

Analysis of NVLAP's Relationship to Related Bodies

Introduction

NVLAP is a program within the National Institute of Standards and Technology (NIST), an agency of the U.S. Department of Commerce (DOC), and is, for the purposes of this analysis, a registered legal entity on the basis of its governmental status. As stated in ISO/IEC 17011:2004, 4.3.7, Note 2, any other part of the government outside of NVLAP is considered a related body. NVLAP has established policies, procedures, and a structure to ensure that other parts of NIST or the federal government cannot influence the accreditation process.

The fundamental policies for operation of NVLAP are documented in Title 15 of the U.S. Code of Federal Regulations, Part 285 (15 CFR 285), which was published on May 30, 2001. The process for publication of regulations in the CFR allows for comment and input from all interested parties. NVLAP policies and procedures are further defined in NIST Handbook 150, *NVLAP Procedures and General Requirements*, which is publicly available.

NVLAP organization and structure

ISO/IEC 17011:2004, 4.3.7 defines four criteria for ensuring that an accreditation body has effective separation from a related body. This section describes how NVLAP has addressed each of those requirements in its organization and structure.

a) Different top management for the activities described in 4.2.5

The Chief of NVLAP has the overall authority and responsibility for the development of policies relating to the operation of NVLAP, supervision of the implementation of the policies and procedures, management of the finances of NVLAP, decisions on accreditation, contractual arrangements, and delegation of authority to undertake defined activities on behalf of himself/herself. This authority is defined in 15 CFR 285, and is further described in NVLAP's management system documentation and the Chief's official statement of duties and responsibilities.

Organizationally, NVLAP is a group within the Standards Coordination Office, which falls under the Associate Director for Laboratory Programs and Principal Deputy, Office of the NIST Director. The Chief of NVLAP reports through that chain of command to the Director of NIST. Because the NVLAP Chief is responsible for ensuring that the NVLAP program is operated in accordance with its controlling regulation and government policies and remains solvent as a fee-supported program, he/she reports to upper management on the status of the program. However, the management above NVLAP has no direct involvement with NVLAP's day-to-day operations or the accreditation process.

b) Personnel different from those involved in the decision-making processes

15 CFR 285 grants the accreditation decision-making authority to the Chief of NVLAP. NVLAP policy allows that authority to be delegated to NVLAP Program Managers. While NVLAP staff may consult with other NIST personnel on technical matters relating to a specific laboratory, at no time is anyone outside of NVLAP involved in the final accreditation decision. Further, any attempt from outside NVLAP to influence the decision-making process would be a potential violation of federal regulations.

c) *No possibility to influence the outcome of an assessment for accreditation*

NVLAP routinely uses NIST personnel, and occasionally personnel from other federal agencies, as assessors. All NVLAP assessors are required to sign the NVLAP declaration, committing them to declare any past, present, or anticipated future interactions with laboratories they assess. The declaration also states that employees of the Executive Branch of the U.S. Federal Government are subject to the rules for employee responsibilities and conduct as set forth in the U.S. Code of Federal Regulations, 5 CFR Part 2635, *Standards of Ethical Conduct for Employees of the Executive Branch*.

While government personnel acting as assessors by definition influence the outcome of the assessments they conduct, they cannot influence the ultimate outcome of the accreditation process for those laboratories. As stated in the previous section, NVLAP maintains control over the decision-making process entirely within its staff.

d) *Distinctly different name, logos and symbols*

The name of the accreditation program, as defined in 15 CFR 285, is “National Voluntary Laboratory Accreditation Program.” This name is distinctly different from that of NIST, and is used in all internal and external references to the program. The term *NVLAP*, the NVLAP logo, and the NVLAP symbol are federally registered marks, whose use by accredited laboratories is defined in Annex A of NIST Handbook 150. NVLAP has its own banner, which is separate and distinct from the NIST banner, on every page of its website.

NVLAP’s relationship with specific programs within NIST

NVLAP collaborates, partners, and forms working relationships with other NIST programs to strengthen the U.S. economy. Even though NIST programs and NVLAP have their own respective missions, the symbiotic relationship between them leads to a stronger measurement system and improved trade, health, and safety for all. The relationships between NVLAP and two NIST programs that may pose a perception of a conflict of interest are addressed below.

Office of Weights and Measures (OWM): The Office of Weights and Measures, a division of the NIST Physical Measurement Laboratory, operates the State Laboratory Program, which provides the basis for ensuring traceability of state weights and measures standards to NIST. That program conducts basic, intermediate, and advanced training for metrologists from the states, industry, and other countries. The training and assistance provided by OWM to state laboratories could be considered consulting, and includes specific assistance with becoming compliant with ISO/IEC 17025. NVLAP has accredited state laboratories that participate in the OWM programs. Conflict of interest is avoided by ensuring that there is no crossover of activities between NVLAP and OWM personnel. NVLAP staff do not contribute to the assistance provided by OWM to state laboratories, and OWM personnel do not participate in any state laboratory assessments.

There is an effective collaboration between NVLAP and OWM on proficiency testing, minimizing the burden on state laboratories to participate in multiple programs and effectively utilizing resources. NVLAP conducts its own analysis of results of such tests, and takes appropriate action when outlying results are detected. This and other collaborations are seen as a positive relationship, strengthening both programs while maintaining appropriate separation. OWM remains free to provide the necessary assistance in training and disseminating measurement traceability to the state laboratories, while NVLAP is free to operate independently and attest to the competency of the state laboratories’ ability to perform calibrations and measurements to specific levels of uncertainty.

National Voluntary Conformity Assessment System Evaluation (NVCASE): NVCASE, established in Title 15 of the U.S. Code of Federal Regulations, Part 286, offers a voluntary program to evaluate and recognize organizations that support conformity assessment activities. The objective of the program is to identify the activities of requesting U.S.-based conformity assessment bodies that have been evaluated as meeting requirements established for their acceptance by foreign governments. The evaluations may be provided by NIST or by bodies recognized by NIST for this purpose under the scope of this program. This could potentially include recognition of a laboratory accreditation body with which NVLAP has signed a mutual recognition arrangement (MRA).

Organizationally, NVCASE is a program within the Standards Services group of the NIST Standards Coordination Office (SCO). As with OWM, conflict of interest is avoided by ensuring that there is no crossover of activities between NVLAP and NVCASE personnel—NVLAP does not include NVCASE personnel in any assessments or accreditation activities, and the Standards Services group does not use NVLAP staff to support NVCASE. Both programs maintain appropriate confidentiality as required in their respective regulations.

Conclusion

The NVLAP structure as defined in the U.S. Code of Federal Regulations precludes any influence on the core of the accreditation program: the accreditation process and decision-making. Enforcement of the rules for employee responsibilities and conduct (5 CFR Part 2635) by the U.S. Office of Government Ethics (see <http://www.usoge.gov/>) ensures the impartiality and independence of all federal employees. Effectively, NVLAP is organized to ensure that no influence is allowed in, and no confidential information is allowed out. This has allowed NVLAP to establish long-standing relationships with other organizations within NIST and the federal government that result in fruitful collaboration and continual improvement while maintaining appropriate confidentiality, impartiality, and objectivity.