THE ROLE OF THE USEPA IN A NATIONAL ACCREDITATION PROGRAM

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Abstract

The United States Environmental Protection Agency (EPA) currently operates two large-scope accreditation programs: one for analyzing drinking water for compliance with the Safe Drinking Water Act (SDWA), and the National Environmental Laboratory Accreditation Program (NELAP). Both programs accredit or certify environmental laboratories and oversee or recognize entities that accredit laboratories. The EPA also maintains programs for accrediting laboratories that test lead in paint and that analyze asbestos.

This paper will present the Institute for National Environmental Laboratory Accreditation's (INELA) vision of a redefined role for the Agency's participation in a national accreditation program. The paper will summarize the current state of EPA's involvement with the NELAP, present ways in which EPA could transition from administrator to full partner of a national accreditation program, and explore options for EPA's future involvement in such a program. The paper will conclude with a brief examination of how the drinking water certification program can become integrated into a national accreditation program.

In the Beginning

The EPA's involvement in accrediting laboratories was catalyzed by the Safe Drinking Water Act (SDWA). The SDWA required states to monitor water supplies for health threats to consumers. The Act gave the Agency authority to implement monitoring and testing programs to determine or ensure the suitability of water supplies to provide safe drinking water to all citizens across the United States.

As states declared their rights to exercise autonomy over Federal mandates and consistent with the Agency's philosophy of delegation, EPA established procedures by which states would be able to obtain and maintain primacy over the administration of the SDWA. In some states, all analyses related to the SDWA compliance were assumed by state health or environmental laboratories. In many other states, either through lack of capacity of government laboratories, or through pressure from existing commercial laboratories, water supply samples came to be analyzed by laboratories other than the "principal" state-owned laboratories.

EPA established procedures to evaluate any laboratory providing results to determine compliance with the SDWA. States desiring to maintain statutory primacy over the SDWA were required to establish certification programs for non-governmental laboratories analyzing drinking water regulatory samples. State laboratories felt, and EPA concurred, that they themselves should be evaluated by the Agency. Thus, a two-tier system of evaluations of drinking water laboratories has been historically in practice

in the United States. Since most states desire primacy over the SDWA, most states conceived programs to certify non-government laboratories, while EPA retained the right to evaluate principal state laboratories.

Once introduced to the idea of certifying drinking water laboratories, many states found it necessary and desirable to certify laboratories analyzing other types of environmental compliance samples, from wastewater effluents to solid waste aimed for landfills. Programs proliferated without the uniform influence of a mandated Federal requirement. By the late 1980s, so many states had different certification programs that the EPA, principally under the pressure of the commercial sector, formed in 1991 the Committee on National Accreditation of Environmental Laboratories (CNAEL). CNAEL was chartered under the Federal Advisory Committee Act (FACA) to evaluate the feasibility of establishing a uniform national program for the accreditation of environmental laboratories.

CNAEL was composed of expert representatives of all the stakeholders involved in laboratory accreditation: members from the laboratory and regulated industry communities, academia, federal agencies, the states, public environmental interest groups, and private accrediting bodies. In its final report, CNAEL recommended the formation of a national accreditation program with Federal oversight, but implemented by states and third parties. Having now the consensus advice it sought, EPA proceeded through a focus group to explore ways of implementing the CNAEL recommendations. This resulted in the eventual formation of the National Environmental Laboratory Accreditation Program (NELAP), under the auspices of the EPA.

EPA delegated the development of standards for laboratory accreditation to a conference attended by all, with voting rights only for government personnel. The National Environmental Laboratory Accreditation Conference (NELAC) debated and approved a set of standards in the mid 1990s designed to accredit any laboratory in the United States producing environmental data for compliance with state or Federal programs.

Not having the authority of an act of Congress to establish an accreditation program, NELAP relies on the voluntary participation of states to become members. States that decide to become part of the program establish rules that adopt the NELAC Standards, submit themselves to evaluation by NELAP, and in turn, hold the environmental laboratories they accredit to the uniform NELAC Standards.

A Self-Sufficient Program

Since the inception of the NELAP, EPA had intended the program to be fiscally self-sufficient. EPA followed the recommendations of CNAEL in retaining oversight of the program, but expected a graduation into autonomy. It is clear that without EPA's leadership and monetary support NELAP would not have progressed beyond the conceptual stage, but lacking an anchoring Federal statute, NELAP could not presume continued funding from EPA or the Agency's perpetual management of the program.

The CNAEL concluded that the most viable way of creating a national program would involve Federal oversight to allay the concerns of states that felt they could only answer to a higher authority. But, CNAEL also noted that Federal oversight with non-Federal implementation of a national accreditation program could include the possibility of delegating the Federal oversight authority and the states' accreditation functions to private sector organizations.

EPA assumed management of the NELAP believing that after its formative years the program would be ready to achieve independence. The states joining NELAP, caught in the momentum of establishing their own programs to accredit to the NELAC Standards, might not have at that time considered other options for the future management of the program.

The Near Past and Present

Currently, there are 13 Accrediting Authorities recognized by NELAP. However, there are more laboratories accredited to the NELAC Standards than would be predicted from the existence of only 13 recognized authorities. Today, most commercial laboratories involved in interstate business are accredited to the NELAC Standards. In addition, many other laboratories are required by state regulations to be accredited to a local code that conforms to the NELAC Standards. In that respect, NELAP accreditation has been the lingua franca among United States environmental laboratories.

Nevertheless, the number of states joining NELAP has not kept pace with the number of years the program has existed and some NELAP states still maintain dual programs based on local certification rules not covered under NELAP.

In 1996, the National Technology Transfer and Advancement Act (NTTAA) directed the National Institute of Standards and Technology (NIST) to increase the reliance of Federal agencies, as well as state and local governments, on voluntary consensus standards with the goal of decreasing dependence on Federal in-house standards, coordinating with private sector technical standards activities, and eliminating duplication. Compliance with the NTTAA is mandatory for Federal agencies, but is voluntary for state and local government bodies.

The Office of Management and Budget (OMB) Circular A-119, revised in 1998 to facilitate compliance with the NTTAA, defines voluntary consensus standard bodies as those that are open, with clear due and appeals processes, and most importantly, having a balance of interest preventing the dominance of any one sector. The NELAC Constitution and Bylaws did not allow private sector members to vote on the adoption of standards. NELAC encouraged the participation of the private sector as contributors, but even at the committee level, could only grant government members the right to vote. Therefore, any future standards developed by NELAC would not meet the definition of consensus standards in the revised OMB A-119. NELAP considered options for maintaining compliance with OMB A-119. To facilitate this, a reconstituted NELAC, authorized to adopt but not to develop accreditation standards, was created in 2003. This

reconstituted NELAC could solicit new standards from consensus organizations or could consider standards already developed by them.

The Institute for National Environmental Laboratory Accreditation (INELA), an independent, not for profit organization, was formed in 2002 to help maintain and promote a system for the accreditation of entities involved in the generation of environmental data. To further this goal, INELA, among other activities, develops and promotes accreditation standards that can be accepted and implemented by laboratories, government accreditation bodies, private accreditation bodies, and entities involved in field sampling and measurements. INELA is a recognized standards development organization operating under consensus that meets the requirements of balance and lack of dominance required by OMB A-119. Other existing standard development organizations are able to develop accreditation standards, but up to now, only INELA has lived up to the task of supplying a comprehensive set of standards to accredit environmental laboratories and entities engaged in environmental measurements. NELAC and INELA have worked and continue to work cooperatively while maintaining their independence.

The Transition

The EPA, faced with the same budgetary constrains faced by all states these days, and the current tide of minimizing the size of governmental institutions, had to remind stakeholders of the self-sufficiency clause in the origins of NELAP. Existing and prospective accrediting authorities were understandably alarmed and started to discuss means to ensure a national accreditation program in the absence of continued Federal funds. While at first glance this may appear like reneging support on the part of EPA, it was the condition under which EPA accepted the management of the program, and is in harmony with the CNAEL's vision.

To its credit, EPA did not sever immediately NELAP's fiscal dependence on the Agency. At the moment, EPA is engaged in a five-year plan to transition NELAP into a self-sufficient program. EPA has constituted a task force to evolve NELAP from a program funded and administered by EPA, to one that can exist and expand fiscally independent from the Agency.

Up to this time, the environmental laboratory regulated community has operated under the assumption that Federal oversight is necessary for implementing a national accreditation program and that states can only, or would only, answer to the Federal government. INELA believes that Federal participation, not oversight, is an essential condition for realizing a true national accreditation program and that states could agree to oversight by a consensus organization, in place of EPA, given sufficient time to modify state regulations when necessary, or to become comfortable with the new order.

EPA's role in a national accreditation program would shift from one of controller to participant, or from commander to full partner. This change is one that EPA has experienced in many of its existing environmental programs.

The Shape of a Partnership

Obviously, assuming the role of a partner would free EPA from the fiscal burden of being the sole provider of funds to administer the NELAP. EPA's participation as a partner in a transformed national accreditation program, whatever its name, would also free the Agency to act less encumbered by its own internal policies and procedures. And, of course, a national accreditation program that is not administered by the Agency would not necessarily be subject to the same rules of conduct. So, while in this arrangement EPA gains breathing ground, the national program could soar and expand beyond its current focus.

In a reconstituted national accreditation program, any participating entity, including EPA, would:

- Have equal voice as a charter member, but would not exert dominance.

- Retain an interest in ensuring that its decisions are made with data of known and documented quality, but would share with others, or defer to others, the responsibility for crafting standards to qualify those decisions.

- Participate in the evaluation of accreditation bodies, without being the final determining agent of their status.

- Set its own internal policies and procedures to manage environmental data, but would not expect those same procedures and policies to be used by others or to become part of a consensus standard.

- Relinquish or refrain from being the sole arbiter of accreditation disputes in favor of becoming a participant in an adjudicating body with other accreditation bodies.

- Cease being a sole source of national accreditation information, and instead, contribute to and utilize the resources of an independent repository.

In practical terms, EPA would scale back or would stop performing some key accreditation activities. For example, EPA would no longer be responsible for organizing evaluation teams to recognize accreditation bodies. EPA and others would honor the conclusions made by an outside party, whether that would be an independent evaluator or a balanced group of accreditation bodies, about the conformance to a standard of an accreditation body. EPA would not have to develop or maintain a national data base of accredited laboratories. The Agency would tap into an independent database to determine the status of any entity providing data to determine compliance with its own or delegated programs. The increased independence of EPA from the management of an accreditation program would facilitate the accreditation of the Agency's national and regional laboratories and would help dispel any lingering notions of conflicts of interest in awarding those accreditations.

A benefit that INELA perceives in redefining the role of EPA in a national accreditation program is that the Agency could direct more concerted efforts to having additional EPA programs rely on a national program to meet their accreditation needs. A majority of the NELAP stakeholders believe that increasing the number of EPA programs that rely on national accreditation is paramount to maintaining and expanding any future accreditation program. EPA may be in a better position to persuade its programs to participate in a national accreditation program, if the Agency were not burdened with the management of the accreditation program.

INELA also believes that as a partner, EPA would be better able to mediate or even help negotiate participation of other Federal agencies in a national accreditation program. Those agencies in turn might be more willing to join a program constituted by a consortium of accreditation bodies that is not managed by a single "competing" agency. Ownership of such a program would be common to all participants, not principally EPA.

The Future

The details are understandably blurry at this time, although the outlines of the bigger picture are becoming visible. INELA believes that a partnership between EPA and other accreditation bodies has the greatest probability of enabling a true national accreditation program.

That program would involve more cooperation and consensus building. It may require those accustomed to functioning by strict chain of command to reorient themselves to make sustainable decisions among peers. It may mean that participants would need to cede part of their assumed authority to a steering few, or it may require that functional accreditation activities be easily separated from final accreditation decisions.

It is conceivable that the future might even produce a greater diversity of entities engaged in the mechanics of accreditation, from assessments of laboratories, to evaluations of accrediting bodies, from overseers of proficiency testing (PT) providers, to deliverers of accreditation support products. This variety could result in greater efficiencies, but would require a certain degree of additional coordination. The coordination could be provided by a meta-entity, somewhat divorced from ultimate accreditation decisions, or a cadre of involved participants incorporated as a not-for-profit organization.

And the question of to what extent a national accreditation program can be vested with the task of producing its own normative accreditation standards needs to be answered. At the moment, there is a separation between the development of accreditation standards and their adoption that is sometimes obscured by the many known participants that engage in both activities. To avoid future upheavals, a definitive answer needs to be formulated sooner than later in the transition process.

What is inevitable is that EPA will play a pivotal non-managing partner role in whatever form a national accreditation program assumes, and that such a program will need to be self-sufficient and fiscally independent. The latter will require participants to contribute

funds to cover costs or to engage in revenue generating activities that can be used for that purpose.

Integrating the Drinking Water Certification Program

This topic alone could be the subject of another paper; however, a few thoughts on the drinking water certification program are in order here.

The implementation of NELAP followed a path that was somewhat independent from that already established by the drinking water certification program. In retrospect, it seems that greater efforts could have been made by NELAP to seek the inclusion of the Office of Water in forming the accreditation program. A more proactive approach might have obviated the need to establish the equivalency of the two programs.

Currently, by virtue of a memorandum signed in 1997 by the Director of EPA's Office of Ground Water and Drinking Water, states can meet the primacy requirements of the SDWA by obtaining NELAP recognition. States are not required to maintain NELAP recognition to operate a drinking water certification program, but are encouraged to do so. Unfortunately, this memorandum has seen limited distribution and applicability.

Laboratories accredited to the NELAC Standards for drinking water are eligible for generating data in support of the SDWA. However, a laboratory certified for analyzing drinking water by an authority not recognized by NELAP is not eligible to provide drinking water data to a NELAP accrediting authority. Drinking water certification is not equivalent to NELAP accreditation, but NELAP accreditation can be used in lieu of drinking water certification.

There are differences between the classic drinking water certification and NELAP accreditation, but they are not so insurmountable that they could not be reconciled or resolved by directed dialogue between the two programs. As EPA continues to renew the primacy of states with drinking water certification programs, it could bring into its negotiations enhancements that would eventually make all states conform to a national accreditation standard. The training courses offered by EPA to drinking water certification officers could, with some relatively minor modifications, also serve to qualify officers to assess to the NELAC Standards or future national standards.

In turn, any developer of accreditation standards could incorporate elements essential to the drinking water program to eliminate redundant certification systems. Training for assessors could also qualify them to perform drinking water assessments that meet the requirements of the SDWA. And, as regional EPA laboratories become accredited to a national standard, their need for maintaining a separate drinking water certification would disappear. Should the principal state laboratories follow suit, the momentum generated in favor or a national program would be considerable.

Paradoxically, the continued existence of the drinking water certification program has proven a disincentive for many states to join a national accreditation program. While

immediate incorporation of a set of national standards might prove to be too radical for many states, gradual transition to a national norm could be achieved reasonably.

EPA's efforts to promote a national accreditation program would be hampered by the existence of a single separate program within the Agency for achieving what essentially has and can be accomplished by a national program. As the Agency refines its involvement in accreditation activities, it should consider the eventual assimilation of the drinking water certification program into a truly national one.

Disclaimer

The power of prophecy is granted to only a few, and then, alas, Cassandra-like, often linked to negative consequences. INELA does not claim to have the gift of clairvoyance, and does not wish to create Trojan horses. INELA presents this paper as an opinion, of this time and of this place, more as stimulus than determinant, more as a conduit of possibilities than of imperatives, and does not presume to direct EPA into taking any specific actions.