

**Summary of the Meeting of the
Environmental Laboratory Advisory Board
July 28, 1997**

The Environmental Laboratory Advisory Board (ELAB) met at the Wyndham Anatole Hotel in Dallas, TX on July 28, 1997. The meeting was led by ELAB Co-Chairs Dr. Wilson Hershey and Ms. Ramona Trovato.

INTRODUCTION

Dr. Hershey opened the meeting with an introduction of attending ELAB members as well as those of an audience of approximately 80. He outlined the agenda, noting its provision for public comments, as well as the Open Forum scheduled for 5pm, immediately following the ELAB meeting.

Ms. Trovato reviewed EPA's commitment to several innovative programs, including NELAC, as documented in the memo of June 11, 1997, from Mr. Fred Hansen, EPA Deputy Administrator. She noted that:

- a) EPA Program Office plans are due by September 1997, for fully implementing Performance Based Measurement Systems in the Agency by September 1998,
- b) A Strategic Monitoring Panel has been established, and
- c) NELAC standards will be implemented across the Agency, and specific funding provisions have been made for NELAC.

NELAC STANDARDS

Dr. Hershey announced that general comments on the proposed NELAC standards would be entertained during the meeting.

CONSTITUTION AND BYLAWS

Ms. Jeanne Mourrain, Designated Federal Officer for ELAB, and Director of NELAC, noted that the EPA Office of General Counsel restricts EPA staff participation on Boards to those having no fiduciary responsibilities. Hence, all such references (e.g., finances, fee) will be deleted from the Constitution and Bylaws. These references are contained primarily in several reserved sections.

CHAPTER ONE: PROGRAM POLICY AND STRUCTURE

The only comment referred to the issue relating to Good Laboratory Practices and their relationship to the NELAC Standards. Dr. Hershey indicated that this specific issue would be addressed as part of the report by the ELAB subcommittee on GLPs.

CHAPTER TWO: PROFICIENCY TESTING

Concern was expressed over implementation-related issues on the timely availability of PT

samples during start-up of the National Environmental Laboratory Accreditation Program (NELAP). It was noted that a Memorandum of Understanding as well as an Interagency Agreement is in preparation to formalize the necessary arrangements and includes funding arrangements. Concern was also expressed regarding preparations and commitments for the NELAC Proficiency Testing Oversight Body (PTOB).

It was noted that EPA will continue their current performance evaluation sample program in support of the Safe Drinking Water Act and the Clean Water Act through the end of 1998 after which the National Institute of Standards and Technology (NIST) is scheduled to accredit private sector proficiency testing producers. Standards have not yet been established for the PTOB, since there is no precedent for its roles and responsibilities as an accreditor of PT providers. In this context, it was noted that since the EPA/NIST relationship is new, EPA wants voting on the Appendices postponed for one year to allow NIST to more fully participate in development of this Standard and ensure an orderly transition to the new system.

ELAB-PT Subcommittee Report

At this point, Dr. Hershey called on Ms. Marlene Moore and Mr. Thomas Coyner, co-chairs of the ELAB-PT subcommittee for their report. Ms. Moore noted that this subcommittee has reviewed Chapter 2, including its four appendices, in detail. The subcommittee believes that the proposed standards provide a well written, sound approach for initiating a PT program. Since the NELAC Standards are an ongoing, improving document, the committee strongly recommends adoption of the chapter and appendices now. Mr. Coyner noted that this subcommittee provided an independent review of the chapter, and found it to be technically sound.

Following an overview of the report of the subcommittee, and general discussion of the five findings, the following recommendations were adopted:

Recommendation 1:

ELAB recommends that EPA prepare a working set of PT sample design criteria which meet Program Office requirements to be used by the Proficiency Testing Oversight Body (PTOB) to include, at a minimum, concentration, interferences, media. (Passed unanimously).

Recommendation 2:

ELAB recommends that NELAC/NIST/EPA develop a protocol which can be used by the PTOB, through review and analysis of data, to assure program equivalence among PT providers. (See attached paper by Dan Tholen for starting point.) ELAB further recommends that this protocol be finalized as soon as possible to ensure the integrity of this program. (Passed unanimously)

It was noted that Chapter 2, Appendix A, specifies “continuous monitoring” by the PTOB of PT providers without indicating how this could be implemented. It was also noted that an important issue is how the variability attributable to one PT provider will be distinguished from other sources of variability such as the method or sample. It was noted that in a PT system having multiple PT providers, selection/approval requires more than simply a “system in place and that

the PTOB must be provided an effective protocol for implementing this essential requirement.

Recommendation 3:

ELAB recommends that the periodic PT studies occur at fixed times throughout the year. ELAB further recommends that initial and remedial PT samples may be obtained outside this schedule. (Passed unanimously)

Recommendation 4

- A. ELAB recommends that the long range goal of NELAC be to develop a consistent approach to both scope of accreditation and PT program sample design, which recognizes the needs of the laboratories, the primary accrediting authorities, and the Agency, particularly with regard to performance based methods, similar technologies, and analytical capabilities. (Passed unanimously)
- B. ELAB recommends that the PTOB, during implementation of the PT program, require that each PT provider record and report PT results to both the accrediting authority and the PTOB on a method basis, by matrix and analyte. (Passed unanimously).
- C. ELAB recommends that a task group monitor the impact on implementation of the discrepancy between PT program design and the scope of accreditation. (Passed unanimously).

It was noted that the subcommittee addressed the differences between a program/matrix/analyte system and a program/method/analyte system, with the latter preferred. It was also noted that there is a rationale for both approaches, depending on one's perspective, since some programs focus on analytes within a common matrix (e.g., drinking water) while others focus on an analyte across matrices (e.g., lead in drinking water and surface wipes). Other considerations include the fact that some small labs use only one method for a particular analyte, and that definition of the term 'matrix' needs clarification during NELAC implementation.

Recommendation 5

ELAB recommends that there is consistency between NELAC Standards and the EPA's PT Externalization program. (Passed unanimously)

Recommendation 6

ELAB recommends that the proposed PT standards (including the Appendices) be adopted as presented. (6 yes, 1 abstain, 1 no).

Dr. Hershey thanked the subcommittee and commended them for their excellent efforts.

CHAPTER FIVE: QUALITY SYSTEMS

Ms. Silky Labie, Chair of the Quality Systems Committee, reviewed progress on this chapter of the Standards since last year's voting in which 6 portions were not adopted.

There being no discussion on this chapter, the Board recessed for lunch.

GLP SUBCOMMITTEE REPORT

Mr. Wynn John and Dr. David Dull presented the work of this subcommittee. Mr. John indicated that his discussion would focus on information that the subcommittee had developed subsequent to its report to the Board in February, 1997. He noted that there had been three task teams with Teams 1 & 2 essentially having completed their work for that previous report.

Team 3 sent 900 surveys and received 51 responses addressing QA costs, R&D Costs, Industry sector, Number/type of studies conducted. It was noted that perceptions differed by respondents, and that QA was generally a budgeted item and generally known; GLP activities and expenses are not well characterized, and appear to be interpreted differently by different respondents. Estimates for expenditures indicate that current costs are not trivial, yet may be overlooked.

The ensuing discussion included the following: preference for a rulemaking approach rather than the consensus-building approach used by NELAC, the use of EPA's Regulatory Negotiation (RegNeg) approach to rulemaking, possible need for accreditation to satisfy international operations, and the need to reconcile the GLP programs of EPA and FDA.

Recommendation 7

ELAB recommends that the GLP decisions and the NELAP timeline be decoupled. ELAB further recommends that the GLP subcommittee report to the ELAB at the Interim Meeting with three options including a) status quo; b) Options 1 + 3 + 5; and c) lab accreditation.

ELAB further recommends that ISO Guide 25 be explicitly considered to understand the value it offers to the GLP process.

ELAB further recommends that the NELAC process be evaluated to identify the value added, if any. EPA will provide language to clarify that the NELAC Constitution and Bylaws reflect that decision-making and implementation of the GLP Program will continue as an exclusively federal program.

The goal of this activity is to provide information to OECA and OPPTS management for a decision regarding the direction of the GLP program. (Passed unanimously)

ELAB will forward the findings of the GLP subcommittee to EPA management. As noted above, three options appear to emerge from this effort:

- a) status quo,
- b) augmentation of reporting and funding (combination of Options 1, 3, and 5 of the subcommittee's report), and
- c) laboratory accreditation.

ELAB-PBMS SUBCOMMITTEE REPORT

Dr. Kathy Hillig presented the report of this subcommittee, noting that the first two recommendations have been approved by this Board in January 1997. Following brief discussion, and rewording, the following recommendations were approved:

Recommendation 8

ELAB recommends that before EPA promulgates a regulation, it must demonstrate and document that MQOs are achievable using available measurement technology. (Passed unanimously)

Recommendation 9

ELAB recommends that EPA demonstrate that any new or revised regulatory measurement requirements are achievable on samples that represent the same level of analytical challenge as the matrix for which the regulation is intended. (Ideally, this would be samples of the actual matrix to be monitored, as defined by the regulation.) (Passed unanimously)

Recommendation 10

ELAB recommends that EPA consider the following remaining important unresolved issues: (Passed unanimously)

- '!! PB Measurement System vs. PB Method
- '!! Sample matrix
- '!! Method Validation
- '!! Method Compliance
- '!! Interlaboratory Comparability
- '!! Cost
- '!! Laboratory Client Relationship

Dr. Hershey thanked the subcommittee for completing its charge, and declared it disbanded.

NELAC TRANSITION AD HOC COMMITTEE REPORT

Dr. Charles Hartwig, NELAC Chair, and Ms. Carol Batterton NELAC Chair-Elect presented this report. Dr. Hartwig indicated his wish to communicate to the Board the planning being done by NELAC as it anticipates passage of the Standards. Ms. Batterton indicated that the two major issues foreseen related to:

1. Capacity of the first state(s) approved as accrediting authorities to accomodate all laboratories that might apply for accreditation, and
2. Unfair competitive advantage for laboratories which were accredited before other applicants.

She then reviewed the anticipated timeline in the Committee's report, noting that all 50 States, the District of Columbia, and 3 territories responded. Forty (40) states indicated their plans to apply for recognition as NELAC Accrediting Authorities. She also noted a June 1, 1998 target for approval of all Accrediting Authorities that submit an application before the end of 1997.

Following discussion the following recommendations from the Committee's report were adopted by this Board:

Recommendation 11

ELAB recommends that the initial approval of accrediting authorities should occur simultaneously. (Passed unanimously)

Recommendation 12

ELAB recommends that the first round of NELAC accreditation of laboratories by accrediting authorities should also occur simultaneously. (Passed unanimously)

Recommendation 13

ELAB recommends that prior to the designation of approved proficiency test (PT) sample providers as required by Chapter 2, accredited labs should be allowed to continue using existing PT sample providers. However, in the interim, frequency of PT sample analysis as required by Chapter 2 must be met. (Passed unanimously)

It was noted that State supplemental requirements may pose practical problems with implementation of the NELAC Standards. They include:

1. Reporting limits and DL
2. Sample frequency and acceptance criteria
3. Method for a given parameter.
4. Sample preservation
5. Extraction method
6. Level and number of calibration standards
7. Calculation procedures
8. Concentration level of QC spikes
9. Contents of data reports.

Subsequently, the issue of conflict of interest and the relationships of private sector and public sector laboratories was discussed, leading to the following recommendation:

Recommendation 14:

ELAB recommends that Chapter 6 be further defined regarding Accrediting Authority recognition of States to address the conflict of interest between public and private sector labs, with respect to a State laboratory conducting routine environmental testing analyses. Further definition will include the specific guidance to avoid conflict of interest for an above stated Accrediting Authority. (Passed with 8 in favor, one opposed)

In addition, the conflict of interest issue among State laboratories was discussed and the following recommendation was made:

Recommendation 15

ELAB recommends that the issue of primacy State laboratories in accrediting non-primacy State laboratories be referred to the Accrediting Authority Committee for further consideration.

OTHER ISSUES

Dr. Hershey asked for additional issues of concern to the Board. It was noted that the limitation

for assessment team composition to State and federal employees (Chapter 6) is clearly addressed in documents from the Office of Federal Procurement Policy, as noted in the July 24, 1997 memo stating EMMC recommendations to NELAC.

Dr. Hershey then referred the Board to the July 21, 1997 letter from AIHA regarding third party subcommittee re-establishment. It was suggested that assessor bodies come to the Third NELAC Interim Meeting prepared to make presentation to this Board..

Dr. Hershey then asked if there were any further discussion. Considering the Board's support for NELAC and the proposed Standards, the following recommendation was presented for vote:

Recommendation 16

ELAB strongly recommends a vote for adoption of the Standards with modifications as specified and passed by ELAB motions on July 28, 1997.
(Passed with 8 in favor, one opposed)

As the result of additional discussion, the following recommendation was presented for vote:

Recommendation 17:

ELAB recommends that EPA Program Offices become more active in NELAC and promulgate regulations that are consistent with the NELAC standards as appropriate. (Passed unanimously)

Ms. Mourrain reminded the all present that she has received some nominations for replacements for ELAB, and encouraged all to use the nomination form in their packet to nominate others, or themselves.

Action	Completed by
Ms. Trovato will schedule a teleconference for the Board in early October to discuss GLP issues	
Board members and others are encouraged to submit ELAB nominations to Ms. Mourrain at the earliest possible date.	
Current Board members are requested to contact Ms. Mourrain to indicate their continued interest in serving on this Board.	
Dr. Hershey and Ms. Trovato will transmit the recommendations of this Board to the EMMC Policy Council.	
Dr. Verstuyft will present the ELAB recommendations during the NELAC Opening Plenary Session	July 28, 1997

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