

**SUMMARY OF THE
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
Face-to-Face Meeting/Teleconference: 866-299-3188/9195415544#
Hyatt Regency Washington on Capitol Hill, Washington, D.C.
August 6, 2012; 9:00 a.m. – 12:00 p.m. EDT**

The Environmental Laboratory Advisory Board (ELAB or Board) face-to-face meeting was held on August 6, 2012, from 9:00 a.m. to 12:00 p.m. EDT. The meeting was held as a session at the Environmental Measurement Symposium. The agenda for this meeting is provided as Attachment A, a list of meeting participants is provided as Attachment B, and action items are included as Attachment C. The official signature of the Chair or Vice-Chair is included as Attachment D.

AGENDA ITEMS:

1. OPENING REMARKS AND ROLL CALL

Ms. Lara Phelps, Designated Federal Officer (DFO) for the Board, and Ms. Aurora Shields, Chair of the Board, welcomed the members and guests to the meeting and explained that the Board is a Federal Advisory Committee to the U.S. Environmental Protection Agency (EPA or the Agency). After these remarks, the Board members introduced themselves and identified the stakeholder communities that they represent.

2. APPROVAL OF JULY MINUTES

Ms. Shields asked whether there were any comments regarding the July 2012 Board meeting minutes; there were none. Mr. Jack Farrell made a motion to approve the July 2012 minutes, which Ms. Judy Morgan seconded. The meeting minutes for July 2012 were approved with no discussion, no changes and one abstention.

3. ELAB CHARTER AND HIGHLIGHTS OF 2011–2012 ACTIVITIES

Ms. Shields explained that ELAB provides advice, information and recommendations to the EPA Administrator, EPA Science Advisor and Forum on Environmental Measurements (FEM) on issues related to enhancing EPA's measurement programs in areas such as method validation and dissemination, appropriate collection of information, environmental monitoring and regulatory programs, quality systems issues and a national environmental accreditation program. The 15 members provide good representation for a variety of areas in the environmental community.

During the past year, the Board has been involved in the SW-846 policy update and provided comments on sufficiently sensitive methods and the methods update rule (MUR). The Board continues to work with the Agency regarding unresolved MUR issues. Currently, the Board is working with EPA regarding its Recreational Water Quality Criteria. In addition to developing a new ELAB logo and website, the Board has been investigating the state of the health of national environmental laboratory accreditation.

4. WORKGROUP ACTIVITIES/ONGOING PROJECTS

ELAB Website Ad Hoc Workgroup

Ms. Patsy Root explained that an *ad hoc* Workgroup within ELAB had volunteered to update the ELAB website (<http://www.epa.gov/elab>) after the Board was made aware that there was technology funding available to make improvements. The Board decided to update the visual appearance of the ELAB website and its functionality to make it more informational and user-friendly while providing more specific information. Ms. Root provided details about the timeline of the effort, which began in April 2012 with the development of a redesigned logo whose colors reflect land and water and a symbol that represents a cooperative “feel.” In July 2012, the Board voted on the website template, which leveraged the new EPA website design, and content. ELAB is waiting for feedback and edits from EPA’s technology group. The new ELAB website is anticipated to be published in early 2013. Ms. Root showed examples of the new website design and navigation.

MUR Ad Hoc Workgroup

Dr. Michael Wichman explained that the proposed MUR had been published in the *Federal Register* on September 18, 2010, and ELAB had submitted comments regarding the rule on December 16, 2010. The final rule was published in the *Federal Register* on May 18, 2012. An *ad hoc* Workgroup within ELAB has examined the final rule.

The Board’s original comments submitted in 2010 included concerns about Method 1668C, new methods required, the method validation and approval process, and Table 1B. ELAB commended the Agency on the use of the collision reaction cell. The comments included requests to revise the method detection limit (MDL) and minimum limit (ML) definitions to minimize confusion and clarify the 12 mandated requirements in Section I, Part 136.7. EPA responded to some ELAB suggestions, but the Office of Water (OW) considered some of the suggestions to be outside of the scope of the rule. In a letter dated July 18, 2012, ELAB expressed its concerns related to the proposed, new Part 136.7, which is vague and confusing and does not harmonize with laboratory accreditation standards. The Board requested a follow-up meeting with Dr. Michael Shapiro (OW), which will occur on August 8, 2012.

Mr. Farrell said that EPA had provided a reasonable update and addressed several concerns. ELAB commends the Agency for this, but the “devil is in the details.” The Board will work with OW to obtain clarification and increase the necessary details. The updated MUR is improved compared to the previous iteration. Ms. Shields said that the quality assurance/quality control (QA/QC) section was particularly improved, although she was disappointed that The NELAC Institute (TNI) standards were not included as an option for wastewater laboratories.

Mr. Jerry Parr (TNI) said that Ms. Susan Wyatt (Minnesota Department of Health) would be presenting during the symposium’s Wednesday afternoon session about how laboratories can use the TNI standards to comply with the MUR. He added that there had been a great deal of confusion expressed about how to relate the MUR to QA/QC and standards during a recent TNI-sponsored webinar.

Ms. Aaren Alger (Pennsylvania Department of Environmental Protection Laboratory Accreditation Program) noted that the preamble of the MUR said that laboratories should use the 20th or 21st editions of the *Standard Methods for the Examination of Water and Wastewater* (*Standard Methods*) for QC. The use of the word “should,” as well as significant differences between these two versions, creates uncertainty. One issue with implementation is that the National Pollutant Discharge Elimination System (NPDES) and the Clean Water Act (CWA) have different method mandates compared to the drinking water program. For example, in some cases, the most recent version must be used for wastewater, but it is not allowed to be used for drinking water. Ms. Shields agreed that the differences between wastewater and drinking water are important, and she would like to see harmonization between the two programs.

Dr. Edward Askew (Askew Scientific Consulting) highlighted the various editions of the manuals that are approved for different methods. There is a whole different area of approvals and disapprovals, which may not be identified specifically in the online version. The wastewater and drinking water programs have been working together, but there will be a dichotomy of approved methods. Mr. Lemuel Walker (EPA) has indicated via email that the intent was not to allow laboratories to “shop around” for the easiest QA/QC procedures, and Mr. Dan Hautman (EPA) has said that there is no reason laboratories cannot use the QC outlined in the most current version of *Standard Methods* to meet drinking water compliance requirements. Dr. Askew’s suggestion to laboratories is to look at the most current versions of methods. Although it is necessary to pay for Part 1020, many of the QC sections (e.g., Parts 2020, 3020, 4020, 5020) can be downloaded from the Web at no cost, which is beneficial.

Dr. Andy Eaton (MWH Laboratories) provided a historical perspective. Before the MUR, many organizations, including consensus organizations, had a conundrum in that they could not make any changes in a method without losing approval. The MUR allows these organizations to move from a 20th-century book to a 21st-century book. The QC sections that Dr. Askew mentioned reflect the increased clarification of QC for specific methods. In the 22nd edition, Part 1000 was meant to be guidance. The sections mentioned above outline specific, mandatory QA/QC and reflect what was previously intended in other sections and codifies them. From TNI’s perspective, laboratories should be using the latest QC method. Mr. Farrell asked whether there was anything that ELAB could do to help with clarification and harmonization. Dr. Eaton suggested that the Board establish a policy similar to what has been articulated so that laboratories use the most current QC version. He thought that it would be beneficial for ELAB to examine the issue. Mr. Farrell said that ELAB could not establish a policy, but it could make a recommendation to EPA. Ms. Phelps added that if OW was amenable, the Board could follow a process similar to its previous work with the Office of Resource Conservation and Recovery (ORCR). Mr. Farrell thought that this would be a worthwhile effort.

Mr. Jim Todaro (Alpha Analytical) noted that when a regulation does not include a date, laboratories may not consider the difficulties in implementing regulations for laboratories that are certified by various states under various programs. Some states are not ready to attempt revision to the certifications under certain circumstances, including when revisions are prompted by legislative changes that cannot occur until the state legislatures reconvene. It can become very confusing for laboratories trying to follow certain specifications, particularly from an information technology point of view. Current software does not always allow stringers (i.e., suffixes) for reports, which could present problems. These issues could be considered in moving

forward with future regulations. Implementation can be difficult when an implementation date is not established. Such a date should be instituted while allowing laboratories time to get their primary and secondary certifications in place. He thanked Mr. Parr and TNI for providing training and webinars on the subject.

Mr. Walker asked the ELAB members why some of the comments received by EPA from individual Board members conflict with the official comments submitted by ELAB. He asked about the Board's process for addressing issues. Ms. Shields explained that when ELAB decides to address an issue, generally it is assigned to a standing or *ad hoc* workgroup. This effort, however, was a consolidated effort of the Board. The comments were assembled and approved by the Board and sent to the Agency. Some members may have decided to provide comments outside of their roles as an ELAB member. The Board comprises a diverse membership with various backgrounds, so even when a consensus is reached, individual Board members may disagree with the consensus. Ms. Phelps agreed that consensus does not indicate 100 percent agreement among the Board members. Dr. Richard Burrows added that his company also provided comments. He had brought forward some of these concerns to ELAB, but the Board might not have found them important enough to include in its comments. He emphasized that his company and ELAB are two different entities, and it is circumstantial that he is a member of both. Mr. John Phillips noted that his company submitted separate comments, including additional comments that were not covered in ELAB's comments.

Ms. Stephanie Drier (Minnesota Department of Health) requested guidance regarding the processes required in the footnote about ammonia distillation. Mr. Farrell indicated that Mr. Walker would be the point of contact for such guidance.

Mr. Hautman explained that he is the point of contact for drinking water issues, and Mr. Walker is the point of contact for CWA issues. Most of the discussion has focused on CWA issues. There has been internal EPA discussion regarding the drinking water MUR, and OW would like a quicker process for taking action compared to a full-blown MUR. This will not come to fruition for several years because there still are issues to be resolved in terms of drinking water methods. The plan is to place 163 methods into the regulatory table, which will allow for clarification and simplification.

Dr. Burrows thought that it would be worthwhile for ELAB to add to its agenda the development of a letter to EPA that recommends that the same method be approved for all Agency offices using the method. Although it will be a difficult endeavor, it will be worthwhile. Ms. Shields agreed, noting that she was unsure why an internal procedure is not in place for offices to collaborate and use the same method. Mr. Hautman explained that wastewater programs have greater latitude regarding QC as a result of the sample media. Although EPA offices look for convergence, the differences among media must be recognized. For example, the Agency previously tried to harmonize the wastewater and drinking water requirements, but the wastewater laboratories responded that it was too difficult to adhere to the drinking water QC standards. Drinking water QC always will be more stringent compared to wastewater. That said, an auditor should not object to a laboratory implementing more stringent QC measures.

Dr. Burrows moved that ELAB develop a recommendation to EPA that when different program offices use the same method, they attempt to use the same version of the method. Ms. Root

seconded the motion. Mr. Farrell asked for clarification about whether Dr. Burrows was referring to the method itself or only QC aspects of the method. QC and system management of the performance of a method may be harmonized, but it may not be possible to harmonize the full method. Dr. Burrows clarified that he was referring to the method; QC is a part of the method, and the full recommendation can be developed within an ELAB Workgroup and approved by the Board. The motion passed unanimously. Dr. Askew inquired whether in pursuing the motion, ELAB would contact consensus organizations. Ms. Shields explained that the Board only can provide recommendations to EPA, but the members may contact any group to request information and/or input. Dr. Askew noted that ASTM International is updating its QC, building on what already is available and expanding methods; Ms. Root is the subchair for biological methods for ASTM International. This effort could be a potential resource.

Mr. Keith Chapman (TNI Small Laboratory Advocate) informed the Board and participants that the Water Environment Federation would be holding a no-cost webinar on August 23, 2012, which would provide another opportunity for laboratories to hear about the MUR from a CWA perspective.

Monitoring Workgroup

Ms. Root explained that EPA is undertaking two efforts of interest to the Board: revision of the Federal Water Quality Standards found in the Code of Federal Regulations (CFR) Title 40 Part 131 and development of new or revised Recreational Water Quality Criteria recommendations with implementation of rapid microbial methods. The draft Recreational Water Quality Criteria (EPA-OW-2011-0466) were published on December 21, 2012, and ELAB submitted comments in response. The Agency must publish the final criteria by October 2012. Target standards are included in the draft for fresh and marine waters, including a new requirement: the statistical threshold value.

Method A (qPCR) is included in the new criteria, and the Monitoring Workgroup had several questions regarding qPCR implementation: What implementation assistance will EPA provide to laboratories that would like to adopt the qPCR method? What guidance will be available to assessors who will audit qPCR laboratories? Will an associated proficiency testing (PT) program be developed, and if so, how will it be managed and by what entity? The Workgroup members also will determine whether there are additional questions that laboratories and/or auditors might have by continuing discussions with laboratories that already have implemented qPCR and those that are considering adding this method. From these discussions, ELAB can outline specific issues that laboratories might have and provide recommendations to EPA so that the laboratories can successfully add qPCR to their scope. The Workgroup has established initial contact with EPA Recreational Water Quality Criteria staff and will start discussing the impact of the changes on laboratories, accreditation bodies (ABs) and PT providers.

The goal of the Workgroup is to understand the constituencies' concerns regarding qPCR implementation and communicate these concerns to the Agency. The Workgroup also would like to work with EPA to better understand how qPCR can be consistently implemented and collaborate with the Agency to provide expert advice on best practices (e.g., laboratory/auditor training, PT) from laboratories that already have implemented the method. It is expected that those laboratories that choose to implement qPCR will do so in 2013.

Measurement and Technology Workgroup

Mr. Phillips explained that the Workgroup is focusing on two tasks: data quality objectives (DQOs) and the Post Federal Advisory Committee on Detection and Quantitation (FACDQ) Pilot Study. The Workgroup is attempting to understand the application of the DQO process within EPA, states, government agencies and standard-setting bodies so that it can make recommendations to facilitate the expanded use of the DQO process for environmental measurements. The Workgroup is in the process of evaluating the Post FACDQ Pilot Study results and has met with OW to determine the next steps in the process.

Mr. Phillips explained that most EPA program offices have implemented the DQO process and have written procedures in place, but OW does not apply this process in the same manner as other program offices and instead relies on method QA/QC. The NPDES and drinking water programs generally do not use the DQO tool, although the *NPDES Permit Writer's Guide to Data Quality Objectives* document was released in 1990. Most government programs and agencies that deal with environmental data apply the DQO process, and the Intergovernmental Data Quality Task Force has established the *Uniform Federal Policy for Implementing Environmental Quality Systems* (EPA-505-F-03-001) and *Uniform Federal Policy for Quality Assurance Project Plans* (EPA-505-B-900A), which incorporate the DQO process. Many consensus standards organizations that deal with environmental data have issued DQO-related standards or reference and/or encourage the DQO process, including TNI.

The Post FACDQ Pilot Study report was issued in December 2011. Three laboratories each evaluated Methods 200.7 and 625 and compared the MDL/ML to FACDQ and the lowest concentration minimum reporting level. The FACDQ procedure was found to outperform the MDL/ML. As a result of the pilot study, EPA concluded that additional data generated using other analytical methods and more laboratories are needed to fully assess the applicability of these procedures to CWA programs. The Workgroup met with OW staff members to discuss how to move the process forward to implement a better process for detection and quantitation. The four main conclusions from this meeting were that: (1) revising the MDL/ML is not of high priority to the Agency because of the limited resources available, (2) a new detection and quantitation limit procedure would be a major policy change for the Agency and likely would require new rulemaking and a subsequent public comment period, (3) a procedure similar to the one developed by the FACDQ would have the greatest likelihood of success, and (4) OW could provide peer review for any plan proposed for validating a new detection and quantitation limit procedure.

Mr. Phillips identified a number of relevant questions related to the two projects: How important is the DQO process for generating usable data? Which program offices are the most/least effective in applying the DQO process? Considering the results of the Post FACDQ Pilot Study, should the existing MDL/ML be replaced? What improvements should be included in a revised detection and quantitation limit procedure?

Ms. Catherine Katsikis (Laboratory Data Consultants, Inc.) thought that the DQO process as well as third-party validation are very important. She encouraged the Board to continue working on the MDL/ML issue.

Dr. Askew inquired about the peer review that EPA had offered to provide. If a consensus organization undergoes the process of comparing MDL/ML to detection and quantitation limits, will the drinking water and wastewater programs provide peer review? Mr. Phillips responded that OW would provide peer review if an organization proposes a validation study for a given detection and quantitation limit procedure compared to the Agency's MDL/ML. Dr. Askew explained that all Part 4000 methods were being validated prior to the publication of the next edition of *Standard Methods*. Data, including those regarding MDL/ML, will be collected from laboratories as part of the effort. If there is a validation procedure that allows comparison, both can be added to the Part 4000 methods. He asked whether the Part 4000 editorial board could obtain from ELAB the contact information for the EPA peer reviewers. Mr. Phillips said that he thought that OW would be coordinating an external peer review and asked how many laboratories are involved with the Part 4000 update. Dr. Askew replied that he would like to use as many laboratories as possible. In the past, six or seven have been involved, but he would like to increase the number to at least nine. If drinking water and wastewater methods are completed, then the goal is 15 (three each for surface and groundwater plus the nine previously mentioned). Mr. Phillips said that the Agency would want to review the procedure. Dr. Askew said that he would obtain EPA review prior to any data collection.

Mr. Parr reported that he had recently completed a webinar survey via TNI. At the beginning of the webinar, 40 percent of respondents believed that EPA's MDL/ML is a scientifically defensible, valid procedure. The participants then discussed the theory and concept of detection with information and data that Dr. Burrows and Ms. Brooke Connor (U.S. Geological Survey) had assembled. Following this discussion, when participants were asked the same question, only one person out of 100 still believed that EPA's MDL/ML is scientifically defensible. This indicates that more work is needed in this area.

Mr. Farrell said that any procedure that is used must have a verification process, and there must be a method to verify the number analytically. A fallacy about 40 CFR 136 Appendix B is that there is no relationship to analytical chemistry, which causes significant difficulties. Including verification in any approach is critical in moving the effort forward.

Dr. Shen-Yi Yang (ORCR) noted that ORCR manages its programs differently than OW and announced that her office is developing a lower limit of quantitation (LLOQ), which has been published online with Method 8276. The office proposed a procedure and definition for LLOQ. ORCR has continued to work on Method 8276 since it was published in March 2010. The revised version includes fish, an improved definition of LLOQ and a verification procedure. The office will be removing all references to MDL in favor of using LLOQ because the method is used widely by many programs outside of ORCR (e.g., Superfund, Homeland Security). She described methods to demonstrate the levels that can be achieved within certain criteria using real matrices. ORCR welcomes feedback regarding this approach. The office will be publishing Update 5 with 18 methods by the end of the year and invites comment on this publication as well. Ms. Shields asked for clarification about the process that ORCR will use to remove references to MDL in the SW-846 compendium. Dr. Yang responded that the office provides method updates periodically based on the feedback that it receives. In response to a question from Dr. Reza Karimi, Dr. Yang invited interested participants to visit the Method 8276 website and noted that Ms. Kim Kirkland (ORCR) has more information about when the method will be published. Dr. Karimi asked whether the approach would be performance based and whether

each laboratory would have a certain latitude in making choices. Ms. Kirkland explained that laboratories must demonstrate that they can meet the LLOQs, and details will be provided in the upcoming notice, which is scheduled to be released in November 2012. She will be presenting on Wednesday afternoon about ORCR methods activities, including how Chapter 1 was refined after the DQO process was examined. Dr. Yang added that Update 5 will include Methods 6010, 6020 and 8000. Ms. Kirkland noted that because there are more than 200 methods, some must use MDL, but it will not be recommended for ORCR programs.

Mr. Hautman commended Mr. Farrell regarding his “show me the money” comments. As a result, the drinking water program has embraced the concept of lowest concentration minimum reporting level (LCMRL) because it incorporates precision and accuracy. He strongly encouraged laboratories to incorporate each of these components in their work instead of choosing those analytical methods that only incorporate precision.

Dr. Burrows said that there are four actions that can be taken regarding MDL: (1) stop performing detection limit studies, (2) replace the MDL, (3) modify the MDL, and (4) include a requirement in the TNI standards. He will be exploring each of these options during his presentation on Wednesday morning. He thought that it would be beneficial to harmonize the use of LLOQ and LCMRL.

Laboratory Management Workgroup

Mr. Dave Speis stated that the Workgroup has been focusing on the state of the health of national environmental laboratory accreditation for 18 months. In addition to the members of the Laboratory Management Workgroup, Ms. Morgan, Ms. Silky Labie, Mr. Eddie Clemons and Ms. Michelle Wade also provided a great deal of help with the effort. Mr. Speis provided background information on the process, which began with an American Council of Independent Laboratories (ACIL) accreditation initiative. ELAB members interviewed their constituents to obtain views on operational and economic program impacts and eventually compiled the information into a summary document. The consolidated information served as a basis for determining whether the Board could recommend EPA action to better promote a national environmental laboratory accreditation program. ELAB evaluated a number of factors that were described during the Board’s previous face-to-face meeting in Sarasota, Florida, in January 2012, asking its constituents: What impact do these factors have on the program from your perspective? What solution would you propose if you perceive their impact to be negative? If constituents did not perceive that there was a negative issue, then they did not provide comment. If a factor was perceived as negative, the constituents generally provided suggested solutions.

Mr. Speis explained that the Board’s findings can be found in a summary document that was recently published to the ELAB website. ELAB is not able to address many of the issues that constituents cited because they are outside of the Board’s purview. ELAB only is able to make recommendations to EPA. The document includes many perspectives, and ELAB focused on general issues. Mr. Speis provided a condensed version of the findings regarding operational and economic issues, noting the following common themes: (1) a desire for expanded EPA involvement, (2) use of the drinking water program for assessment and PT specifications, (3) use of the third-party AB community as a resource, (4) a desire for standardized administrative requirements, and (5) the goal of achieving full state participation using creative mechanisms.

ELAB developed a set of recommendations for EPA on issues that the Board thought that the Agency could address; the recommendations have been approved by the Board but have not been sent to EPA. The benefits of these recommendations include improved data usability and comparability, resources, PT programs, uniformity and oversight. ELAB recommended that EPA:

- Emphasize that program data be of known and verifiable quality.
- Provide leadership/support in making accreditation uniform from a requirements and implementation perspective.
- Establish processes that enable the Agency to team with states with limited resources to develop rules establishing the TNI National Environmental Laboratory Accreditation Program (NELAP) as their state laboratory accreditation standard.
- Continue to aggressively support activities promoting continued small laboratory training that enables NELAP participation.
- Incorporate requirements specifying consensus-developed standards use for regulatory activities requiring laboratory accreditation when applicable.
- Convene an EPA regional and program office and state forum to collaborate on a recognition system to ensure successful implementation of a national accreditation program.
- Continue to support the National Environmental Monitoring Conference held annually in conjunction with the TNI Forum on Laboratory Accreditation.
- Provide monetary grants for the development of a PT database for PT data management.
- Consider an Agency-wide mandate to conform to the NELAP requirements for all compliance testing based on the directives specified in 15 CFR 287, the Office of Management and Budget's *Circular A-119*, and U.S. Code Title 7 § 138a, following the precedence established by EPA in support of public and private organizations.

Mr. Speis clarified for Mr. Farrell that "NELAP program" referred to the existing program rather than the *TNI Environmental Laboratory Sector Standards Volumes 1 and 2*.

Mr. Parr reported that he had shared the Board's summary document with TNI, and there are concerns. The first concern is that the report appears to be based on hearsay and not supported by evidence. The second concern is that the report goes beyond ELAB's charter and provides advice to a nonprofit organization. He recommended that the document be withdrawn from the EPA website and used as an internal document to make recommendations. Mr. Speis explained that the Board discussed extensively the amount of information that should be made public. Members had concerns about not publishing all information in favor of publishing a digressive summary. Mr. Speis said that Mr. Parr's point is well taken, and the Board will discuss it. In terms of the concern that the information reported was hearsay, ELAB asked its constituents about their

perceptions of the health of national accreditation. The constituents include users, administrators and those affected by the program. Many of these constituents have been working with the program for many years and have a great deal of experience to share. Ms. Shields emphasized that the constituents interviewed were those who have used the program for many years and understand it very well. Although the Board and others may not agree with all of the comments because some of them reflect past issues that do not reflect the current situation, it is necessary to take them all into account.

Ms. Sharon Mertens (Metropolitan Milwaukee Sewerage District) clarified that the suggested solutions within the document were comments received by the constituents and asked about the recommendations. Mr. Speis responded that the recommendations to EPA have not been released yet; there will be a final report with these recommendations addressed to EPA. The document is a summary of ELAB's process and condenses comments from many different constituents. Each stakeholder group had different needs and desires; however, all of the constituents agreed on the major points and thought that EPA needs to get involved to promote a national environmental laboratory accreditation program. Ms. Mertens thought that this summary document was unclear about the suggestions; she thought that additional explanation was needed in the introduction to the document. Ms. Shields explained that the Board tried very hard to label the document as a summary rather than a report of recommendations. ELAB explained its process within the introduction to ensure that readers would understand the background and scope of the document.¹ The Board was very open during the process, publicly presenting and communicating its progress during each step while requesting input. It was very difficult to compile the information because of the vast numbers and differences of opinions regarding what should be included in a national program. Mr. Farrell emphasized that it is important to understand that the solutions found in the summary document are not ELAB's solutions; they constitute information received from the stakeholders who were interviewed.² If there is unclear information in the document, it is because the responses were unclear. The Board needed to choose those solutions that could form recommendations to EPA. The effort was neither an assessment nor a review of the TNI program; rather, it was an assessment to determine where EPA could help promote a national program. The Board engaged in significant amounts of discussion regarding how and when to post the summary documents and whether to obtain feedback.

Dr. Wichman explained that the Board would not solicit comments about the summary document, but anyone is free to provide comments to ELAB. He would be interested in seeing the comments from the stakeholders. Mr. Speis explained that ELAB received a good deal of information in response to its questions, and the Board did not censor the information. All of the information has been included for informational purposes, and the Board understands that many of the suggestions that it received are outside of its purview. The recommendations that ELAB made to the Agency are within the scope of ELAB's charter. Ms. Merten thought that if readers did not peruse the summary document carefully, they would not understand that the suggestions

¹ The introduction of the summary document states, "Finally, it is important to note that the suggested solutions detailed in this document were provided by the stakeholders and are not endorsed by ELAB in any way; they are included for informational purposes only."

² Prior to each list of suggested solutions, the summary document states, "Potential solutions that the stakeholders suggested are as follows:".

were not from ELAB. Ms. Shields explained that a TNI representative serves on the Board and keeps the institute informed of all Board activities, so the contents of the summary document should have been familiar to TNI prior to publication.

Mr. Hautman stated that OW will respond to the recommendations when the office receives them from the Board. He understood that many of the constituents are involved directly with NELAP; he thought that perhaps the constituents represented a small group, which may have skewed the results. All states have issues, and the report did not include the perspective of non-NELAP states that have successful programs. Ms. Wade rebutted that she had spoken to a variety of states that spanned the spectrum of NELAP and non-NELAP states. Therefore, the comments of non-NELAP states were included in the summary document. Mr. Farrell added that he had contacted the TNI Assessment Forum and interviewed 60 to 90 representatives from a variety of NELAP and non-NELAP states. The Board's samples size could have been larger, but it made an earnest attempt to gather information from as many different entities as possible.

Mr. Hautman thought that information regarding who was interviewed should be made available. Dr. Karimi explained that the interviewees were interviewed with the understanding of anonymity, so the Board decided not to provide this information. Mr. Farrell said that the sources of information could be clarified in a general manner. Ms. Phelps thought that it was necessary to generically clarify the spectrum of stakeholders that were interviewed and emphasize that ELAB published one piece of a greater whole. Dr. Karimi said that the summary document was a snapshot of stakeholder perception and should be viewed with some skepticism. Ms. Shields agreed that this aspect of the summary document would not be revisited, but ELAB could include an additional explanation on its website per Ms. Phelps' suggestion.

Mr. Hautman noted that the Agency is attempting to develop programs even within the current economy with available resources.

Mr. Stephen Arms (Florida Department of Health) said that he would like to see a report of what is positive with respect to national accreditation. Ms. Labie explained that based on how the questions were posed to the interviewees, this was not the focus of the effort. The goal was to determine what issues needed to be improved so that ELAB could make relevant and useful recommendations to EPA about a national program. Mr. Arms thought that the questions focused on the negative and that questions about positive aspects of the program were needed. Ms. Shields stated that some positives were identified in the responses, but the focus was on what could be improved. Overall, there were few negative comments, and the PT program received very positive comments. The document with the recommendations to EPA, which has not been released, reflects the positives.

Ms. Phelps stated that Ms. Morgan had written a positive report that ELAB decided to use as a basis for this effort. The Board is not authorized to conduct a survey of the scope that participants are suggesting. If an organization would like to undertake such a survey and provide the data to ELAB, the Board would welcome these data. She emphasized that the first report was positive. Ms. Morgan added that more than 86 percent of more than 500 respondents to her initial query provided positive responses. In terms of a national program, the health will increase when participation increases and a true national program is implemented. Dr. Karimi noted that the

program is good, but expectations were higher than the program delivered; no one expressed the belief that the program is bad but rather that the program has not yet delivered on its promises.

Mr. Farrell stated that the recommendation letter to EPA, which has not been released yet, will include positive aspects of the program. During the previous meeting, participants were “hungry” for information and asked for a document detailing the results of the interviews. ELAB complied with this request by releasing this summary document. He moved to provide ancillary information on the ELAB website that clarifies what the state of national accreditation summary document is and where the effort is heading, emphasizing that the summary document is a small piece of a larger whole and contains raw information. Ms. Labie seconded the motion. The Board passed the motion with one abstention and one nay vote.

Mr. Alfredo Sotomayer (Wisconsin Department of Natural Resources) was happy that the Board passed the motion because he thought that the information needed to be presented in a slightly different manner so that it is clear that it reflects a snapshot of respondents’ thoughts. He was surprised about the comments for increased EPA involvement because the original goal for the program was to be self-sufficient. Mr. Farrell responded that many of these types of comments came from those in non-NELAP states. Ms. Shields added that the program only could be self-sufficient with increased participation, and the program did not receive the participation that was expected.

Mr. Todaro thought that the summary document read more like a “report card” rather than a “warning note.” He was confused about the makeup of the stakeholder groups. He wondered why the effort was at the point of providing recommendations to EPA and where the report falls within the context of ELAB. Ms. Shields responded that ELAB is responsible for providing comment and advice to the Agency regarding national accreditation, so the report falls within its scope. Because ELAB is not allowed to conduct surveys, it was not able to provide percentages regarding the makeup of the stakeholder groups. The questions were kept within the structure that allowed the Board to examine the issues in which it was interested to determine whether it could gather information from the comments to advise EPA on how to promote national accreditation.

Dr. George Detsis (U.S. Department of Energy) advised that the Board should consider the authority, responsibilities and role of the Agency, as well as current EPA activities, prior to making recommendations. This will help crystallize what actions the Agency needs to take to move national accreditation forward. Mr. Speis said that a multitude of stakeholder comments provided the basis for the recommendations. EPA may consider implementing none, some or all of the recommendations. If the Agency chooses not to follow the recommendations, then the program will remain unchanged. If EPA has or pursues the necessary authority to implement the recommendations, then changes to the program can be made. If EPA does not have the authority, then ELAB’s recommendations still stand. Ms. Shields added that the recommendations allow the Agency to grasp what the community would like to see in a national program. Dr. Detsis thought that the Board should consider EPA’s past activities before asking it to take additional action. Ms. Shields responded that the recommendation document, which has not been released, commends the Agency on its prior efforts.

Mr. Stephen Stubbs (Texas Commission on Environmental Quality) asked whether another report would be released that disaggregated which stakeholders were involved. Ms. Shields explained that the stakeholder groups that the various ELAB members had interviewed were detailed in several prior ELAB meeting minutes and face-to-face meeting presentations. An additional report would not be released, but clarifying information would be provided on the website based on the motion passed during this meeting.

Mr. Doug Leonard (Laboratory Accreditation Bureau) said that he had introduced the ACIL white paper that initiated this effort at the January 2011 ELAB face-to-face meeting. The white paper introduced concerns about the state of national accreditation but did not mention concerns about specific states or TNI. ACIL's concern was that the United States needed a national accreditation program to accredit laboratories and recognize ABs given the state of the economy. He thought that ELAB performed admirably in terms of identifying the right questions to ask. In examining the economy and the implementation of standards, ACIL found that the ELAB document emphasizes the council's concerns. At this point, it is necessary to allow task forces to work toward solutions.

Ms. Phelps sought to clarify perceptions about the report, emphasizing that none of the questions that the ELAB members asked their constituents specifically mentioned TNI; the focus was the state of national accreditation. It is a huge compliment in terms of the quality of TNI's program that the respondents exclusively mentioned TNI as a vehicle for national accreditation. There are plenty of alternative accreditation programs, but these were not mentioned by the stakeholder community. Although the participants can choose to look negatively at ELAB's report, it is a positive result that the respondents chose to focus on the TNI accreditation program as a template for national accreditation.

5. OPEN DISCUSSION/NEW ITEMS

Neither the ELAB members nor the participants brought forth new items for the Board to consider.

6. NEWS/UPDATES FROM THE DFO

Ms. Phelps applauded the Board members for their efforts during the previous 2 years. The current term will be concluded in September 2012, with a new Board commencing its activities in October 2012. Four members have served the maximum three-term limit: Ms. Morgan, Dr. Flowers, Dr. Karimi and Dr. Pletl. She thanked these members for volunteering to serve on the Board above and beyond the daily commitments that their jobs require.

7. REVIEW ACTION ITEMS/CLOSING REMARKS/ADJOURNMENT

Ms. Kristen LeBaron reviewed the action items identified during the meeting, which can be found in attachment C. Ms. Shields encouraged the participants to discuss any relevant issues with the ELAB members during the remainder of the Environmental Measurement Symposium.

Citing no additional comments or issues, Ms. Shields asked for a motion to adjourn. Ms. Labie made the motion, which Ms. Morgan seconded. The meeting was adjourned at 12:06 p.m.

AGENDA
ENVIRONMENTAL LABORATORY ADVISORY BOARD
Face-to-Face Meeting/Teleconference: 866-299-3188/9195415544#
Hyatt Regency Washington on Capitol Hill, Washington, DC
August 7, 2012; 9:00 a.m. – 12:00 p.m. EDT

- 9:00 a.m. Opening Remarks and Roll Call
- 9:10 a.m. Approval of July Minutes
- 9:15 a.m. ELAB Charter/Highlights of 2011–2012 Activities
- 9:25 a.m. Workgroup Activities/Ongoing Projects
- ELAB Website *Ad Hoc* Workgroup
 - Method Update Rule *Ad Hoc* Workgroup
 - Monitoring Workgroup
 - qPCR Method for Recreational Water Quality
- 10:15 a.m. Break
- 10:30 a.m. Workgroup Activities/Ongoing Projects (continued)
- Measurement and Technology Workgroup
 - Data Quality Objectives and Method Detection Limits
 - Laboratory Management Workgroup
 - State of National Accreditation Issue
- 11:30 a.m. Open Discussion/New Items
- 11:50 a.m. News/Updates From the Designated Federal Officer
- 11:55 a.m. Review Action Items/Closing Remarks/Adjournment

MEMBERSHIP LISTING AND GUESTS

ELAB MEETING
August 7, 2012; 9:00 a.m. – 12:00 p.m. EDT

| Attendance (Y/N) | Name | Affiliation |
|------------------------------|---------------------------------|---|
| Y | Ms. Aurora Shields (Chair) | City of Lawrence, Kansas Representing: Wastewater Laboratories |
| Y | Ms. Patsy Root (Vice-Chair) | IDEXX Laboratories, Inc. Representing: Laboratory Product Developers |
| Y | Ms. Lara P. Phelps, DFO | U.S. Environmental Protection Agency Representing: EPA |
| Y | Dr. Richard Burrows | TestAmerica Laboratories, 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 (via teleconference) | 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 | Ms. Judith (Judy) R. Morgan | Environmental Science Corp. Representing: Commercial Environmental Laboratories |
| 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 | Mr. David (Dave) N. Speis | QC 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 | Ms. Aaren Alger (Guest) | Pennsylvania Department of Environmental Protection Laboratory Accreditation Program |
| Y | Mr. Stephen Arms (Guest) | Florida Department of Health |
| Y | Dr. Edward Askew (Guest) | Askew Scientific Consulting |
| Y | Mr. Keith Chapman (Guest) | TNI Small Laboratory Advocate |
| Y | Dr. George Detsis (Guest) | U.S. Department of Energy |
| Y | Ms. Stephanie Drier (Guest) | Minnesota Department of Health |
| Y | Dr. Andy Eaton (Guest) | MWH Laboratories |
| Y | Mr. Dan Hautman (Guest) | EPA |
| Y | Ms. Catherine Katsikis (Guest) | Laboratory Data Consultants, Inc. |
| Y | Ms. Kim Kirkland (Guest) | EPA |
| Y | Mr. Doug Leonard (Guest) | Laboratory Accreditation Bureau |
| Y | Ms. Sharon Mertens (Guest) | Milwaukee Metropolitan Sewerage District |
| Y | Mr. Jerry Parr (Guest) | TNI |
| Y | Mr. Alfred Sotomayer (Guest) | Wisconsin Department of Natural Resources |
| Y | Mr. Stephen Stubbs (Guest) | Texas Commission on Environmental Quality |
| Y | Mr. Jim Todaro (Guest) | Alpha Analytical |
| Y | Mr. Lemuel Walker (Guest) | EPA |
| Y | Dr. Shen-Yi Yang (Guest) | EPA |

ACTION ITEMS

1. Ms. Kristen LeBaron will finalize the July 2012 teleconference minutes and send them via email to Ms. Phelps.
2. The Board will develop a recommendation to EPA that when different program offices use the same method, they attempt to use the same version of the method.
3. ELAB will provide ancillary information on the ELAB website that clarifies what the state of national accreditation summary document is and where the effort is heading, emphasizing that the summary document is a small piece of a larger whole and contains raw information.

Attachment D

I hereby certify that this is the final version of minutes for the Environmental Laboratory Advisory Board Meeting held on August 7, 2012.

A handwritten signature in cursive script that reads "Aurora Shields".

Signature Chair

Ms. Aurora Shields

Print Name Chair