THE ENVIRONMENTAL LABORATORY ADVISORY BOARD'S ASSESSMENT OF THE STATE OF NATIONAL ACCREDITATION

INTRODUCTION

The U.S. Environmental Protection Agency's (EPA) Environmental Laboratory Advisory Board (ELAB or the Board) was asked by the stakeholder community that it represents to assess the state of the national accreditation. Because ELAB has provided advice regarding national accreditation from the inception of the National Environmental Laboratory Accreditation Program (NELAP), the Board chose to limit its review to NELAP, associated NELAP accreditation bodies (ABs), non-NELAP ABs, current NELAP accredited laboratories, suppliers to NELAP laboratories and data users.

The stakeholder community represented by ELAB is concerned that economic issues will hinder the progress of this national program, potentially stalling implementation by current nonparticipatory states. To investigate this concern, each ELAB Board member volunteered to interview constituents within his or her stakeholder community to collect representative feedback on specific areas of interest. The Board collectively selected two main areas of focus in gathering input: (1) operational/implementation issues and (2) economic issues. Numerous subcategories addressed areas such as assessments, leadership, non-NELAP states/agencies, small laboratories, accreditation processes, program standardization, training, budget issues and effects, perceived versus known barriers, assessment options, standards development and existing organizational committees.

To successfully discover stakeholder information, the Board agreed on a set of interview questions for each Board member to use; this measure ensured consistency in information collection. The resulting data were combined and organized by topic and stakeholder group. Utilizing teams, the Board vetted the information for common threads, stated issues, opinion polarization and suggestions. Input that did not appear to be supported or of concern to the consensus was not included. This final summary document represents all constituents within each stakeholder group and lists consensus agreements, common concerns and potential solutions to address the issues of concern. It is important to note that not all stakeholders responded to every question and that some of the available stakeholder populations were small and thus may not be a complete representation of the entire group. 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.

I. OPERATIONAL AND IMPLEMENTATION ISSUES

A. ASSESSMENT UNIFORMITY—STANDARD INTERPRETATION

All respondents identified uniform standard interpretation as a significant issue, indicating that uniformity of interpretation and application appear to be key concerns. Assessor training and qualification inconsistencies among state ABs are the key contributors, and AB task force remedies cannot be implemented quickly enough to resolve these issues.

Potential solutions that the stakeholders suggested are as follows:

1. Provide more oversight and supply the needed guidance to ensure that the standard is applied uniformly among the states.

2. Provide standardized checklists and additional tools, along with a single source of information, to reduce questions and eliminate confusion.

3. Develop interpretive guidelines and provide better training.

B. ASSESSMENT UNIFORMITY—ASSESSMENT FREQUENCY UNIFORMITY

Stakeholders generally agreed that this is a serious concern. Assessment frequency among the states is not uniform, and many states do not meet the 2-year requirement as a result of budget issues. The difference between the frequency of NELAP audits compared to the federal drinking water requirement is an impediment to laboratories and state programs and results in potential cost increases for drinking water laboratories.

Potential solutions that the stakeholders suggested are as follows:

1. Allow for third party accreditation or assessment, and utilize the existing services of these providers to support some of the administrative functions of the AB.

2. Provide data auditing training to NELAP assessors.

3. Place standardized methodology checklists and additional tools into a centralized information source to resolve questions.

C. LEADERSHIP

Most respondents indicated that the term “leadership” is directed primarily at an increased level of EPA oversight. The majority believes that the EPA needs to take a more substantive role in the development and direction of a national standard and must be more definitive in what it wants and expects. Without EPA direction, state ABs and third-party accreditors cannot sustain the expertise and technical oversight that is necessary for the program’s success.

Potential solutions that the stakeholders suggested are as follows:

1. Centralize the program under a single entity with defined expectations and oversight, using a nongovernmental approach to obtain broad state participation.

2. Encourage the NELAP Accreditation Council (AC) to provide more leadership; the NELAP AC should solicit more support and assistance from The NELAC Institute (TNI), and the TNI board needs to increase support for the NELAP AC.

3. Increase TNI outreach at the non-TNI state level.

4. Provide assistance and leadership to help stabilize the situation.

D. NONPARTICIPATING STATES

The stakeholder community agrees that the absence of full state participation has a negative impact on the comparability of laboratory quality from state to state. The stakeholders believe that all states should participate at an appreciable level. Where staff or funding is a problem, there should be a national body (or independent qualified accreditors/assessors), which can perform audits on the states' behalf. There are a number of states that cannot support the move to NELAP without a directive from the EPA. The lack of an assertive directive from the EPA results in a weak, fragmented program with sustainability difficulties.

Potential solutions that the stakeholders suggested are as follows:

1. Encourage EPA financial and leadership support.

2. Partner with third-party accreditors to help resolve resource shortages by providing alternative resources to state ABs and laboratories.

3. Encourage nonparticipating states to seek a more active role in the entire TNI process.

4. Centralize accreditation under a third-party system, allowing states to easily employ the system for laboratory recognition, in turn encouraging broader state support.

5. Teaming with state ABs to offset the costly off-site effort will allow state ABs with limited resources to participate in the effort; these partnering relationships will provide nonparticipating states with the means to participate.

E. SMALL LABORATORY PARTICIPATION

All of the respondents thought that small laboratories are overwhelmed. These laboratories cannot meet the requirements and/or afford to implement the program because of time and/or resources. Because many small laboratories have found it necessary to subcontract tests either in part or whole, there is a perception that the industry is losing expertise and the ability to self-monitor, which may be the result of an undefined difference between process control and compliance monitoring as it relates to

accreditation. The respondents also agreed that smaller laboratories do not perceive a value in participation unless required by state or federal mandate.

Regardless of size, laboratories must meet the standard; however, certain considerations could be made, such as reducing the frequency of proficiency testing (PT), thus reducing costs.

The TNI's Small Lab Advocacy Group (SLAG) has made giant strides in educating the small laboratory community and providing support in implementing the standards.

Potential solutions that the stakeholders suggested are as follows:

1. Continue to support the SLAG.

2. Develop more tools to help small laboratories streamline their operations.

3. Aggressively promote small laboratory implementation approaches to achieve small laboratory buy-in of a national program.

F. ACCREDITATION SCOPE

There is general agreement that the fields of accreditation (FOAs) are not consistent across ABs. Because ABs do not offer the same FOAs, some laboratories have had to apply to multiple ABs to accredit to all capabilities. The FOAs offered by an AB are based on differing state needs or objectives; some offer accreditation for the Resource Conservation and Recovery Act, the National Pollutant Discharge Elimination System and/or drinking water, whereas others offer accreditation for nonpromulgated methods. In addition, the current system is confusing as ABs do not use the same analyte name in their accreditation certificates.

Because of the disparity in FOAs, there are inconsistencies with the required PTs. Additional PTs also increase the overhead costs of the laboratory.

Potential solutions that the stakeholders suggested are as follows:

1. Standardize the FOAs. This was a universal suggestion, but there were differing opinions as to the scope of a standardized list:

    a. Establish a core list of FOAs that all ABs must offer.
    b. Require that ABs offer the same FOAs.

2. Employ one common application format for all accreditation venues.

3. Encourage the EPA to play a role in standardizing methods.

4. Encourage the EPA to mandate standard FOAs for all programs.

5. Encourage the EPA to promulgate methods that can be utilized in multiple matrices and/or programs.

6. Convert to a technology-based accreditation that would eliminate the need to be accredited to a specific method (unless mandated by a specific program).

G. ACCREDITATION MODIFICATION TIMELINESS

Although most ABs are flexible in allowing laboratories to add analytes to methods, the process to add methods/analytes is time-consuming and inconsistent. There appears to be more emphasis on the process rather than on the quality or technical benefits. Clients always will confront the need to add new compounds or tests, but the current processes are not timely to allow for such additions.

Potential solutions that the stakeholders suggested are as follows:

1. Develop a process that will streamline added analytes or test methods.

2. Ensure that the process is sufficiently flexible to address client needs.

H. NATIONAL PROGRAM STANDARDIZATION

All stakeholders agreed that, in terms of a standardized national program, "we are not there yet." Many think that the EPA needs to take a lead in making a national program a reality, although they concede that the EPA will not mandate a national program for all of its programs.

Even if a national program becomes a reality, uniform implementation is an issue, and although inconsistencies always will exist, there must be a concerted effort to minimize differences, especially in on-site visit and standard interpretation.

Some think that the TNI/NELAP program overemphasizes quality systems, and laboratories are not implementing the system properly.

Potential solutions that the stakeholders suggested are as follows:

1. Separate the management activities from the on-site activities, and use credentialed trained assessors to perform the on-site assessment; the use of third-party assessors may standardize the assessment.

2. Encourage the EPA to recognize accreditation (if not mandated) by:

    a. Issuing a policy statement recognizing the value of accreditation.

    b. Providing recognition of NELAP-accredited laboratories by a policy that encourages states to use/rely on accredited laboratories for regulatory data.

    c. Establishing a forum that represents all state interests and allows EPA regional and program offices to work together on a solution that would result in a national program.

d. Reimplementing data auditing to ensure the proper implementation of the quality system.

I. PT DATA EVALUATION

There appear to be inconsistencies in PT scoring and state processes for review and management of PT data. PT data evaluation procedures must be followed. There is a belief that the PT program is the least useful part of the overall accreditation process, and states put too much emphasis on PTs. Laboratory clients, however, think that PTs are essential for verifying competency.

In general, the stakeholders focused on PT frequency rather than data evaluation. Consistency of PTs must be established, with the drinking water program as the benchmark. As long as this discrepancy exists, there is no incentive for drinking water laboratories to become NELAP-accredited.

Potential solutions that the stakeholders suggested are as follows:

1. Adopt the PT frequency and requirements of the drinking water program to reduce costs to laboratories and reduce administrative processes for the ABs

2. Automate the process at a national level to allow state use without state oversight or staffing.

J. UNQUALIFIED LABORATORY ELIMINATION

There is a consensus agreement that this is an issue. Eliminating a “bad” laboratory from the system can be a difficult process. In addition, there is no mechanism in place to alert other certifying authorities in cases in which laboratories have multiple accreditations or when there are serious deficiencies in a laboratory’s process.

Potential solutions that the stakeholders suggested are as follows:

1. Establish one system for all, which would streamline the communication process when laboratory deficiency notification is needed; elimination factors would be consistent in severity.

K. USE OF ASSESSMENT REPORTS

The stakeholders expressed a variety of thoughts regarding this topic, most of which addressed use and interpretation. Many states use the on-site reports conducted by the laboratory’s home state (using drinking water-approved assessors) to determine reciprocal certification status. States should have the ultimate authority regarding data submitted to their programs, but not all assessment reports are equivalent. The service sector relies on these reports during the laboratory selection process, but another thought is that the interpretation is based on assessor capability, thus causing variation.

Potential solutions that the stakeholders suggested are as follows:

1. Standardize the report format.

2. Structure the assessor forum at TNI meetings to address some of the issues.

L. STANDARDS DEVELOPMENT

Stakeholders commonly indicate that the process is of good quality; however, it is obvious that the majority thinks that the response times from TNI committees and the NELAP AC are too long and need to be more timely. Others are concerned that nonparticipating states are precluded from input. Some respondents also expressed concern that the number of stakeholders involved in standards implementation impedes the process.

Potential solutions that the stakeholders suggested are as follows:

1. Streamline the process using other organizations (e.g., AOAC INTERNATIONAL) as a model process to improve efficiency.

2. Engage more state ABs in the process; because they hold the ultimate authority for implementation, the language must be suitable for their programs.

M. COMMITTEE OPERATIONS

The stakeholders all point to poor communication between TNI committees. The committees do not explain the process that they use to develop the standards and often are perceived to act in their own interest rather than in the broader interest of fulfilling a common goal of establishing a national accreditation program.

Potential solutions that the stakeholders suggested are as follows:

1. Improve communication transparency between the committees and from the committees to the TNI community.

2. Increase the timeliness of issue resolution.

3. Involve the states more in the process.

4. Improve TNI oversight of committee activities.

N. STAKEHOLDER CONCERN ACKNOWLEDGEMENT

The stakeholders point to limited input from the broader community of nonmembers. The issues are slow to be addressed and need to be addressed prior to voting. The ABs need to make a stronger effort in expressing issues prior to adoption of the final standard.

Potential solutions that the stakeholders suggested are as follows:

1. Increase timeliness of response to concerns.

2. Strongly restrict the use of "nonresponsive" labels on stakeholder concerns (identify another means to address comments).

3. Allow nonmember comments to be expressed.

4. Perform outreach to nonparticipating states during the development process.

5. Encourage ABs to fully participate in the process.

O. VOTING PROCESS

The voting process is generally well received by stakeholders. One stakeholder notes that the voting process meets the requirements of a consensus organization; another suggests more formality in the voting.

II. ECONOMIC ISSUES

A. PROGRAM FUNDING

All stakeholders agreed that program funding is an issue. Some states are having funding difficulties, and laboratories should be able to afford the program. Efficiencies should be established within the program to reduce the cost of running it, thereby reducing the cost to laboratories.

Potential solutions that the stakeholders suggested are as follows:

1. Support or provide funding mechanisms similar to existing programs, such as the Safe Drinking Water Act and Clean Water Act, to support states.

2. Establish uniformity and reciprocity among states without requiring additional fees.

3. Reevaluate the value of PTs and assessment frequency.

4. Centralize accreditation operations through a third-party approach.

5. Encourage nonfee-funded states to adopt a fee-funded approach to their programs.

B. NONPARTICIPATING STATES

Some nonparticipating states perceive the cost of running a national program as an obstacle, and there is no incentive to participate because accreditation objectives can be achieved by other participating states. Some states continue to perceive a national accreditation program as a loss of autonomy. Laboratories and data users agree that if all states participated in a uniform and well-coordinated program, overall program costs and cost variability would decrease.

Potential solutions that the stakeholders suggested are as follows:

1. Eliminate multiple state recognition programs, which drive up accreditation costs.

2. Lower the cost of the state AB to a level that achieves a higher percentage of AB participation by separating the offsite operations from the core management operations of the accreditation process.

3. Establish a national funding mechanism or provide incentives to nonparticipating states.

C. ASSESSOR TRAINING

Lack of training often is identified as the root cause to nonuniformity in the accreditation system. Robust assessor training is necessary to establish and maintain uniformity and consistency. The training and skills needed by an assessor should be specified. For some ABs it is difficult to afford the training or to obtain travel approval.

Potential solutions that the stakeholders suggested are as follows:

1. Encourage the EPA to assist with and sponsor assessor training.

2. Offer complimentary training for ABs in a variety of locations.

3. Make drinking water certification training more widely available and open to nongovernmental assessors.

4. Encourage the EPA to take a stronger role in assisting state primacy laboratories in becoming accredited; this could be linked to the EPA's national accreditation policy.

5. Establish analyst and assessor credentialing and include upfront training and continuing education.

6. Train and credential third-party assessors to a high standard that is reinforced through additional training.

D. STAFF REDUCTION

The stakeholders considered this issue from two perspectives, laboratory staffing and accreditation/certification program staffing. Reduced staffing within the laboratory and among trained assessors performing evaluations is a common problem across the nation. Reduction in staff may result in limited analytical services, laboratory closures, inequities in assessment frequency, and decreased ability to maintain programs and accreditation accountability.

Potential solutions that the stakeholders suggested are as follows:

1. Establish a national funding mechanism to address these circumstances.

2. Increase consistency and relieve problems with reduced staff by establishing or encouraging a national environmental laboratory accreditation program that is managed by private groups.

3. Promote use of third parties

4. Assist laboratories in lobbying for legislature that creates jobs.

5. Promote "limited use" or contract employees within ABs

6. Adjust program needs to the actual situation (i.e., shrinking staff is a reality).

E. TRAVEL RESTRICTIONS

Restrictions on travel (e.g., type, distance) appear to be variable across the states, and in some cases the travel ban is restricted to participation in training and conferences but does not impact accreditation and/or certification travel. This is a continuing problem based on the current economy and causes hardships for laboratories, especially those in nonparticipating states. Travel for site assessors should not be a problem because the audited laboratories pay the travel expenses.

Potential solutions that the stakeholders suggested are as follows:

1. Raise awareness of national accreditation and its benefits among state officials.

2. Write into program requirements that AB staff must participate at conferences.

3. Offer training closer to laboratories.

4. Enhance regulations to require participation in national standards meetings as a part of drinking water/wastewater primacy.

5. Utilize electronic voting, conference calls and web meetings as appropriate.

6. Delegate face-to-face meetings to representatives using a common pool of funds.

7. Find new tools to improve effectiveness (e.g., Skype, teleconferencing, other virtual meeting technologies).

F. FUNDAMENTAL TASKS

Stakeholders had different views in this topic area, and the responses were associated with PT and assessment frequency, renewal cycles, followup and enforcement.

Some respondents thought that the biannual PT requirement may be beneficial, but that the value of the additional PT must be clearly demonstrated. Two PTs per year increases costs to the laboratories and the workload for the ABs. Staffing or lack thereof is an issue for completing necessary tasks. Other issues identified included the fact that some laboratories (i.e., new laboratories) are not assessed frequently enough, at least initially. Renewal cycles with multiple certificates expiring simultaneously results in problems with the renewal process. The EPA drinking water program requires laboratory assessment on a 3-year cycle, whereas NELAP requires assessments every 2 years; this is not a major issue but does increase costs.

These questions are associated with a national accreditation system but do not address followup and enforcement. States are responsible for followup and enforcement, which presents challenges to state personnel in terms of training, standards interpretation and potential legal problems. All fundamental AB tasks have been impacted by the current economic situation, resulting in a degradation of program execution because states cannot meet the program specifications effectively. Separating state decision-making requirements from third-party operational tasks will allow market-managed costs while maintaining the governmental authority required by the drinking water program. Fundamental tasks, PT data review and frequency, reciprocal accreditation, assessment frequency and completion, renewal cycle, and interstate primacy accreditation should be quality driven rather than economically driven.

Potential solutions that the stakeholders suggested are as follows:

1. Establish biannual PT using a performance-based approach that allows laboratories/methods with high performance to decrease to one per year to help reduce costs.

2. Provide ABs with tools to assist with PT management.

3. Centralize some of the PT tasks for all ABs.

4. Perform PT on a national level with the data provided to the ABs for the laboratories that they certify.

5. Require that new laboratories be under surveillance for at least 1 year.

6. Use resources as best as possible.

7. Implement a nongovernmental solution.

8. Separate state decision-making requirements from third-party operational tasks.

G. CONTINUING AVAILABILITY OF ASSESSMENTS IN NONPARTICIPATING STATES

The general consensus is that availability of assessments in nonparticipating states must be maintained. Beyond that there is disagreement on how laboratory assessment should be funded (i.e., whether additional costs should be assessed on nonparticipating states, whether a third-party process should be utilized). Maintaining assessments in nonparticipating states affects the fundamental NELAC framework and leaves laboratories without options. Stakeholders are concerned that recognized NELAP ABs may limit their services to reduce their cost burden. Because fewer services would be available to laboratories in nonparticipating states, the national program could eventually cease to exist.

Potential solutions that the stakeholders suggested are as follows:

1. Standardize fees for laboratories.

2. Charge a fee for nonstakeholders to offset the cost of the assessment and PT data.

3. Provide all laboratories equal access by establishing third-party processes.

4. Separate the process into its two functions to permit off-site functions to continue to be managed and allow existing or new ABs to be capable of providing continual accreditation to laboratories in nonparticipating states.

H. BARRIERS FOR NONPARTICIPATING STATES

The specific barriers depend on the entity (i.e., state, laboratory or user), but in general program cost and resource requirements are cited as two barriers. States also have legislative hurdles and other legal requirements.

Potential solutions that the stakeholders suggested are as follows:

1. Encourage the EPA to make accreditation mandatory or at least preferred for all programs, which would allow the states to more easily manage legislative challenges.

2. Encourage states that are not ABs to accept other state accreditations or a third-party AB, with each state providing the management function for its program.

3. Provide more education about the program to resolve any misunderstandings or perceptions.

4. Keep accreditation costs to a minimum, especially for reciprocal accreditations.

I. STRAIN ON NELAP STATES FROM NATIONAL PARTICIPATION

Because only a few states participate in NELAP and there are no third-party accrediting bodies to relieve some of the pressure on these states, NELAP states have additional burdens. The lack of a sufficient amount of ABs (states or third parties) results in higher accreditation costs (primarily because of distance) and delays in on-site audits. If NELAP was mandated nationally without additional ABs, the result will be greater pressure, higher costs and longer delays in accreditation.

Potential solutions that the stakeholders suggested are as follows:

1. Allow establishment of third-party ABs so that the free market will fill in the gaps to meet national participation needs and demand.

2. Encourage the EPA to make NELAP accreditation a national requirement but allow sufficient time for existing NELAP states, third-party accrediting bodies and new NELAP states to prepare for the demand.