms. Root said that the information was so vague that it was difficult to develop comments, let alone recommendations. She envisioned that the Board's comments would focus on the fact that the members, as professionals, do not understand how this method will be implemented successfully. Dr. Mike Wichman said that the questions could be modified into comments. The Board members expressed concern that the Agency would not accept additional ELAB input following the closing of the public comment period. Ms. Root thought that EPA would be amenable to receiving additional input or extending the comment period, especially as she did not think that the states would have time to comment by the deadline.

Mr. Farrell thought that the first paragraph of ELAB's comments should focus on the difficulty of the method and training issues and then introduce the six talking points. Ms. Silky Labie thought that the opening statement should include the fact that there are questions that need to be answered about the method before the Agency can expect states or laboratories to implement qPCR. Ms. Root said that a request to extend the public comment period also should be included in the opening paragraph. Mr. Farrell said that the Board's comments should make it clear that ELAB is willing to work with the Agency to develop the method and make recommendations. Ms. Root agreed.

Mr. Phillips moved to accept the six talking points as the basis for ELAB's comments to EPA regarding Recreational Water Quality Criteria development; Dr. Wichman seconded the motion. Mr. Phillips made a motion for the Monitoring Workgroup to develop the comments based on these six topics for full Board approval via e-mail, which Ms. Root seconded. In response to a procedural question from Mr. Farrell, Ms. Autry explained that as long as the final letter approved by the Board members via e-mail contained each of the six talking points without additional substantive issues, then the Board could approve the comments via e-mail without meeting again. In response to a question from Ms. Root, Ms. Autry said that the Board, at the very least, could submit a comment to EPA requesting that the public comment period be extended; the Board also could request a future meeting with appropriate EPA staff to further discuss issues with the guidance that was released. Both motions were approved unanimously.

Measurement and Technology Workgroup

Mr. Phillips reported that the Measurement and Technology Workgroup was having difficulty scheduling a meeting based on the members' schedules. The Workgroup has a great deal of information to discuss regarding Data Quality Objectives. He reported that Ms. Autry had put the Workgroup in contact with Mr. John Warren (EPA). The other project on which the group is working involves EPA's second pilot study on method detection limit quantification, but the Workgroup members have not had a chance to discuss this issue. He explained that Dr. Richard Burrows plans to present about the second pilot study at an upcoming meeting in Washington, DC, but Mr. Phillips was unsure whether he had been able to submit his proposal before the deadline. He strongly encouraged the Board members to read the study if they had not already.

Mr. Phillips asked Ms. Morgan whether the PowerPoint presentation from the January 2012 face-to-face meeting had been published to the website because there were several slides with information about the second pilot study that were not presented because of time issues. Ms. Morgan said that they had not been published yet because of the Board's stipulation that a disclaimer be added. She said that she could mark the presentation as a draft and send it to the Board members via e-mail.

The Board discussed the motions made during the face-to-face meeting regarding the publishing of the PowerPoint presentation and realized that the two were in conflict with each other. Mr. Farrell thought that several of the slides focusing on the health of national accreditation needed to be edited prior to publication, which would support the first motion. Mr. Phillips suggested that the slides not dealing with the health of national accreditation could be posted in the interim until the Board approves and publishes those slides. Ms. Morgan agreed that the slides regarding Workgroup updates could be published separately. Mr. Speis moved that the Board remove the slides regarding national accreditation and publish the remainder of the slides with the appropriate "draft" watermark; Ms. Root seconded the motion, which passed unanimously. In response to a question from Mr. Phillips, Ms. Morgan said that ELAB members would be notified after the presentation was published to the website.

Laboratory Management Workgroup

The Laboratory Management Workgroup's main focus is the health of national accreditation, which the Board discussed as a current action needing update/review.

4. CURRENT ACTIONS NEEDING UPDATE/REVIEW

Mr. Speis explained that the Board had not had a chance to discuss some of the information presented at the face-to-face meeting. The members currently have two pieces of information: (1) a 12-page document with the condensed findings from the constituent groups and (2) a summary of the findings of the 12-page document. Mr. Speis thought that the Board should address the 12-page document first and consider the following questions: Is this the right information that the Board would like to portray? Is it the right set of findings based on the information received from constituents? Can the information be used to make recommendations to the Agency? The document includes discussions of each of the categories of information. There have been a number of requests to publish the information, but Mr. Speis was unsure whether this was feasible based on the amount of raw information in the document. He did not

think that ELAB was obligated to develop a final report because the goal was to develop recommendations to the Agency based on the findings.

Ms. Morgan said that each section in the 12-page document was created by its respective team based on the distillation of information from each stakeholder group. The Board decided to discuss the 12-page document by addressing each section individually. Mr. Farrell asked whether the “possible remedies” listed in the document constituted recommendations to the Agency. Mr. Speis said that they could be the basis for the final recommendations to EPA. Mr. Phillips noted that there were many redundancies within the document, so the final recommendations should be a consolidation of the possible remedies.

In terms of Section B, Dr. Wichman said that his stakeholders would agree with allowing third-party assessors but not third-party accreditation. There is a conflict between his stakeholders and what is written. Mr. Speis asked whether it would serve the purpose to add that there is a conflict between the constituents providing input regarding whether third-party accreditation or assessment would be helpful to indicate that not everyone uniformly agrees. Dr. Wichman said that this should be incorporated and he will send revised language to Mr. Speis via e-mail.

Mr. Farrell suggested that ELAB acknowledge that uniformity of assessment has improved in quality but still needs attention. He said that the terms needed to be consistent and standardized, particularly in regard to “third-party accreditation” and “nongovernmental accreditation.” Ms. Morgan said that she had introduced the term because she thought that it was the most accepted term and asked Mr. Farrell about the distinction. Mr. Farrell explained that third-party accreditation includes commercial organizations that provide accreditation, but there may be others. He thought that the point was use of nongovernmental resources potentially for accreditation or assessment. Dr. Wichman stated that this is a significant and sensitive issue for state laboratories because they are required to be accredited by the regions for the drinking water program. He was not sure that the states would allow these programs because they are required by the Safe Drinking Water Act to have a certification program to maintain primacy. Mr. Farrell suggested separating the two so that there is one for accreditation and one for assessment.

Mr. Speis thought that some of the suggestions might reach further than currently allowed by law, as states currently are responsible for the regulatory requirements; this may not be the best method. If the Board decides to work within the existing framework, then it is limited in action. If there are broadly supported suggestions that make the framework more efficient, then the recommendation can be made despite the fact that the authority currently is not present. Mr. Phillips noted that “third-party” does not necessarily mean “nongovernmental.” Ms. Morgan explained that she had used the term to be inclusive and thought that the most commonly used term within the stakeholder communities should be used within the document. Mr. Speis said that it was necessary to use the “least offensive” term. Although none of the Board members found the term offensive, Mr. Farrell did not want ELAB to be placed in a situation in which someone found the term offensive. He again suggested separating the accreditation from the assessment, and Ms. Labie agreed. Mr. Speis suggested using both terms universally as follows: “third-party and nongovernmental accreditation.” The Board members agreed to this compromise.

Mr. Phillips thought that Section D accurately represented the feedback, but feasibility is another issue.

In terms of Section E, Mr. Farrell asked about participation from small laboratory groups in addition to the Small Lab Advocacy Group (SLAG) . Dr. Wichman said that a number of states had enacted a two-tier system to address small laboratory issues. Mr. Farrell noted that other organizations (e.g., Water Environment Foundation) also have small laboratory groups. Ms. Root wondered whether it could be worded more generically: “Continue to support laboratories through organizations such as SLAG or others.” Mr. Phillips commented that the State of Michigan has the Michigan Environmental Laboratory Association, which is comprised of many but not solely small laboratories. Mr. Speis said that he would make this change.

Mr. Farrell asked whether Section F referred to The NELAC Institute (TNI) accreditation bodies (ABs) or any ABs. Mr. Speis said that his stakeholders considered TNI ABs. Mr. Farrell said that the title needed to be updated if TNI was the focus; the health of national accreditation as stated needs to include other organizations. Mr. Phillips thought that public input indicated that programs in addition to TNI’s should be considered. Mr. Speis reminded the members that they were discussing a national accreditation program, and the TNI standards essentially are national, as they referenced and/or used by 42 states. Several Board members pointed out that the drinking water and lead programs were additional programs. Mr. Speis responded that the drinking water program references the TNI standards. Mr. Farrell said that the current title requires the Board to broaden its scope to include other programs; if ELAB is focusing on TNI and/or drinking water, then the title needs to be updated to reflect this.

Dr. Wichman commented that some state programs (e.g., food testing) will require ISO, which has prompted the states to consider requiring ISO for all programs. Although the TNI standards are based on ISO 17025, TNI is not an ISO signatory. In response to a request from Mr. Speis, Mr. Farrell indicated that he was willing to create language to be included in the document, but he was unclear about the specific scope and direction of the review. Mr. Speis was curious why this issue was being introduced now, as the input has been primarily focused on TNI. Ms. Morgan agreed that most of the input is TNI-focused, but the drinking water program is limited to testing drinking water samples. The TNI standards include all EPA programs (e.g., water, soil) and are the most pervasive and heavily employed standards by U.S. laboratories, including laboratories performing drinking water analysis. Mr. Speis said that the standards serve the role of drinking water analysis in at least 15 states. Mr. Farrell said that not all of the 15 states accredit to drinking water under these standards; some only accredit wastewater and solids. Mr. Phillips commented that the responses had been focused on NELAP and perhaps the Board could explain that although the statements focus on NELAP, ELAB recognizes that there are other programs available. Dr. Wichman mentioned that some states use NELAP for all accreditation except for drinking water, which is derived from EPA; some states use a combination of the two. Mr. Farrell suggested that ELAB declare that the review focuses on the 2003 NELAC standards because they cross multiple matrices and EPA programs and accredit the largest number of U.S. environmental laboratories. The Board recognizes that there are other programs that could be considered, including drinking water, but this review is restricted to those issues surrounding implementation of accreditation programs under the 2003 NELAC standards.

Ms. Root observed that laboratories that seek advice from her do not know how to list the methods. ISO 17025 includes a list of methods for auditors that can be used for compliance purposes. There is frustration among laboratories that each state employs its own scheme for describing the same method. She wondered whether the ELAB members thought that it was

possible in the future that each method would have a universal number (e.g., TNI method code). Mr. Farrell did not think that this would ever occur. Mr. Speis said that ELAB had made recommendations for uniformity in the fields of accreditation, methodology and application processes. In response to a question from Ms. Root, Mr. Farrell explained that the TNI method code was used in the database and within the NELAP program. Although the question of why states each assign their own codes is rhetorical, it is a compelling question, especially in terms of laboratories that are accredited by multiple states.

Mr. Phillips brought up two technical edits for Section H: (1) Bullets 2 and 3 should be one bullet. (2) “Reimplement” may not be an actual word.

In terms of Section I, Mr. Phillips recalled that there had been discussion regarding a national database of PT data that is accessible to laboratories and data users in addition to the states. If this point has not been included in this document, Mr. Phillips will draft relevant language. In response to a question from Ms. Root, Mr. Phillips responded that PT providers did not currently have publicly available data. Mr. Speis said that the recommendation would be to expand the usability of the PT database. Ms. Root asked whether access to the database would be at no cost. She did not think that laboratories would be amenable to making their PT data public. Mr. Farrell thought that if this issue had been introduced by the stakeholders, then it should be included whether it is feasible or not. Ms. Root saw potential issues as a result of the lack of uniformity of PT samples, and data comparability would be difficult across the various samples and preparations.

Under Section J, Dr. Wichman asked whether it was accurate that there was no mechanism in place to alert additional certifying agencies of severe deficiencies in laboratories with multiple accreditations. Ms. Morgan reported that this was an accurate statement; she knew of situations in which a laboratory lost its accreditation in one state, and the other accreditation states were unaware of this loss of accreditation. Dr. Wichman and Mr. Phillips agreed that determining which certifications are current is a complex process, although notification should be part of the standards. Mr. Speis was unclear about what such a mechanism would entail. Mr. Farrell said that from the TNI perspective, it probably would be linked to the Laboratory Accreditation Management System (LAMS). Ms. Morgan said that TNI administration could perform the service of notifying non-NELAP states. Mr. Speis thought that this would overstep TNI’s authority. It almost needs to be the responsibility of an AB through the accreditation because the secondary accreditors are depending on the primary AB to take care of their interests. If the primary ABs do not provide notification, then they are not looking out for their colleagues’ interests. Mr. Farrell thought that notification was the responsibility of many entities. The standards state that the laboratory has the responsibility to properly use its accreditation and accreditation status. There could be due process issues that could keep the states from notifying others, but if laboratory status could be updated in LAMS, then the other states can be aware and make appropriate decisions. LAMS is available to states, although it is not mandated. Mr. Farrell and Mr. Speis agreed that in some instances, it is the state’s responsibility to take corrective actions. In Mr. Speis’ experience, the vigilance is not present to ensure that notification and corrective actions occur. Mr. Farrell added that there is no requirement that a laboratory notify other states when it loses accreditation.

The Board members agreed that Section K was acceptable as written.

Under Section L, Ms. Root asked to what “response times” referred. Ms. Morgan explained that it referred to interpretations. Mr. Speis will add this clarification.

In terms of the stakeholder comments under Section M, Ms. Root thought that communication was good among the committees. Ms. Morgan agreed but thought that sometimes there was overlapping of tasks. Mr. Speis added that not all input needed to be used to form the Board’s recommendations.

Mr. Farrell asked about the term “nonresponsive labels” in Section N. Mr. Speis thought that it should be “not persuasive.” Mr. Phillips and Ms. Morgan noted that some organizations use the term “nonpersuasive.” Mr. Speis will update the document to include this term. Mr. Phillips thought that it should be “nonpersuasive determinations” rather than “nonresponsive labels.”

In response to a question from Mr. Phillips, Mr. Speis explained that once the Board members who were identified to provide additional language send it to him via e-mail, he would update the document and send the revised document to the Board members for their review. The Board will need additional time to discuss the document.

Ms. Morgan thought that the document was concise, and if it was prefaced correctly regarding the intent of the document, she did not have a problem sharing it. Ms. Root was not comfortable sharing the document. Ms. Autry said it was necessary to consider whether the Board wanted to publish a “deliberative” document in addition to the final document/recommendation that ELAB releases to the Agency. The Board is not required to publish deliberative documents, but if the members think that such a document would be useful for other stakeholders, then ELAB can publish the information in any form that it decides would be useful. The Board can consider what information should be included in the final version that will benefit EPA or contribute to the relevant knowledge of the Agency.

Ms. Root asked what the next step was for the distilled information. Mr. Speis responded that the next step, following discussion of the economic issues, is to examine the presentation from the January 2012 face-to-face meeting, make additions and/or deletions, and determine whether there are any actions that the Board needs to undertake as the basis for recommendations to EPA. Mr. Phillips thought that the 12-page document was for ELAB’s use. It might be helpful to attach it as an appendix to the Board’s ultimate recommendations to EPA, but he did not see the benefit in publishing it broadly. Ms. Root and Mr. Speis agreed, especially as the Board has not discussed this information with the Agency. Mr. Farrell thought that the issue of what the Board needed to publish had been resolved during ELAB’s deliberations on a previous issue. Ms. Autry responded that this had been discussed during the comparison of the TNI standards with the Drinking Water Certification Manual, and the Board had decided to issue a disclaimer. The same approach could be utilized with this effort, and ELAB could issue a disclaimer. Mr. Farrell thought that the Board might want to, when it is at the appropriate stage, ask for additional input to ensure that it has not missed any major issues. The Board members agreed that the information is too raw to seek that input at this point.

The Board members offered no comments on the following Operational and Implementation Issues sections: A, C, G and O.

5. UPDATES FROM THE DFO

Ms. Autry explained that she would send more details via e-mails, but the Board members needed to begin considering who should be nominated for Chair or Vice-Chair, as Ms. Morgan's term almost is finished. Past precedence has been that the Vice-Chair is promoted to Chair, but the Board members have the right to nominate and vote for a new Chair if they so choose. She thanked Ms. Morgan for her magnificent job as Chair. Ms. Autry explained that a few members are not eligible to continue on the Board after their terms end in October 2012, so they cannot be nominated to serve as Vice-Chair. Those members who are eligible and interested in serving a second term need to provide Ms. Autry with a letter of interest, current resume and letter of support from their representative organizations, if applicable. Ms. Autry is developing a *Federal Register* notice to announce the ELAB membership drive.

6. OTHER ITEMS

The Board members did not identify any additional items for discussion.

7. WRAP-UP/REVIEW ACTION ITEMS

There was insufficient time to review the action items, which are included in Attachment C.

8. CLOSING REMARKS/ADJOURNMENT

The meeting was adjourned at 3:03 p.m.

Attachment A

AGENDA ENVIRONMENTAL LABORATORY ADVISORY BOARD

Monthly Teleconference: 866-299-3188/9195415544#

February 15, 2012; 1:00 – 3:00 p.m. (EST)

Opening Remarks	Autry/Morgan
Approval of January Minutes	Morgan
General Workgroup Activity	
Monitoring Workgroup	Root
Measurement and Technology Workgroup	Phillips
Laboratory Management Workgroup	Flowers
Current Actions Needing Update/Review	
- State of National Accreditation	Morgan/Speis
- Response From OW	Morgan
Updates From the DFO	Autry
Other Items	All
- Transition Chair/Vice Chair in March	
- Membership Interest	
Wrap-Up/Review Action Items	Morgan
Closing Remarks/Adjournment	Autry/Morgan

Attachment B**MEMBERSHIP LISTING AND GUESTS**

ELAB TELECONFERENCE
February 15, 2012; 1:00 p.m. – 3:00 p.m. EST

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
N	Dr. Richard Burrows	TestAmerica Laboratories, Inc. Representing: Commercial Laboratory Industry
N	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)
N	Dr. Jeff Flowers	City of Maitland, Florida Representing: Elected Officials of Local Government
N	Dr. Reza Karimi	Battelle Memorial Institute Representing: Nonprofit Research and Development Organizations
N	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. John H. Phillips	Ford Motor Company Representing: Alliance of Auto Manufacturers
N	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)
Y	Mr. Jim Christman (Guest)	Hunton & Williams LLP

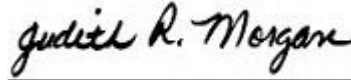
Attachment C

ACTION ITEMS

1. Ms. Kristen LeBaron will finalize the January 2012 meeting minutes after the Board receives clarification from Ms. Alger and send them to Ms. Autry via e-mail.
2. Ms. Morgan will send the six talking points regarding the Recreational Water Quality Criteria development to the Board members.
3. Ms. Root will develop a letter based on the six talking points that the Board agreed on for the ELAB members to discuss and approve via e-mail.
4. Ms. Morgan will mark the PowerPoint presentation from the January 2012 face-to-face meeting as a draft version and send it to the Board members.
5. Dr. Wichman, Mr. Phillips and Mr. Farrell will send draft language to Mr. Speis via e-mail to include in the health of national accreditation document. Mr. Speis will update the document per the discussion and distribute it to the Board members via e-mail.

Attachment D

I hereby certify that this is the final version of the minutes for the Environmental Laboratory Advisory Board Meeting held on February 15, 2012.

A handwritten signature in black ink, reading "Judith R. Morgan", written over a horizontal line.

Signature Chair

Ms. Judith R. Morgan

Print Name Chair