

**Summary of the
Environmental Laboratory Advisory Board
February 6, 1997**

The Environmental Laboratory Advisory Board (ELAB) met at the Hyatt Regency Hotel in Bethesda, MD, on February 6, 1997. The meeting was led by ELAB Co-Chairs Dr. Wilson Hershey of Lancaster Laboratories, Inc., representing ACIL, and Ms. Ramona Trovato of the U.S. Environmental Protection Agency's (USEPA's) Office of Air and Radiation (OAR). In attendance were Board members Mr. Milton Bush of the 'M Companies, former Chair of the Committee on National Accreditation of Environmental Laboratories; Ms. Linda Christensen of the International Association of Environmental Testing Laboratories (IAETL); Dr. Kathy Hillig of BASF Corporation, representing the Chemical Manufacturer's Association; Dr. William Kavanagh of Science Application International Corporation, representing A2LA; Ms. Cynthia Lee of Analytical Services Laboratory, Inc.; Dr. Michael Smolen of the World Wildlife Fund; Dr. Evelyn Torres of the Fairfax County (VA) Water Authority; Dr. Allen Verstuyft of Chevron Research and Technology, representing the American Petroleum Institute; and Ms. Jeanne Mourrain of USEPA's Office of Research and Development (ORD), the ELAB Designated Federal Official.

INTRODUCTION

Dr. Hershey opened the meeting and Ms. Trovato reviewed the agenda, which included the following topics:

- Good Laboratory Practices (GLPs) Subcommittee Report,
- Proficiency Testing (PT) Subcommittee Report,
- Discussion on National Environmental Laboratory Accreditation Conference (NELAC) participation by Native American Tribal Nations,
- Third-Party Assessors Subcommittee Report,
- NELAC National Database *Ad Hoc* Committee Report,
- Performance-Based Methods System (PBMS) Subcommittee Report,
- ELAB nominations for 1997-1999,
- Summary of the results of the Second NELAC Interim Meeting,
- New issues, and
- Next steps.

Ms. Mourrain announced that the current ELAB charter expires at the end of July 1997. Since ELAB is a continuing committee, USEPA will apply for another two-year charter. The July 28 meeting of ELAB will, therefore, be the last held under the existing charter. Ms. Mourrain also reviewed the Federal Advisory Committee Act rules that apply to ELAB meetings and announced that anyone who would like to be added to the ELAB mailing list should provide her with a business card. She noted that, as always, ELAB encourages members of the public to provide written statements concerning any issues they would like to address, and she noted that anyone may attend an ELAB meeting and that time will be allotted for public comments.

GOOD LABORATORY PRACTICES SUBCOMMITTEE REPORT

Mr. Wynn John, Co-Chair of the GLP Subcommittee, presented an overview of the Subcommittee's draft report. The final report is expected to be complete in approximately three months. Mr. John reminded ELAB that the Subcommittee's goal is to identify options for GLP laboratory accreditation that meet USEPA's needs and address the concerns of USEPA's Environmental Monitoring Management Council (EMMC) and NELAC. The Subcommittee is also addressing cost considerations and international and interagency concerns.

Mr. John reported on the activities of five different teams established by the Subcommittee:

- **Team 1A**, charged with identifying and characterizing the needs of USEPA and industry;
- **Team 1B**, charged with defining program options for consideration by the Subcommittee;
- **Team 2A**, charged with examining interagency concerns;
- **Team 2B**, charged with examining international concerns; and
- **Team 3**, charged with collecting and analyzing data on the potential cost of accreditation for GLP laboratories.

He noted that in October 1996, the Subcommittee met to review and evaluate a list of 35 different program options developed by Team 1B. At the conclusion of that meeting, the list for consideration was narrowed to four options. Since that time, one additional option has been added, and the Subcommittee's final report will address these five options in detail.

The five options under consideration are:

1. Augmentation of the existing USEPA GLP program with increased funding,
2. Third-party accreditation for GLP laboratories,
3. A sponsor (i.e., industry) monitoring program,

4. Inclusion of the GLP program under NELAC, and
5. A Federal Insecticide, Fungicide, and Rodenticide Act/Toxic Substances Control Act (FIFRA/TSCA) testing facility registration program.

Mr. John briefly reviewed the Subcommittee's preliminary list of advantages and disadvantages for each option. He noted two general conclusions.

- The Subcommittee believes that most of the options under consideration will require a change in statutes or regulations, and
- The options need to be defined in greater detail before a final evaluation of their relative advantages and disadvantages can be completed.

He noted that the Subcommittee will be working between now and July to more fully describe the options. The Subcommittee is also discussing issues of equability because some members believe that certain options would provide unfair advantages to selected segments of the industry.

Mr. John also reported that Team 3 has developed a survey to gather data on the current cost of GLP compliance to laboratories and industry. The survey will be sent to laboratories and industry users of GLP laboratories through a cooperative effort with several trade associations.

PERFORMANCE EVALUATION SUBCOMMITTEE REPORT

Mr. Tom Coyner of Analytical Products Group, Inc., and Ms. Marlene Moore of Advanced Systems, Inc., Co-Chairs of the PT Subcommittee, presented the Subcommittee's report. Mr. Coyner noted that the Subcommittee was constituted in September to examine the inter-relationship and potential impact of USEPA's effort to externalize the water laboratory performance evaluation PE studies on the NELAC proficiency testing (PT) program. The Subcommittee was asked by ELAB to make recommendations regarding coordination of the two programs.

Mr. Coyner stated that the Subcommittee has agreed on three recommendations to date:

1. That the NELAC basis for accreditation and the definition for fields of testing should be that advocated by the NELAC Program Policy and Structure Committee (i.e., program/method/analyte);
2. That ELAB should recommend to the NELAC Board of Directors that the goal of the NELAC PT program should be provision of full-volume, real-world samples;
3. That ELAB should recommend to the NELAC Board of Directors that the multiple-provider system envisioned by both USEPA and NELAC must have a designated oversight body in order to be successful.

ELAB discussed each of the three recommendations individually.

With respect to the first recommendation, Mr. Coyner stated that the issue of whether to make laboratory accreditation method-specific is important when more than one method can be used to analyze a particular analyte. He provided the example of lead in drinking water. In the discussion that followed, ELAB recognized that one of the chief concerns is the number of PT samples that a laboratory would need to purchase in order to be accredited for more than one method per analyte, in the event that accreditation is method-specific and successful performance on a PT sample is required for each method accredited. Ms. Lee noted that this would impose a high cost burden on small laboratories. Dr. Hershey suggested that the PT samples should be provided in a volume sufficient to allow analyses of a single sample by multiple methods. Other ELAB members agreed. Three important points were made by members of the audience:

- Dr. Ken Jackson of the NY State Department of Health, noted that if accreditation is analyte-specific rather than method-specific, PT results may give a less accurate indication of a laboratory's performance for analytes with multiple methods because the laboratory could successfully run a PT sample by one method and be certified to run an analyte by that method and by other methods with which it was unfamiliar.
- Dr. Michael Miller of the NJ Department of Environmental Protection stated that laboratories should have the option of analyzing PT samples and reporting results for more than one method per analyte. He also stated that performance on PT samples does not provide a full picture of laboratory performance and that the accreditation decision should not be made without a comprehensive on-site assessment.
- Ms. Athene Thacker of EA Laboratories related an experience in which her laboratory lost its drinking water certification for all methods pertaining to a particular analyte when it developed a performance problem with only one of the methods. The incident occurred because the Drinking Water Certification program is analyte- (rather than method-) specific.

At the conclusion of the discussion, ELAB agreed to report to the NELAC Board of Directors that the issue of how to define the basis for NELAC accreditation is of concern to the laboratory community and should continue to be addressed jointly by the NELAC Committees on Proficiency Testing and Program Policy and Structure. ELAB participation in the effort will be the responsibility of Mr. Coyner and Ms. Moore, who are members of the Proficiency Testing and Program Policy and Structure Committees, respectively. Mr. Verstuyft suggested that in its report the Subcommittee provide a written description of the lead in drinking water example and discuss the implications for accreditation raised by Ms. Thacker. Mr. Coyner agreed that the Subcommittee will provide a detailed write-up on this issue.

With regard to the second recommendation, Mr. Coyner stated that the Subcommittee members believe that full-volume, real-world PT samples are necessary to ensure consistency and equivalency of the studies and will contribute to ensuring that the results reflect routine laboratory

performance. He stated that the Subcommittee members believe that it is important to make this formal recommendation because documents published by USEPA regarding externalization of the water laboratory PE studies are silent on this issue. After a brief discussion, ELAB members agreed to forward a recommendation to EMMC and the NELAC Board of Directors that the goal of the NELAC PT program should be to provide full-volume, real-world samples, keeping in mind considerations of practicality and cost.

In discussing the third recommendation, Ms. Trovato asked the ELAB to consider two separate issues:

1. Is a national oversight body necessary for the multiple-provider system envisioned by USEPA and NELAC?
2. If so, should the national oversight body be a government organization?

After some discussion, ELAB members agreed unanimously to recommend that an oversight body be established as an essential element of a multiple-provider system. ELAB members further agreed to recommend that there should be only a single oversight body for the program. Several State representatives from the audience commented that there are numerous reasons why States prefer a government oversight body. Mr. Jerry Parr of Quanterra Environmental Services stated that he believes ELAB should state that there is a strong preference for USEPA to serve as the oversight body and that if USEPA is unable to serve in this capacity, another government organization such as the National Institute of Standards and Technology (NIST) should be named the oversight body. After some discussion, ELAB agreed to recommend that USEPA serve as the oversight body for the PT program, with the necessary resources and commitment to improve the current system. Alternatively, ELAB members recommended that the oversight body be another government organization and that steps be taken to ensure a smooth transition.

NELAC RECOGNITION OF NATIVE AMERICAN TRIBAL NATIONS

Dr. Roger Bucholz of Red Hawk Laboratory, Inc., representing the Sioux Nation, made a brief presentation regarding the need to establish a means for official participation and recognition of Tribal Nations by NELAC. He stated that various sovereignty issues prevent Tribal Nations from participating through, being represented by, or being accredited by State accrediting authorities. After a brief discussion, ELAB members recognized that an amendment to the Constitution and/or Bylaws may be necessary to provide specifically for Tribal Nations in NELAC and agreed to recommend that the Program Policy and Structure Committee address this issue.

THIRD-PARTY ASSESSORS SUBCOMMITTEE REPORT

Mr. Bush, Chair of the Subcommittee, made a brief presentation concerning the results of the Subcommittee's deliberations. He reminded ELAB that the purpose of the Subcommittee is to examine the issue of an appropriate role for third parties in the accreditation process. He noted

that a contingent of third-party accrediting bodies had provided the Subcommittee with a letter that made the following three requests:

1. That NELAC set up a centralized program for recognition of private-sector accrediting bodies;
2. That, in the event USEPA Regional Offices implement the accrediting authority approval and oversight functions of NELAP, USEPA provide for coordination among the Regions to avoid duplication of effort in reviewing private-sector accrediting bodies; and
3. That an information clearinghouse be established regarding the assessment and approval status of private-sector accrediting bodies participating in NELAC.

Mr. Bush noted that the chief concern of the third-party organizations is to avoid duplicative assessments by USEPA and the States. He stated that the Subcommittee's recommendation is that USEPA and private accrediting bodies work together to set up a cooperative program for assessment of State accrediting authorities and third-party accrediting bodies. The Subcommittee further recommended that, if ELAB agrees with the recommendation, it should establish a permanent subcommittee to define the specifics of such a program.

In the discussion that followed, several State representatives from the audience noted that the States, for a variety of reasons, would be required to use their own selection procedures and criteria for selecting private-sector organizations to assist with their programs. Dr. Kavanaugh suggested that ELAB recommend to the NELAC Board of Directors that the NELAC national database include publicly available information describing the functions performed by individual private organizations for specific State programs. ELAB members agreed unanimously with Dr. Kavanaugh's suggestion.

NELAC NATIONAL DATABASE *AD HOC* COMMITTEE REPORT

Dr. Charles Hartwig, Chair of the NELAC Board of Directors, provided ELAB with a brief presentation of the results of the first meeting of the NELAC *AD Hoc* Committee on the National Database. In his charge to the Committee, he requested that it examine a number of issues, including:

- Selection of an existing database for NELAC,
- The data elements to be included in the database,
- The process for data entry,
- The need for controlled access to data files,

- The time frame for data entry,
- The format for data entry and display, and
- The responsibility for housing and maintaining the national database.

Dr. Hartwig stated that the Committee is preparing to finish its work in time to make a presentation and to offer recommendations at the Third NELAC Annual Meeting in July.

PERFORMANCE-BASED METHODS SYSTEM SUBCOMMITTEE REPORT

Dr. Hillig, Chair of the PBMS Subcommittee, reported on the Subcommittee's initial recommendations, which are:

1. That ELAB encourage USEPA to coordinate implementation of PBMS throughout the Agency,
2. That training in implementation of PBMS is needed for State laboratory inspectors,
3. That PBMS implementation should include the use of reference methods, and
4. That all reference methods should be fully validated and that the results of validation studies should be documented.

Dr. Hillig further stated that the Subcommittee is in full agreement that USEPA should proceed with implementation of PBMS, although there are some differences in understanding concerning the definition of PBMS. After some discussion, ELAB members asked that Dr. Hillig re-write the third and fourth recommendations. ELAB members agreed to make the following recommendations:

1. That USEPA's programs and regions and the States work to implement PBMS consistently, and
2. That training on implementation of PBMS is needed for State laboratory inspectors.

ELAB members further agreed to recommend that a representative from the EMMC Work Group on PBMS work with this ELAB Subcommittee in the future.

ELAB NOMINATIONS

Dr. Hershey explained to ELAB members that their appointments officially expire at the end of September. He stated, however, that for continuity purposes, some of the Board members should

continue to serve. He and Ms. Trovato will, therefore, be working with Ms. Mourrain and ELAB members to determine which of them can continue to serve and which cannot.

Ms. Mourrain noted that there are a variety of mechanisms that could be used to solicit nominations for new ELAB members, including publishing a notice in the Federal Register or distributing a request to everyone on the ELAB mailing list. Dr. Verstuyft recommended that ELAB solicit brief statements of qualifications and interest from all nominees. Mr. Parr suggested that ELAB consider adding a representative from the engineering consulting community. ELAB members agreed with Mr. Parr's suggestion. Ms. Christensen suggested that ELAB develop a policy of asking members who are routinely unable to attend meetings to step down. ELAB members also agreed with this suggestion. In closing the discussion, Ms. Mourrain stated that she would solicit further thoughts from ELAB members concerning an open nominations process, prepare a notice for the Federal Register, and speak to members who regularly do not attend meetings about stepping down.

RESULTS OF THE NELAC INTERIM MEETING

Ms. Mourrain announced that, as a result of the committee working sessions held during the Second NELAC Interim Meeting, NELAC will have a complete set of standards adopted at the close of the Third NELAC Annual Meeting in July. She also noted the following next steps for NELAC:

- The Third NELAC Annual Meeting will be held July 28-31, 1997, in Dallas, TX.
- NELAC committee chairs will provide revised copies of the standards by May 30. The documents will be posted by June 30 on the NELAC Internet web site at <http://134.67.104.12/html/nelac/nelac.htm#NL102>.
- The *Ad Hoc* Committee on the National Database will be meeting regularly to prepare its recommendations for presentation at the Third NELAC Annual Meeting.
- The NELAC Board of Directors will take steps to begin addressing implementation issues.
- The National Environmental Laboratory Accreditation Program (NELAP) will continue working with the USEPA program offices to ensure incorporation and implementation of the NELAC standards.
- NELAP will be examining options for staffing its State program approval function.
- NELAP and the On-Site Assessment Committee will be discussing the assessor training program and will make recommendations at the Third NELAC Annual Meeting.
- NELAP will meet with USEPA's EMMC Policy Council on March 21 and will discuss the issue of long-term funding for NELAP, among other topics.

- The Proficiency Testing Committee will be working on some additions to Chapter 2 of the standards, including an appendix that provides standards for the PT oversight body.
- NELAP will be meeting regularly with representatives from NIST to discuss NIST's potential involvement as the PT oversight body.
- NELAP will be initiating plans for the political leadership at USEPA and NIST to meet and agree on their support for NIST's potential role in the NELAC PT program.
- NELAP will meet regularly with other Federal agencies to work toward eventual inclusion of the NELAC standards in their programs.
- The Implementation Committee will be working with the National Conference of State Legislators (NCSL) to survey its members concerning their willingness to implement NELAC programs.
- NELAP will be meeting with the International Standards Organization (ISO) to discuss similarities and differences between the NELAC and ISO standards.

Mr. Parr reminded ELAB members that EPA Administrator Carol Browner's nomination of NELAC for the Innovations in American Government Award may mean that the selection committee may contact them for their input. He also asked whether ELAB members could provide a letter endorsing NELAC for the award. Ms. Christensen agreed to generate and distribute the letter.

NEW ITEMS

Dr. Hershey noted that two important issues were raised during the ELAB open forum on Wednesday, February 5. These were:

- Concerns regarding access to confidential business information (CBI) during on-site assessments, and
- Concerns regarding the logistics of the NELAC implementation process.

ELAB members addressed these issues individually.

With regard to the CBI issue, Mr. Parr explained that there are two chief concerns:

1. Protection of laboratories' intellectual property, and
2. Disclosure of laboratory client data.

He noted that of these, the latter is of far greater concern. After some discussion, ELAB members agreed that a legal viewpoint may help clarify the responsibilities of laboratories, the rights of laboratory clients, and the rights of government inspectors with regard to inspection of data. Mr. Parr and Ms. Christensen agreed to coordinate an effort to obtain such a viewpoint and to provide information to ELAB members by the end of March.

With regard to implementation of NELAC, Dr. Hershey stated that numerous concerns have been raised about the timing of implementation, particularly the timing of issuance of State program approvals. Mr. Parr summarized the concerns raised and stated that there is a general belief that all laboratories in the country will act swiftly to seek accreditation from the first State or from one of the first States to be approved. This situation was recognized as being potentially problematic for States. After some discussion, ELAB members agreed to make themselves available to provide information concerning the private sector's response to implementation and to recommend to the NELAC Board of Directors that the Program Policy and Structure Committee begin examining implementation issues as soon as possible.

Dr. Kavanaugh asked about the extent to which the provisions of ISO Guide 58 have been incorporated into Chapter 6 ("Accrediting Authority") of the NELAC standards. In response, Ms. Trovato agreed to speak with the appropriate committee chair and request a briefing on the subject for ELAB at its next meeting.

Before closing the meeting, Ms. Trovato summarized the following outcomes:

1. The GLP Subcommittee will present a final report and recommendations at the next ELAB meeting in July.
2. ELAB members will make the following recommendations to EMMC and the NELAC Board of Directors regarding proficiency testing:
 - a. The issue of how to define the basis for NELAC accreditation is of concern to the laboratory community and should continue to be addressed jointly by the NELAC Committees on Proficiency Testing and Program Policy and Structure. ELAB participation in the effort will be the responsibility of Mr. Coyner and Ms. Moore, who are members of the Proficiency Testing and Program Policy and Structure Committees, respectively.
 - b. That the goal of the NELAC PT program should be to provide full-volume, real-world samples, keeping in mind considerations of practicality and cost.
 - c. That USEPA serve as the oversight body for the PT program, with the necessary resources and commitment to improve the current system. Alternatively, ELAB recommends that the oversight body be another government organization and that steps be taken to ensure a smooth transition.

3. ELAB will recommend to the NELAC Board of Directors that the Program Policy and Structure Committee address the issue of how to recognize an appropriate role for Native American Tribal Nations in NELAC.
4. With regard to the role of private-sector accrediting bodies in NELAC, ELAB will recommend to the NELAC Board of Directors that the NELAC national database include publicly available information describing the functions performed by individual private organizations for specific State programs.
5. With regard to PBMS, ELAB will recommend to the EMMC and the NELAC Board of Directors that:
 - a. USEPA's programs and Regions and the States work to implement PBMS consistently.
 - b. That training in implementation of PBMS is needed for State laboratory inspectors.
 - c. That a representative from the EMMC Work Group on PBMS work with the ELAB PBMS Subcommittee in the future.
6. ELAB will conduct a broad search for nominees for the upcoming two years and will add representation for the consulting engineering community to the next charter.
7. ELAB will seek a legal viewpoint concerning the importance and substance of the CBI concerns raised at the ELAB open forum.
8. ELAB will recommend to the NELAC Board of Directors that the Program Policy and Structure Committee begin examining implementation issues.
9. The Chair of the NELAC Accrediting Authority Committee will be asked to provide a briefing at the next ELAB meeting on incorporation of ISO Guide 58 into the NELAC standards.

Following Ms. Trovato's summary, Ms. Mourrain declared the meeting adjourned.