SUMMARY OF THE
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
Face-to-Face Meeting/Teleconference: 866-299-3188/9195415544#
Hyatt Regency Bellevue, Bellevue, Washington
August 15, 2011; 9:00 a.m. – 12:00 p.m. PDT

The Environmental Laboratory Advisory Board (ELAB or Board) face-to-face meeting was held on August 15, 2011, from 9:00 a.m. to 12:00 p.m. PDT. 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, ROLL CALL, MISSION STATEMENT AND OVERVIEW OF BOARD GOALS

Ms. Lara Autry, Designated Federal Officer (DFO) for the Board, and Ms. Judy Morgan, 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 Agency). Board meetings are held on the third Wednesday of each month from 1:00 p.m. to 3:00 p.m. Eastern Time. These meetings are open to the public, and Ms. Autry encouraged the attendees to participate. She supplied the telephone number and passcode, which are provided above.

Mr. David Speis, former Board Chair, explained that ELAB has been active during the past several years, moving forward a significant number of agenda items brought forth from the laboratory community and EPA. Several of the items were related to rulemaking that affected the environmental laboratory community, including several comments that the Board made within the past year. The Board has several new initiatives on which it is working, including a recommendation to the Office of Water (OW) regarding adoption of The NELAC Institute (TNI) quality systems standards and an information-gathering initiative about the health of national accreditation. Each of the Board members are engaged in ensuring that they represent the environmental laboratory community when making recommendations to the Agency. Many of the issues on which ELAB works take time to come to fruition because of the need to work within the federal framework. Following Mr. Speis' remarks, Ms. Morgan asked the Board members to introduce themselves.

2. APPROVAL OF JULY MINUTES

Ms. Morgan asked whether there were any changes to or comments on the July 2011 Board meeting minutes; there were none. Mr. Jack Farrell made a motion to approve the July 2011 minutes, which Dr. Reza Karimi seconded. The meeting minutes for July 2011 were approved unanimously with no discussion.

3. NEWS/UPDATES FROM DFO

Ms. Autry explained that ELAB's charter was renewed on July 15, 2011, for 2 years. The charter is available electronically on the ELAB website (http://www.epa.gov/elab), and hard copies are available at the technical information booth. The membership of the Board is reconstituted every 2 years in years alternate to the charter renewal. If any of the participants is interested in becoming a member of ELAB, he or she should contact Ms. Autry. The Agency ensures that the membership is diverse in many aspects (e.g., discipline, geography) so that it may provide advice to EPA that is relevant to measurement, monitoring and laboratory issues. ELAB is in the process of updating and redesigning its website to ensure that information is being shared in a user-friendly manner and that the website conforms to EPA's new website format.

4. PRESENTATIONS ON RECENT RECOMMENDATIONS

Ms. Morgan explained that the purpose of ELAB is to provide advice and recommendations to the Administrator of EPA on issues associated with enhancing the Agency's measurement programs and the systems and standards of environmental accreditation. The recently approved charter is expanded compared to the previous charter to include the systems associated with environmental accreditation. The Board intends to increase the visibility of the new charter with a formal effort targeting all programs within the Agency to market ELAB's diverse expertise, emphasize Board member availability and willingness to participate, and request proactive involvement when applicable regulations or methods are targeted for review or revision. During the previous year, Board activity was a combination of formal Federal Register responses and work on issues of stakeholder interest. Formal responses to EPA were supplied regarding Sufficiently Sensitive Test Methods, Improving EPA Regulations, Methods Update Rule and National Emission Standards for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymers Production. Activities of interest to stakeholders include proficiency testing (PT) programs, recommendations to OW and Recreational Water Quality Criteria.

Sufficiently Sensitive Test Methods

Mr. John Phillips provided an update for the Sufficiently Sensitive Test Methods Rule Task Group's work on the sufficiently sensitive tests methods rulemaking (*40 CFR Parts 122 and 136. National Pollutant Discharge Elimination System [NPDES]: Use of Sufficiently Sensitive Test Methods for Permit Applications and Reporting*) in the absence of the Task Group Chair, Dr. Jim Pletl. The rulemaking would codify existing EPA guidance on the use of "sufficiently sensitive" analytical methods with respect to measurement of mercury and extend the approach outlined in that guidance to the NPDES program more generally. The rule was proposed on June 23, 2010, in the *Federal Register*, with a 45-day comment period that ended on August 9, 2010. During a previous face-to-face meeting in August 2010, ELAB submitted a letter of concern on the last day of the comment period as a placeholder for later comments. The Board submitted a comprehensive set of comments on October 18, 2010, based on the Task Group's recommendations. The ELAB Sufficiently Sensitive Test Methods Task Group spoke with OW representatives via teleconference on March 30, 2011, to discuss the Board's comments.

Under the proposed rules, EPA would specify that a method is sufficiently sensitive if it meets one of three tests: (1) The method minimum level (ML) is "at or below the level of the applicable water quality criterion or permit limitation." (2) The ML is above the applicable criterion or permit limit, "but the amount of the pollutant or pollutant parameter in a facility's discharge is high enough that the method detects and quantifies the level of the pollutant or pollutant parameter in the discharge." (3) The method has the lowest ML of the methods approved by EPA under 40 CFR 136 for the pollutant or pollutant parameter. In regard to the third test, the technology has not kept up with water quality standards. ELAB voiced concerns about NPDES data quality objectives (DQOs); method validation; method accuracy, precision, and sensitivity; method selectivity; method detection limit (MDL) and ML definitions; and the rule's impact on data cost. ELAB recommended that the Sufficiently Sensitive Test Methods Rule should not be implemented as written, and the concerns specified by ELAB and the general public should be addressed before promulgation. The Board also provided recommendations on how the Agency could address each concern.

OW staff members present on the March 30, 2011, teleconference included Ms. Kathryn Kelly (rule lead), Dr. Maria Gomez-Taylor, Ms. Sarita Hoyt and Mr. Brian Frazer. Mr. Paul Bangser of EPA's Office of General Counsel (OGC) also was present. The Agency was unable to provide any response to comments or inform the Task Group about potential revisions to the rule because the rule had not been finalized. The teleconference was meant to be a listening session so the Agency could better understand ELAB's comments.

EPA's impetus for the rule was that EPA believes that in some circumstances insufficiently sensitive methods are being utilized for NPDES. This rule extends the policy initiated with the August 23, 2007, memorandum, "Analytical Methods for Mercury in NPDES Permits," which introduced the idea of Sufficiently Sensitive Methods for mercury analysis. In this memorandum quantitation limits (QL) were specified for all approved mercury methods, but they were not always specified in OW methods. The goal of the rule is to phase out the use of outdated methods.

OW staff members provided comments regarding the ML and stated that the ML is interchangeable with the QL, but the term ML is preferred. The ML is the lowest calibration point and may be derived from a multiple of the MDL. There are multiple methods to derive an ML; however, no additional guidance will be provided. When an ML is not listed in the method, each laboratory can generate its own, which may be used for NPDES compliance.

The Board stressed that EPA's cost analysis was flawed and offered additional data regarding the cost implication of the rule. EPA considered additional data from ELAB regarding the cost issue despite the fact that the comment period had expired. ELAB provided sealed bid cost data from the City of Orlando, Florida, for water analysis using various mercury methods, showing a 540 percent increase in cost for the most sensitive method. EPA stated that its existing guidance on MDL, ML and DQOs will not change, but the Agency will consider accuracy, precision and selectivity when finalizing the rule. EPA expects to promulgate the rule before the end of 2011, and states will have 1 year to implement the rule.

Ms. Nan Thomey (Environmental Chemistry, Inc.) asked whether EPA's guidance on MDLs, MLs and DQOs is known. Mr. Phillips responded that MDL is defined in 40 CFR 136, but the

definition of ML is nebulous. The Sufficiently Sensitive Testing Methods Rule will not change the Agency's current position. Dr. Richard Burrows added that NELAC's Environmental Measurement Monitoring Methods Committee is focusing on calibration during a presentation the following day.

Dr. Ed Askew (Askew Scientific Consulting) noted that the ML varies per the "pumpkin book" if wastewater samples are diluted to overcome the matrix effect, causing violation of NPDES permits as a result of producing analytical data that provide a precise number value. He thought that EPA tends to overlook the science during rulemaking. Mr. Phillips commented that this specific issue had not been addressed in ELAB's comments. Dr. Askew remarked that his NPDES clients will receive automatic violations because their ML is above the most sensitive methods.

Mr. Farrell asked whether ELAB's efforts on this issue were finished or whether the Board should follow up with next steps. Dr. Karimi thought that it was complete. Mr. Speis said that the comments were left open so that ELAB could continue to pursue the issue following the final *Federal Register* notice.

Improving EPA Regulations

Mr. Speis provided an update on Improving EPA Regulations in the absence of Dr. Jeff Flowers. An EPA public notice invited direct comments, and ELAB chose to focus its comments in the areas of: (1) Environmental Measurements and Accreditation Management and (2) Laboratory Accreditation and Testing Methods. The Agency also asked for comments regarding the impact of topical area recommendations to selected areas of consideration (e.g., integration, state and local governments, economic and market impact, compliance). ELAB provided input on factors that simplify and economize environmental requirements applied to laboratories without sacrificing data quality and/or usability or human health and the environment.

The Board's laboratory accreditation recommendations took a strong position on laboratory accreditation for all Agency programs and specified that environmental data used to comply with federal environmental regulatory programs be produced by laboratories accredited to consensus national standards. ELAB also recommended that EPA recognize professional third-party accreditation for environmental laboratories as a viable alternative to government accreditations, which in turn could be utilized by state programs. The term "professional" refers to internationally recognized bodies whose business is accreditation. The benefits of these recommendations include formation of a single national program, elimination of replicate infrastructure, development of a nationally synchronized quality systems approach, establishment of a simplified national accreditation approach, uniform application of accreditation requirements and reduction of the accreditation cost burden to laboratories.

ELAB's testing method recommendations suggested that the Agency: (1) standardize quality assurance (QA) and quality control (QC) requirements, terms and definitions using consensus standards that follow the Office of Management and Budget's *Circular A-119*; (2) establish DQOs and measurement quality objectives (MQOs) to determine the acceptability of existing, new and modified methods; and (3) allow use of any existing EPA methods or consensus organization methods for environmental sample analysis if it achieves the program's MQOs.

Benefits of these recommendations are stimulated innovation, chemical reductions in analytical testing, decreased tracking and auditing of multiple requirements and lower costs.

Ms. Debra Waller (New Jersey Department of Environmental Protection [NJDEP]) thought that it sounded as though small laboratories that perform their own monitoring under their own NPDES permits would not be able to continue to perform their work producing legally defensible, consistent and reliable data if they are not certified by an entity such as TNI. Mr. Speis responded that it is difficult to produce data intended to protect human health and the environment using standards of various rigor. He provided an analogy regarding city size and medical doctor certification and noted that producing regulatory data for compliance purposes is another issue. The question is in regard to maintaining the infrastructure required for a laboratory that produces compliance data. Mr. Farrell added that consensus standards do not need to be implemented by a bureaucracy, and small organizations can implement them in a thoughtful manner. The basics of quality standards as applied to the organization need to be present and followed. Mr. Speis noted that there is a misconception regarding the process of setting up a laboratory under the National Environmental Laboratory Accreditation Program (NELAP).

Mr. Doug Leonard (Laboratory Accreditation Bureau) noted that an advisory of small laboratories is that the person in charge of data is dedicated and involved, and the cost of implementation is pennies compared to the cost of not applying quality systems. Method 17025 reduces the cost of doing business. He asked whether the Board had followed up on his previous request to examine the American Council of Independent Laboratories (ACIL) white paper and whether this output was a result of that review. Mr. Speis explained that the initiative that arose from that review would be discussed later.

Dr. Askew stated that the Midwest and West are seeing this in terms of accreditation. Small drinking water and wastewater laboratories view NELAC accreditation as cost prohibitive because they do not have the resources to hire a second dedicated staff member. Regarding sending out samples, violations of the 40 CFR 136 6-hour requirement have occurred, indicating that sending out samples is not always a viable option. Small laboratories do not have the resources to hire dedicated QA personnel. He stressed that the TNI Small Lab Advocate Group (SLAG) needs to be involved and that a multitiered step for national accreditation is needed because geographical considerations do not allow small laboratories to send out their samples for outside testing. Mr. Speis explained that he had heard this argument in Minnesota, and complaints only were received when a new name was placed on an already-existing requirement. Education will be needed to move forward with this approach. Dr. Askew agreed that small laboratories would need guidance. Mr. Farrell said that neither ISO 17025 nor the NELAC standards state that a dedicated QA position is required. The SLAG has been working diligently to develop guidance, which will be unveiled during a session of this meeting on Wednesday, August 17, 2011. The guidance document was reviewed by the SLAG and the Technical Assistance Committee.

Methods Update Rule

Ms. Morgan said that the Board had provided comments to EPA regarding *40 CFR Parts 136, 260, 423, et al. Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures; Proposed Rule* (Methods Update Rule or

MUR). ELAB stakeholder diversity allowed for a comprehensive review and response, and the review resulted in commendations and recommendations. The Board recommended an update to 136.6 to provide clarification regarding method modification and analytical requirements and the addition of 136.7 to provide a requirement for essential QA/QC.

ELAB commented on Tables IB, IC, ID, and II and their footnotes and on Section I (QA). In terms of Table IB, the Board recommended that EPA clarify distillation requirements and which QA would apply to the standard methods; cleanup of referenced elements, including method referenced materials, also was recommended. The use of limits was identified as a key topic for Table IC, and ELAB recommended an update of Series 600 methods within Table ID. In terms of Table II, ELAB recommended that EPA add methods to the holding times for microbiology tests for sludge. The holding times should be a function of the sample and not of the method. Section I provides the full weight of the TNI Standards. The recommendations regarding Section I were that the Agency: (1) use TNI references to replace the 2003 NELAC references; and (2) adopt the QA and quality control requirements listed in the appropriate sections of the consensus body compendium.

Ms. Morgan reported that she had spoken to Mr. Lemuel Walker (EPA), and all comments have been reviewed by EPA's Office of Science and Technology. Responses have been generated and are being reviewed by OGC. Many comments that were received are being acted on favorably, with finalization of the rule expected in October or November 2011. Mr. Walker reiterated that if OGC's review goes well, the rule will be finalized during the fall. The QA/QC issue has been clarified, and options are provided for methods that do not have associated QA/QC. Some controversial methods may not be included in the rule. Most of the comments have been addressed, but some are difficult to address because information was included in the comments that is outside the purview of the proposed rule.

5. WORKGROUP ACTIVITIES

Monitoring Workgroup

Ms. Patsy Root provided an update on Monitoring Workgroup activities regarding Recreational Water Quality Criteria. EPA is revising the 1986 Federal Water Quality Standards at 40 CFR 131 and developing new or revised Recreational Water Quality Criteria recommendations per the Beaches Environmental Assessment and Coastal Health (BEACH) Act, which is accompanied by the effort to implement rapid microbial methods (specifically quantitative polymerase chain reaction [qPCR]). ELAB is interested in these efforts because water quality criteria are critical to the Clean Water Act and used in water quality assessments, total maximum daily load and NPDES determinations, and recreational water monitoring and notification programs. New recreational water quality criteria will be accompanied by new or revised analytical methods, and the fecal indicator target likely will be enterococci. The new criteria must include at least one rapid method, with qPCR to be used at some, but unlikely all, beaches. Bather load and potential impact from publicly owned treatment works likely will be used to determine which beaches will require rapid monitoring. States likely will make the decision on which beaches require rapid methods and determine how many laboratories are needed to properly manage their beach

monitoring program. The possibility of providing same-day notification to remote beaches is unclear.

There are several questions to consider prior to the publication of the criteria in October 2012: Which beaches will require rapid methods versus traditional testing? When do samples have to be taken to have relatively same-day notification? What implementation assistance will EPA or the states be able to provide to laboratories that must adopt qPCR? What guidance will be available to assessors? How will an associated PT program be managed and by whom? How will qPCR be adopted in laboratories? Will EPA provide assistance in implementation of qPCR? Who will assess laboratories (e.g., EPA or state accreditation bodies [ABs])? When will EPA have assessment criteria? How and when will assessors be trained? Has there been discussion with PT providers? How will PT providers be assessed?

The new water quality standards and criteria likely will be announced by February 2012 and will be in place by October 15, 2012, with adoption in 2015. Laboratories will need guidance regarding how to adopt new rapid methods (e.g., cost, training, audit expectations), and ABs will need guidance regarding how to assess laboratories that are using qPCR (e.g., training, universal auditing procedures). Additionally, PT providers will need to be assessed. The next step for the Board to address these issues is for the Monitoring Workgroup to discuss the laboratory implementation process (e.g., cost, barriers, dealing with interference) with experienced laboratories. From this, ELAB can better determine the impact and cost to laboratories that may have to add qPCR to their testing repertoire. The Board will hold future conversations with the EPA Recreational Water Criteria Group to discuss the impact of the changes on laboratories, ABs and PT providers.

Dr. Askew stated that he had asked EPA whether the Agency had determined any guidance for holding times, and it had not. Holding times for qPCR are strongly needed. Also, qPCR tends to have false positives. Ms. Root said that her understanding was that the holding times for recreational samples would be 6 hours, although this is not conducive to same-day notification.

Ms. Waller stated that Region 2 has been performing parallel tests with Method 1600 and PCR for 5 years. PCR is not used for beach closures in New Jersey, but it provides options for advisories. PCR captures viable and nonviable cells. Region 2 currently is developing correlations between Method 1600 and PCR. Samples can be frozen prior to PCR to sustain their viability. The region also is trying to validate beach methods, and has made a good deal of progress during the previous 5 years. Ms. Waller suggested Mr. Jim Ferretti (EPA Region 2) as a possible “expert” contact in this area. Ms. Root added that incorporating modeling makes sense as well.

Dr. Karimi asked whether the Centers for Disease Control and Prevention (CDC) had been involved in this effort and could provide guidance, as the topic deals with human health. Ms. Root was not aware of any CDC involvement. Ms. Waller noted that PCR has been used for many years now in the realm of human health and only recently was starting to be utilized in environmental laboratories.

Measurement and Technology Workgroup

Mr. Phillips provided the report for the Measurement and Technology Workgroup in the absence of the Workgroup Chair, Mr. Jeff Lowry. In 2011, the Workgroup received input from EPA regional and program offices regarding the current Safe Drinking Water Act PT program and found that, in general, the PT program met the program needs of the various users. Suggested improvements were to expand the PT concentration range, especially around the MCL; proceed with the development of a central PT database; and provide clarification regarding Drinking Water Certification Manual guidelines versus requirements. The Workgroup corresponded with OW regarding the use of TNI PT statistical data to inform decisions regarding new PT performance limits. Also in 2011, the Workgroup provided recommendations to EPA regarding methodology as it related to the proposed rule concerning polyvinyl chloride hazardous air pollutants (EPA-HQ-OAR-2002-0037; FRL 9298-7).

The next Workgroup task is to seek clarification regarding the use and applications of DQOs, MQOs and data quality indicators as they relate to environmental analytical measurements within the DQO process. The Workgroup will attempt to understand the application of the DQO process within various EPA offices by performing a comprehensive document search within EPA, developing a glossary of DQO-related terms and definitions and meeting with various program offices. Ultimately, the Workgroup's efforts will allow the Board to make recommendations to facilitate expanded use of the DQO process for environmental efforts.

Mr. Speis noted that this initiative relates well to the comments that ELAB provided to the Agency regarding Improving EPA Regulations. A common set of terminology must be applied throughout EPA to decrease confusion.

In the absence of Mr. Lowry, Mr. Speis provided an update regarding the ELAB recommendations to OW for the certification of laboratories that analyze drinking water. The straightforward recommendations were for OW to: (1) employ the TNI ISO-17025-based standard as the quality system standard for drinking water laboratories as the TNI standard meets or exceeds the quality system requirements of the Drinking Water Certification Manual and (2) employ the Drinking Water Certification Manual for Drinking Water Program technical specifications, retaining requirements that are unique to drinking water accreditation and referencing the TNI quality system specifications as the quality system for this program.

The benefits of these recommendations are that they substitute an ISO 17025 consensus standard as the quality system framework for drinking water laboratories, promote unification of quality system standards across EPA program offices, consolidate duplicate state accreditation programs into a single (national) quality system program, place all accredited drinking water laboratories within the same assessment plane and enable OW to focus on drinking water compliance technical prescription to assure programmatical, analytical and QC needs are satisfied.

Mr. Greg Carroll (OW) explained during the January 2011 ELAB face-to-face meeting that the process of examining and possibly implementing these recommendations would take some time. The Board had hoped that OW personnel could be present at this meeting to provide an update, but that was not possible. Mr. Speis reported that he, Ms. Morgan and Ms. Autry had spoken to Mr. Carroll and Mr. Dan Hautman (OW), who had explained that OW had presented the

recommendations to the Forum on Environmental Measurements and the Quality Community Information Exchange (Q6), which is comprised of Agency QA staff[1]. Q6 would prefer to advocate for ISO 17025 as the overall quality system standard because it has international recognition and is perceived as more comprehensive than the TNI NELAP standard. OW still is awaiting feedback from EPA regions. OW requires broad Agency and regional support to promote the recommendation prior to review by OGC and will not move forward at this time.

A misconception exists regarding differences between ISO 17025 and the TNI quality system standard, which is affecting the Agency's ability to act on the Board's recommendation. The next steps are for ELAB to clarify this misunderstanding within EPA and emphasize how the stakeholder community employs the TNI quality system standard and why ISO 17025 alone is insufficient.

Mr. Farrell wondered how it was possible to consider ISO 17025 as more stringent than the TNI standards as the TNI standards incorporate ISO 17025 in addition to industry standards. Mr. Speis agreed and stated that the Workgroup concluded that this misunderstanding must be eliminated before the Q6 group can understand the recommendation. Ms. Autry added that EPA must make certain considerations and generally does not endorse the activities of a specific group. ISO 17025 is generic and has been incorporated into Agency documents. Additionally, TNI has not been incorporated into all EPA programs because of the perception that TNI does not meet their specific needs. Mr. Carroll reaching out to other programs is a step forward, but these programs are not interested in TNI.

Dr. Burrows asked whether it was implied that neither ISO 17025 nor the TNI standards would be implemented because they are too costly. Mr. Speis said that this was not stated, but it was implied, and that was what Ms. Morgan, Ms. Autry and he inferred. Dr. Karimi wondered whether this was a "dead" issue as far as the Agency was concerned. Ms. Morgan said that the next step is education. The Board will need to provide information because there are knowledge gaps regarding the purpose, intent and use of ISO 17025 and the TNI standards. The Agency cannot support a program that it does not understand, and ISO is more common.

Ms. Autry said that ELAB would have to decide whether to take the recommendation to the next step; the original recommendation was to OW and not the entire Agency. Mr. Carroll has provided the opportunity to increase consistency throughout EPA, not just within OW. OW needs broader Agency support to move forward with the recommendation. ISO 17025 is an international standard and viewed as such. Certain groups are discussing an international basis for accrediting laboratories, and if these groups move forward with ISO 17025, TNI will need to make the determination whether it wants to accredit to ISO 17025 to ensure international recognition.

Mr. David Friedman (Friedman Consulting, LLC) agreed with the discussion and stated that initiatives have not moved forward because of misinformation. He strongly encouraged an organization (e.g., TNI, ELAB) to develop a robust education program in this area. Mr. Leonard

[1] This statement accurately reflects the meeting discussion; however, Q6 can more accurately be described as being comprised of Agency QA management staff.

said that another avenue is the U.S. signatories of the International Laboratory Accreditation Cooperation. Part of the misunderstanding is that NELAC accreditation has additional requirements to ISO 17025. The Agency must be informed that ISO 17025 is not as stringent. The American Clinical Laboratory Association is another resource that could educate EPA. Dr. Bruce Godfrey (Curtis & Tompkins Laboratories) said that this is a branding issue.

The Board members discussed the issue to develop a motion. Mr. Farrell made a motion that the Board would add this issue to its agenda, forming a Task Group to gather additional information from entities internal and external to the Agency and provide education to reduce misconceptions, with the overall goal of providing EPA with a recommendation regarding broader Agency adoption of the TNI quality systems standards. Mr. Speis seconded the motion, which passed unanimously.

Laboratory Management Workgroup

Mr. Speis provided the report for the Laboratory Management Workgroup in the absence of the Workgroup Chair, Dr. Flowers. ELAB needed to determine whether the ACIL third-party accreditation initiative had merit and whether the Board could support this type of initiative. Ultimately, ELAB must be able to make recommendations to EPA based on the initiative. Curiosity regarding program performance raises questions about the health of national accreditation. ELAB began by gathering information to evaluate such a program. Teams of ELAB members interviewed the constituencies that they represent to obtain views on operational and economical program impacts. This information will be consolidated and serve as a basis for determining whether ELAB can recommend EPA action to promote a better national program. The evaluations teams included commercial environmental laboratories, QA consultants and accreditation standard developers and assessors, research and development organizations, users and providers of commercial laboratory products, ABs and accredited wastewater laboratories, municipal and public health laboratories, and the Alliance of Automobile Manufacturers.

The Board focused on two areas: (1) operations and implementation and (2) economic factors. Health matrix factors that could impact accreditation operations and implementation include assessment uniformity, national program leadership, nonparticipation states participation, accreditation scope offering, accreditation modification timeliness, national program standardization, PT data evaluation uniformity, laboratory disqualification process, assessment report use and the standards development process. Health matrix factors for the economic focus include state-level program funding, nonparticipating state burden, assessor training completeness, shrinking AB staff, government travel restrictions, accreditation to non-NELAP states, NELAP state burden in relation to non-NELAP states, PT data evaluation uniformity and fundamental task execution. The ELAB members asked their constituents the following questions: What impact do these factors have on the program? What solution would you propose if the impact is negative? Once the information has been completely gathered and then compiled, ELAB will be able to determine whether there is enough information available to make a recommendation to EPA that is within the Agency's purview.

A participant asked about the timeline of the effort. Mr. Speis said that the goal is to complete the information gathering and compilation process as quickly as possible, but the interview

process took longer than was expected. The information will be discussed during ELAB's September meeting.

Ms. Waller was concerned that EPA does not accredit, and the states will look to the Agency for guidance. She asked whether the Board members had received input from the states, which most likely will not want to relinquish their authority. Mr. Speis explained that the ELAB members were working within their charter to gather information to be able to make a recommendation to EPA and focused on the constituencies that they represent. Ms. Michelle Wade stated that she had contacted several states via e-mail, but not many states had the time or desire to respond. Ms. Wade is working with those states that responded, and she is open to receiving remarks from any additional states who would like to comment. Ms. Autry emphasized that all Board members are open to receiving comments from those who are interested. Dr. Michael Wichman added that he had contacted several state laboratories. Mr. Speis explained that diverse stakeholders had been contacted, so diverse opinions are expected. The Board will determine whether there is a consensus strong enough to make a recommendation to EPA on this issue. Mr. Farrell explained that he plans to obtain feedback from the state assessors, who meet every other month, and asked the TNI Advocacy Committee for input as well.

Mr. Leonard thanked the ELAB members for acting on this issue as the health of a national accreditation program is critically important for all stakeholders. His constituency expressed concern, and he asked what materials ELAB would be releasing (e.g., the ACIL white paper). Mr. Speis explained that the Board was not in a position to use the ACIL white paper as a result of its charter. The members used the white paper to ask questions about the process. Once the information has been compiled, it will be possible to make a determination about the feasibility of crafting a recommendation for EPA. It is outside the Board's charter to endorse a third-party white paper, but it can use the white paper as evidence that changes are needed.

Mr. Leonard thought that, in terms of states giving up their authority, states could accredit laboratories as they see fit and would not need to give up their rights to use third-party accreditors.

Dr. Askew commented that one of the American Water Works Association laboratory committees was holding a conference call in a few weeks, and he invited the municipal and public health laboratory team members (Drs. Pletl and Wichman) to present about this during the teleconference. He asked whether the interview questions were available in electronic format and suggested that they be placed on the Water Environment Foundation laboratory website, which would facilitate responses from small- and medium-sized laboratories, particularly because they often are ignorant about these types of issues. Mr. Farrell responded that the questions were not in electronic format, because this approach is not optimal; direct, interactive interviews work best, particularly because of the Board's inability to survey large groups without Office of Management and Budget approval.

Ms. Thomey suggested that stakeholder groups could survey their members, as they do not have these limitations. Ms. Autry encouraged this as an ideal method for ELAB to receive input without violating any federal mandates. Dr. Michael Shepherd (Shepherd Technical Services) asked for clarification about what information ELAB desired. Mr. Speis said that the goal was for the Board to develop a consensus opinion about whether there is enough information

available for ELAB to make a recommendation. The Board members have not begun to compile the information, so they are open to receiving more input from interested stakeholders. Ms. Waller said that it would be beneficial for all stakeholder groups to ask the same questions of their members and suggested that if ELAB could generate questions, it would be helpful.

Dr. Shepherd asked whether the Board expected to be able to provide more information during the next face-to-face meeting. Mr. Speis said that the ELAB members are anxious to complete the process and expect to be able to have a consensus opinion by the next face-to-face meeting.

Dr. Andy Valkenburg (Energy Laboratories, Inc.) said that the analyte list for the Clean Water Act differs among states. The NPDES Discharge Monitoring Report-Quality Assurance paperwork is very intensive, and improvements in the process are needed. He commended the Board on its MUR work and agreed that there are approximately 20 different definitions of MDLs from various EPA entities. Integrating several programs under a single umbrella would be helpful. The Drinking Water Certification Manual is a good guidance document, and integrating it into the TNI standards could be helpful. Mr. Speis said that the Board included similar comments in its response to Improving EPA Regulations.

6. OPEN DISCUSSION/NEW ITEMS

Dr. Burrows introduced the topic of Method 524. A new method (Method 524.4) is undergoing peer review currently, and the only difference compared to the old method (Method 524.3) is that it requires purging with nitrogen rather than helium. It is helpful that EPA is broadening the method, but publishing it as a new method instead of an update will cause accreditation problems. He thought that if there was not a quality issue involved, then a new method should not be assigned and only an update should be issued. Ms. Morgan added that an ELAB Task Group is gathering information on this issue and hopes to have more information for the stakeholders as it is available.

Mr. Stuart Nagourney (NJDEP) agreed with Dr. Burrows, especially in terms of the multiplicity of the methods. He provided the example of Method 1060, which is creating similar problems. It would be helpful to have one version of a method or require laboratories to use the latest so that there is not confusion regarding which version is used by which laboratory for what purpose. It is a very confusing situation that he hopes will be addressed. Dr. Burrows noted that ELAB has had several discussions with the Office of Resource Conservation and Recovery regarding this issue, and the goal is to move other programs within the Agency forward as well. Mr. Roger Kenton (Eastman Chemical Company) noted that the most recently promulgated method version must be used, so to follow the law, laboratories must use that and not the most recently approved version.

7. REVIEW ACTION ITEMS/CLOSING REMARKS/ADJOURN

Citing no additional comments or issues, Ms. Morgan asked for a motion to adjourn. Dr. Karimi made the motion, which Dr. Burrows seconded. The meeting was adjourned at 12:03 p.m.

Attachment A

AGENDA
ENVIRONMENTAL LABORATORY ADVISORY BOARD
Face-to-Face Meeting/Teleconference: 866-299-3188/9195415544#
Hyatt Regency Bellevue, Bellevue, Washington
August 15, 2011; 9:00 a.m. – 12:00 p.m. PDT

9:00 a.m. Opening Remarks, Roll Call, Mission Statement, and Overview of Board Goals
Approval of July Minutes
News/Updates from DFO
Presentations on Recent Recommendations
- Sufficiently Sensitive Methods
- Improving EPA Regulations
- Methods Update Rule

10:00 a.m. Break

10:30 a.m. Workgroup Activities
- Monitoring Workgroup
- Measurement and Technology Workgroup
- Laboratory Management Workgroup

Open Discussion/New Items
Review Action Items/Closing Remarks/Adjourn

Attachment B

MEMBERSHIP LISTING AND GUESTS

ELAB MEETING
August 15, 2011; 9:00 a.m. – 12:00 p.m. PDT

Attendance (Y/N)	Name	Affiliation
Y	Ms. Judith (Judy) R. Morgan (Chair)	Environmental Science Corp. Representing: Commercial Environmental Laboratories
Y (via teleconference)	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)
N	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
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
N	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 (via teleconference)	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	Dr. Edward Askew (Guest)	Askew Scientific Consulting
Y	Mr. David Friedman (Guest)	Friedman Consulting, LLC
Y	Dr. Bruce Godfrey (Guest)	Curtis & Tompkins Laboratories
Y	Mr. Roger Kenton (Guest)	Eastman Chemical Company
Y	Mr. Doug Leonard (Guest)	Laboratory Accreditation Bureau
Y	Mr. Stuart Nagourney (Guest)	New Jersey Department of Environmental Protection (NJDEP)
Y	Mr. Joe Pardue, Jr. (Guest)	Pro2Serve
Y	Dr. Michael Shepherd (Guest)	Shepherd Technical Services
Y	Dr. Andy Valkenburg (Guest)	Energy Laboratories, Inc.
Y	Ms. Nan Thomey (Guest)	Environmental Chemistry, Inc.
Y	Ms. Debra Waller (Guest)	NJDEP
Y	Mr. Lemuel Walker (Guest)	EPA

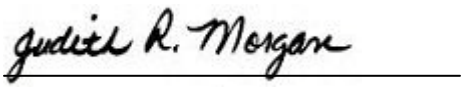
Attachment C

ACTION ITEM

1. ELAB will form a Task Group to gather additional information from entities internal and external to the Agency and provide education to reduce misconceptions, with the overall goal of providing EPA with a recommendation regarding broader Agency adoption of the TNI quality systems standards.

Attachment D

I hereby certify that these are the final version of minutes for the Environmental Laboratory Advisory Board Meeting held on August 15, 2011.



Signature Chair

Ms. Judith R. Morgan

Print Name Chair