

NELAC AND THE DOE COMPLEX

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ABSTRACT

The Department of Energy's National Analytical Management Program (DOE NAMP) has launched an initiative to join the National Environmental Laboratory Accreditation Conference (NELAC) program for accrediting environmental radioanalytical laboratories serving the DOE Complex. Radioanalytical expertise within the DOE Complex will complement and enhance current NELAC accreditation efforts. This paper will discuss the rationale for participation and the planned implementation of the initiative. The paper will be of interest to laboratories performing analyses for the DOE Complex, as well as to individuals who rely on data from these laboratories, those who contract analytical services, and those who perform laboratory audits or supplier evaluations.

INTRODUCTION

NAMP has launched an initiative to join the National Environmental Laboratory Accreditation Conference (NELAC). I want to discuss NELAC and our rationale for participation, and our plans for implementation of this initiative. Then I'd like to go over some of the benefits of this initiative from the perspective of the customers of laboratories that perform analyses for the DOE Complex, those who contract analytical services, and finally those of you who work in these laboratories, whether you're in marketing, part of management, or a bench chemist.

WHAT IS NELAC?

In the years after 1990, following complaints to the EPA from the laboratory community about the burden of multiple accreditations, the Agency considered the feasibility of a single, nationally-recognized environmental laboratory accreditation program. This study led to the National Environmental Laboratory Accreditation Program (NELAP), whose goal is to foster cooperation among existing state and federal accreditation activities, unify standards, and reduce overall accreditation costs.

NELAP coordinates this program at the national level, but various state, territorial and federal agencies will actually be the accrediting authorities, as affiliates of NELAP. NELAP recognizes applicants for accrediting authority after they have met certain programmatic requirements.

The scope of accreditation is at the discretion of the accrediting authority. It can include a single field of testing, or all types of analyses for all types of media (hazardous waste, waste water, drinking water, air, soil), under all five EPA statutes (CAA, CERCLA, CWA, RCRA, and SDWA). Other options include limiting the type of laboratories accredited, whether

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accreditation is voluntary or mandatory, the assessment of fees, and the use of third-party assessors.

One mandatory feature of the program, however, is reciprocity with other NELAP accrediting authorities. Approval as an accrediting authority within NELAP requires recognition of laboratories accredited by other NELAP accrediting authorities. This reciprocity is the major mechanism for eliminating multiple accreditations and the associated costs.

The standards-setting body within NELAP, tasked with unifying accreditation standards, is NELAC, a voluntary association of State and Federal Agencies formed to establish and promote mutually acceptable performance standards for the inspection and operation of environmental laboratories.

NELAC's goal is to assure that decisions being made from analytical data have a sound technical, scientific, and statistical basis, and that NELAC-accredited laboratories deliver data of the required level of quality.

NELAC solicits private sector input through a variety of mechanisms: open semi-annual meetings, committee participation, and interaction with the federally-chartered Environmental Laboratory Advisory Board, which receives advice from a balanced representation of the private sector.

Through this consensus process, NELAC developed a constitution and bylaws (1) and six standards (2-7) which provide the foundation for recognition among the various accrediting authorities. These standards are designed chiefly around ISO/IEC Guides 25 and 58 (8,9). The NELAC quality system (6) has been enhanced beyond the specifications of ISO/IEC Guide 25 to satisfy environmental program requirements. All of the ISO Guide requirements are maintained, but because of the inclusion of technical and regulatory requirements unique to environmental laboratories, Chapter 5 of the *NELAC Standards* (6) is a much bigger document than ISO Guide 25, which was written for a generic testing laboratory. When we prepared a comparison table with ISO requirements in one column and the corresponding NELAC requirements for a radioanalytical laboratory in the other, the NELAC column ran three times longer than the ISO column. But the additional requirements have sound technical and regulatory bases: the *NELAC Standards* aren't loaded up with the best management practices and pet ideas that you often find in consensus standards.

The NELAC website lists eighteen applicants requesting NELAP recognition as accrediting authorities. The actual accreditation of laboratories is scheduled to begin this year.

WHAT IS NAMP'S CONNECTION WITH NELAC?

Besides EPA, NAMP, representing DOE, is the first federal agency to join the state programs seeking recognition as accrediting authorities. NELAC values DOE's preeminence in

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radioanalytical expertise, and has asked NAMP to help develop standards for radiological analyses.

NAMP/NELAC Accreditation Program

Recognizing that this expertise is the most valuable contribution that DOE can provide to NELAP, NAMP has restricted the scope of its laboratory accreditation program to environmental radioanalytical fields of testing for laboratories serving the DOE Complex.

NAMP's program will be provided as a service to the DOE Complex analytical community. NAMP has adopted NELAP's policy that a laboratory's decision to seek accreditation be strictly voluntary. As the program develops and becomes more visible throughout the complex, gaining accreditation may become a condition for participation in certain activities at the Field Office and Headquarters levels. But it is our intention to leave that to the funding sources to decide based on the merits of our program.

Status

NAMP is working through NELAC's administrative requirements to become an Accrediting Authority. These include development of a programmatic quality system and a program description, along with supporting procedures. These procedures include typical management, performance, and assessment procedures, as well as procedures unique to an accreditation program: usage of the NELAC logo, demonstrating no conflict-of-interest, and evaluating assessor performance. NAMP has also formed a Technical Committee to assist in interpretation of requirements and for advising on technical matters relating to the operation of its environmental laboratory accreditation program.

What's Ahead

Once the entire management system is in place, NAMP will prepare an application to NELAC along with supporting documentation to demonstrate readiness. When NELAC has reviewed the application and is convinced that NAMP is satisfactorily prepared, a team will be dispatched for an on-site assessment to evaluate objective evidence of the program's implementation. At the conclusion of the assessment, and the completion of any corrective actions, the team will make a recommendation to the NELAP Director, who will either accept or reject NAMP for recognition as an Accrediting Authority.

HOW WILL NAMP/NELAC ACCREDITATION WORK?

In general, achieving NELAC Accreditation is described in Chapter 4 of the *NELAC Standards* (5). NAMP-specific procedures for accreditation will be developed around this Standard.

Preliminaries

Paralleling the process that NAMP will go through to become an accrediting authority, the applicant laboratory must prepare for an on-site assessment by assuring certain organizational and programmatic controls are in place. The laboratory must also participate in a proficiency testing program for each analysis for which it seeks accreditation.

On-Site Assessment

Once the entire management system is in place, the laboratory prepares an application to NAMP along with supporting documentation to demonstrate readiness. When NAMP has reviewed the application and is convinced that the laboratory is satisfactorily prepared, it will send a team for an on-site assessment to evaluate objective evidence of the program's implementation.

Accreditation

At the conclusion of the assessment, and the completion of any corrective actions, the team will make a recommendation to NAMP, which will either accept or reject the laboratory as accredited. The standards include provisions for recourse for any laboratory that desires to challenge rejection of accreditation. Information about accredited laboratories, including accredited fields of testing, will be posted to a NELAP national database.

Accreditation is valid for twelve months. To maintain accreditation, the laboratory must be able to demonstrate that it has maintained its quality system, and apprise NAMP of any changes to key accreditation criteria, such as changes in its organizational structure, quality system, or analytical program. Subsequent on-site assessments are conducted every two years following the initial accreditation.

As mentioned before, the NAMP/NELAC accreditation program will have a narrow scope. Laboratories may seek accreditation for analyses outside the scope of NAMP's program from any other NELAP-approved accrediting authority. These laboratories will need to follow the development of the program and determine which accrediting authorities would be appropriate to meet their accreditation needs.

WHAT WILL NAMP/NELAC ACCREDITATION MEAN?

The benefits of NELAC Accreditation range from more business opportunities to intangibles such as a climate of professionalism in the laboratory.

Customers of analytical services will find benefits for themselves and for their own customers.

If you're a regulator or an end-user who relies on data from these laboratories, use of accredited laboratories promotes confidence, predictability, consistency, comparability and defensibility, because of the uniform set of standards by which environmental data is produced across the various states, agencies and programs. Not only will your data become more cost-effective due to the savings that labs can pass along to you from the reduction in the number of assessments they have to undergo, but also because of its acceptability throughout the DOE Complex and across regulatory boundaries to multiple stakeholders. In time, as more laboratories and states participate in NELAP, you may see some standardization of baseline expectations for environmental projects, which would reduce the amount of effort you have to put in to define project expectations, communicate data quality objectives, and specify project deliverables. Promoting the use of accredited labs ultimately improve the quality of laboratory services available to the DOE Complex because of NELAC's collaborative approach, which pooled expertise from multiple agencies, states, and various private sector groups.

If you contract analytical services or if you perform laboratory audits or supplier evaluations, the program, through its national database, provides a means of identifying those labs which already measure up to nationally endorsed standards.

If you're an image-conscious program manager, use of accredited laboratories demonstrates your commitment to environmental protection, and provides you assurance that the lab is engaged in continuous review and improvement, and that it is accountable for achieving what is promised.

Providers of analytical services will realize benefits for their customers, their business, their laboratory operations, and their employees.

If your job is to market analytical services, then you're trying to think like a customer, and everything said previously about the benefits to customers should be of interest to you. Additionally, accreditation leads to a marketing advantage and more opportunities to provide analytical service within the DOE Complex, and very likely in other regulatory realms. By incorporating the ISO Guides, it provides a foundation for certification so your laboratory to compete internationally. Accreditation brings national recognition to laboratories, especially those that may be little known outside a community or region. Through reciprocity, accreditation strengthens your appeal to prospective customers outside your community.

If you're a laboratory manager or supervisor, whether it be a commercial, government-owned-contractor-operated, municipal or industrial lab, NAMP/NELAC accreditation replaces multiple, often redundant and contradictory inspections, with a single comprehensive standardized inspection. This single recognition system provides confidence in analytical results and establishes credibility of your data, as well as improving its acceptability to regulators and other customers. This significantly reduces all those indirect costs associated with assessment activities, which can be substantial.

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Assessments associated with accreditation provide an independent, impartial and objective evaluation of your lab's facilities and performance. Achieving accreditation signifies a commitment to excellence within the radioanalytical community, to governments and outside agencies, and to the public. It enhances confidence in your laboratory by demonstrating that your analytical processes are consistent with national goals and objectives. It enhances professional staff recruitment and retention.

The accreditation process fosters the development of clearly articulated policies and procedures that help laboratories run smoothly, use resources efficiently, and better define all aspects of operations. This ongoing evaluation and improvement process helps management, analysts, and customers work together in enhancing the laboratory's mission. Laboratories emerge from the accreditation process with a better-defined mission and a clearer understanding of institutional strengths, goals and priorities.

Accreditation develops and maintains criteria which you can use to assess your laboratory's level of performance and to strengthen its operation. Accreditation is a valuable tool for regular self-evaluation and improvement which allows the laboratory to refocus on the fundamentals that motivate and justify its work.

Developed and administered by laboratory professionals, the accreditation program reflects, reinforces, and promotes the best practices in analysis and the strictest accountability to the customers served. Accreditation promotes a nationwide focus on radioanalytical laboratory management and a voluntary consensus-standards approach to radioanalytical improvement. It can eventually lead to the harmonization of national radioanalytical practices and methods and improvement of radioanalytical performance.

And, for everyone in the laboratory, accreditation improves the working relationship between the laboratory's staff and management. Members of management become more familiar with standard laboratory practices while staff achieve a higher level of professionalism. Inherent in the accreditation process is the need for all departments and levels of staff and leadership to be involved, which builds cooperation, morale, and a spirit of teamwork as everyone works toward a common goal.

The commitment to seek accreditation can be a powerful incentive and provide a source of momentum for the development and implementation of needed changes in a laboratory's equipment or physical plant, including sample storage, security systems and work spaces. The value of accreditation to customers can also give laboratories the leverage needed to obtain support for capital improvements.

In addition to providing recognition for the laboratory, accreditation also contributes to the staff's professional satisfaction and image, and a certain professional pride from meeting standards established by their peers in the analytical community. The laboratory's internal culture becomes sensitized to performance matters and stimulated in its quality improvement efforts.

CONCLUSION

In the months ahead, NAMP will be applying for NELAC recognition as an accrediting authority for environmental radioanalytical fields of testing for laboratories serving the DOE Complex. By achieving NAMP/NELAC accreditation, a lab demonstrates that it operates, on all levels, according to current regulatory and professional standards and practices. This single accreditation brings benefits to the laboratory from both external and internal perspectives, and, through reciprocity, will be recognized by EPA and participating states. While NELAC's accreditation initiative offers an unprecedented opportunity to the DOE Complex, radioanalytical expertise within the DOE Complex will complement and enhance NELAC's efforts.

REFERENCES

1. *National Environmental Laboratory Accreditation Conference (NELAC) Standards^a* "Constitution and Bylaws" (1998)
2. *NELAC Standards* Chapter 1, "Program, Policy and Structure" (1998)
3. *NELAC Standards* Chapter 2, "Proficiency Testing" (1998)
4. *NELAC Standards* Chapter 3, "On-Site Assessment" (1998)
5. *NELAC Standards* Chapter 4, "Accreditation Process" (1998)
6. *NELAC Standards* Chapter 5, "Quality Systems" (1998)
7. *NELAC Standards* Chapter 6, "Accrediting Authority" (1998)
8. ISO/IEC Guide 25: "General Requirements for the Competence of Calibration and Testing Laboratories" (1990)
9. ISO/IEC Guide 58: "Calibration And Testing Laboratory Accreditation Systems - General Requirements for Operation And Recognition" (1993)

ENDNOTE

- a. The *NELAC Standards* are available on-line at the NELAC Home Page (www.epa.gov/ttn/nelac).