

### **Q: What is the history of NELAC?**

**A:** Although environmental regulations in the United States are primarily written by the Federal government, the authority to implement and monitor compliance with the regulations is retained by the states, referred to as primacy. Included in a state's primacy authority is the responsibility to accredit laboratories performing environmental analyses. As a result, over the past twenty years most states have developed accreditation programs of varying complexity. Laboratories that conducted business in multiple states discovered in the 1980s that they were being forced to obtain and maintain several accreditations for these states. These laboratories soon discovered that they were undergoing numerous on site audits and participating in redundant and expensive performance evaluation studies.

In the 1990 the USEPA formed a committee to define issues and decide whether or not a national system was needed. In 1992 the committee issued its final report recommending the formation of a national environmental laboratory accreditation program.

Draft standards were written and published in 1994. These documents were to serve as a starting point of discussion at the first annual National Environmental Laboratory Accreditation Conference (NELAC). NELAC's first Board of Directors was elected as well as Standing Committees. Since then, NELAC has held annual conferences and interim meetings. As a result, a National Environmental Laboratory Accreditation Program (NELAP) has been approved and laboratories across the country are now being certified under the NELAC national standards.

### **Q: What is NELAC?**

**A:** The National Environmental Laboratory Accreditation Conference (NELAC) is a cooperative association of States and Federal agencies, formed to establish and promote mutually acceptable performance standards for the operation of environmental laboratories. The standards cover both analytical testing of environmental samples and the laboratory accreditation process. Private sector input to the process is obtained through a variety of mechanisms including open semiannual meetings, participation in NELAC committees, and through the Environmental Laboratory Advisory Board (ELAB), a federally chartered advisory committee with a balanced representation of the private sector, that provides advice to EPA and NELAC. The goal of NELAC is to foster the generation of environmental laboratory data of known and acceptable quality on which to base public health and environmental management decisions.

### **Q: What is NELAP?**

**A:** The National Environmental Laboratory Accreditation Program (NELAP) is the program that implements the NELAC standards. States and Federal agencies serve as Accrediting Authorities with coordination facilitated by EPA to assure uniformity. Accreditation by one NELAP Accrediting Authority is mutually recognized by the other State and Federal Accrediting Authorities approved under NELAP. NELAP recognized 11 State programs as Accrediting Authorities in the summer of 1999. Additional states have begun preparing, or have already applied, for approval as Accrediting Authorities.

### **Q: What laws or regulations required the development of NELAC?**

**A:** None! In the late 1980s and early 1990s, regulators and laboratories recognized a need for controlling the quality of environmental data being generated, and also the need to reduce the burden of multiple and sometimes conflicting accreditation requirements imposed by various regulatory bodies that accredit laboratories. A cooperative effort evolved that resulted in the formation of NELAC and the development of the NELAC standards.

### **Q: Don't States already accredit environmental laboratories?**

**A:** Yes, but prior to NELAC, the existing State programs varied widely in scope and requirements. Some states had only drinking water laboratory accreditation, while a few accredited laboratories for drinking water, wastewater, air, and solid and hazardous waste. Currently, in order to select a laboratory to analyze samples from a given location, it is first necessary to determine whether there is an applicable State accrediting program, obtain a list of accredited laboratories, and contact accredited laboratories to determine if they are able to perform the analysis.

**Q: How will laboratory selection under NELAC be different?**

**A:** As each laboratory becomes accredited under a NELAP-recognized accrediting authority, the laboratory and its accredited scope of testing will be entered into a national database. One of the fundamental principles of NELAC is that of reciprocity among NELAP accrediting authorities. Once a laboratory is accredited by one State for testing under a specific EPA program, it can be accredited in another State for that EPA program without having to meet additional accreditation requirements. The national database will simplify the search for a laboratory capable of performing testing under the requirements for a given EPA program and sampling location(s) in one or more states.

**Q: What EPA programs are served by NELAC?**

**A:** NELAC is intended to provide accreditation for laboratories under all EPA programs, with the exception of work done under the EPA Good Laboratory Practices (GLP) requirements in support of TSCA and FIFRA.

**Q: Do approved methods already contain sufficient quality control to assure data quality?**

**A:** Quality control is not the whole answer to assuring acceptable data quality! NELAC specifies a standardized quality system, including requirements for management qualifications; documentation of policies and procedures; calibration and maintenance of equipment; quality control; qualifications and training of personnel; maintaining sample integrity; management of audit findings, corrective actions, customer complaints, records, supplies and subcontracting; and review of the entire system by management to ensure that it is performing as expected. The ability of laboratories to demonstrate their competence will become more important as EPA moves toward a Performance Based Measurement System, in which the burden of proof of the applicability and quality of testing lies primarily with the laboratory. By including such quality system requirements, NELAC is building a foundation to assure that future environmental data are traceable, reproducible, and of known quality. This will facilitate interpretation of results, and will minimize the risk of making decisions based on data of doubtful authenticity.

**Q: What is the basis of the NELAC quality system?**

**A:** NELAC is based on several guidance documents that originated with the International Standards Organization (ISO), a body that develops consensus standards in a variety of technical fields. The two primary documents are ISO/IEC Guide 25: "General Requirements for the Competence of Calibration and Testing Laboratories", and ISO/IEC Guide 58: "Calibration And Testing Laboratory Accreditation Systems - General Requirements For Operation And Recognition". The NELAC quality system has been enhanced beyond the specifications of ISO/IEC Guide 25 to satisfy environmental program requirements.

**Q: With all of these requirements, what will be the impact on cost?**

**A:** Besides the expected savings in accreditation costs, many laboratories find that a well-run quality system lowers the 'cost of quality' by emphasizing activities that assess quality and prevent problems, while reducing costs associated with failure, such as retesting, resampling, downtime, loss of accreditation, and customer dissatisfaction (lost business). As a result, services provided by NELAP accredited laboratories should provide higher value and improved cost-effectiveness compared to the industry norm prior to NELAC/NELAP.

**Q: Where can I learn more about NELAC?**

**A:** Point your Web Browser to <http://www.epa.gov/ttn/nelac>, where you can find a variety of resources, including copies of the NELAC standards and a list of the approved Accrediting Authorities.

For more information contact:

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