

SUPPORTING STATEMENT
U.S. Department of Commerce
National Institute of Standards and Technology
National Voluntary Laboratory Accreditation Program (NVLAP)
Information Collection System
OMB CONTROL NO. 0693-0003

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary.

The mission of the National Institute of Standards and Technology is “to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.” The National Voluntary Laboratory Accreditation Program (NVLAP) directly supports this mission by providing world-class accreditation services to testing and calibration laboratories. Accreditation is available to commercial laboratories, manufacturers’ in-house laboratories, university laboratories, and federal, state and local government laboratories. Accreditation is granted to a laboratory following successful completion of a process that includes:

1. submission of application information;
2. on-site assessment;
3. resolution of identified nonconformities;
4. proficiency testing, as appropriate; and
5. technical evaluation and accreditation decision.

NVLAP-accredited laboratories are recognized as conforming to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, *General requirements for the competence of testing and calibration laboratories*. This recognition allows for and promotes trade by U.S. industries, resulting in positive benefits to the U.S. economy.

Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR), *National Voluntary Laboratory Accreditation Program*, sets forth the procedures and general requirements under which NVLAP operates and has been uploaded into ROCIS as a supplemental document. Section 285.6 requires an applicant laboratory to provide a completed application to NVLAP in order to apply for accreditation. NVLAP must collect this information to fulfill its mission and meet federal regulations.

The information collection is also required for NVLAP to be compliant with the international standard ISO/IEC 17011, *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies*. Compliance with ISO/IEC 17011 (relevant excerpts have been uploaded into ROCIS as a supplemental document) is required for NVLAP to be recognized worldwide as a competent accrediting body, which ultimately, will facilitate and promote acceptance of test and calibration results between economies (through Mutual Recognition Arrangements) and decrease barriers to trade.

2. Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with all applicable Information Quality Guidelines.

NVLAP uses the information collected to assess laboratory conformance with applicable criteria (see Section 285.14, *Criteria for accreditation*, of 15 CFR Part 285). The NVLAP operations staff perform an administrative review to ensure that the information submitted by applicant laboratories is complete. NVLAP program managers perform technical reviews of the information to ensure that the requested accreditation services are available and have been clearly identified. To maintain its accreditation, a laboratory must apply for renewal every year; therefore, the administrative and technical reviews are conducted annually prior to renewing the laboratory's accreditation (see 285.10, *Renewal of accreditation*, of 15 CFR Part 285). The decision to grant or renew an accreditation is based upon NVLAP's determination of whether or not all requirements for accreditation have been fulfilled.

Basic identifying information provided by an accredited laboratory (laboratory name, address, phone and fax numbers, URL, contact name, etc.) is published in the online directory of accredited laboratories on the NVLAP website, <http://www.nist.gov/nvlap> (click on *Directory of Accredited Laboratories*). This directory benefits both the laboratories and the users of their services. The publication of the list of accredited laboratories provides those laboratories with worldwide recognition of their competence and encouragement to sustain and raise their levels of performance. Users, including regulatory agencies, purchasing authorities, and product certification systems, have the assurance of reliable and accurate testing and calibration services.

This information is collected, maintained in a secure database, and used in a way that is consistent with the applicable NIST CIO Information Quality Guidelines and Standards. Information quality is ensured through the effective implementation of NVLAP's management system, which is documented through a quality manual and supporting procedures, instructions, and forms. The management system documentation addresses the three elements of information quality: utility, integrity, and objectivity. Internal audits and reviews of NVLAP's management system are conducted on a regular basis to ensure that NVLAP verifies that its activities conform to the requirements of the management system.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.

A new laboratory seeking accreditation, will complete the NVLAP General Application for New Laboratories (which collects only basic contact information) and submits the completed application to NVLAP via email. A copy of the application has been uploaded into ROCIS as a supplemental document. NVLAP administrative staff uses the form to set up the laboratory record and create login credentials within the NVLAP Interactive Web System (NIWS) which then allows the lab to complete the application information submission electronically. A renewal

applicant laboratory electronically submits its application for NVLAP accreditation through the NIWS. This method of collection allows renewing laboratories to review their current application data online, make any changes needed to renew their accreditation, and upload supporting documents required by the application. The system also provides the ability for users to maintain their own profile information. The public URL for the NIWS portal is <https://www-s.nist.gov/niws>. Periodically, a laboratory's authorized representative may change and the new representative completes the Conditions for Accreditation (copy has been uploaded into ROCIS as a supplemental document).

The NIWS is available to laboratories applying for or renewing accreditation in all NVLAP laboratory accreditation programs: Acoustical Testing Services; Asbestos Fiber Analysis; Biometrics Testing; Calibration Laboratories; Carpet and Carpet Cushion; Construction Materials Testing; Efficiency of Electric Motors; Electromagnetic Compatibility and Telecommunications; Energy Efficient Lighting Products; Fasteners and Metals; Radiation Detection Instruments; Information Technology Security Testing (encompasses Cryptographic and Security Testing, Common Criteria Testing, and Healthcare Information Technology Testing); Ionizing Radiation Dosimetry; Personal Body Armor; Thermal Insulation Materials; Wood-Based Products; and Voting System Testing.

4. Describe efforts to identify duplication.

Information requirements contained in NVLAP application forms are specific to NVLAP and are not duplicated by other government programs.

5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

This information collection will not have a significant impact on small entities. Accreditation is available to both public and private laboratories, regardless of size. The criteria for accreditation are uniformly applied to all applicant laboratories. NVLAP complies with requirement 4.4.10 of ISO/IEC 17011, which states: "Access [to NVLAP's services] shall not be conditional upon the size of the applicant conformity assessment body [laboratory] or membership of any association or group, nor shall accreditation be conditional upon the number of conformity assessment bodies already accredited."

6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.

If the collection is not conducted, NVLAP could not fulfill its mission and operate in accordance with 15 CFR Part 285. Laboratories enrolled in NVLAP accreditation programs that were established upon receipt of a mandate through legislative or administrative actions (such as the asbestos fiber analysis testing program) could no longer meet federal regulations. Most NVLAP programs directly support the needs of federal regulatory agencies and their stakeholders. Recent

examples include the Department of Homeland Security (biometrics testing and radiation detection instrumentation), Department of Health and Human Services (healthcare IT testing), and the Environmental Protection Agency (ENERGY STAR program).

If the collection is conducted less frequently, the result would be an increased risk that an accredited laboratory may depart from accreditation requirements; ultimately, the NVLAP accreditation would be of less value to its customers. Per ISO/IEC 17011, 7.9.2, “[NVLAP] shall apply an assessment programme for assessing the conformity assessment body activities during the accreditation cycle to ensure that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle.”

Per ISO/IEC 17011, 7.9.3, NVLAP must assess a sample of the conformity assessment bodies scope of accreditation at least every two years.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

No special circumstances apply to this information collection.

8. Provide information of the PRA Federal Register Notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A 60-Day Federal Register Notice to solicit public comments was published on August 24, 2018, on pages 42874-42875, Vol. 83, No. 165. NIST received no comments.

A 30-Day Federal Register Notice to solicit public comments was published on November 15, 2018, on page 57408, Vol. 83, No. 221.

9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

NVLAP does not provide any payment or gifts to applicant laboratories.

10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.

NVLAP’s policy regarding confidentiality is set forth in 15 CFR Part 285, Sec. 285.2: “To the extent permitted by applicable laws, NVLAP will protect the confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation, and accreditation of laboratories.” NIST also has authority under a provision of the United States Code (USC) to strengthen this confidentiality policy. For the text of this code, see USC, Title 15, Chapter 63, Sec. 3710a, *Cooperative research and development agreements*.

The completed application data is reviewed only by NVLAP staff and contractors who are technical experts in the various fields of accreditation. Both staff and contractors are required to sign a declaration stating they will maintain confidentiality of all information relating to applications, hold in strict confidence all information obtained during on-site assessment of laboratories, and reveal information about individual laboratories only to NVLAP, the laboratories themselves, and members of a NVLAP assessment team or review panel.

Information collected includes PII (such as name/contact information), however the data is referential in nature only. Records will not be retrieved by a personal identifier; therefore, this is not a Privacy Act System of Records and does not require a SORN or Privacy Act Statement.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

There are no questions of a sensitive nature.

12. Provide an estimate in hours of the burden of the collection of information.

Table 1 shows how the annualized burden has been calculated for this collection. The estimates shown are based upon consultation with six accredited laboratory representatives: five testing laboratories and one calibration laboratory. There was a wide range in the hour burden estimates provided because of differences in the size and complexity of the scopes of accreditation of NVLAP’s 19 different laboratory accreditation programs (35 minutes per response to 420 minutes per response). Therefore, a weighted average was calculated based upon the number of respondents in each program.

Each representative was asked to estimate how long it took to complete the most recent renewal application using the new NVLAP Interactive Web System (NIWS), including time spent reviewing instructions, contacting NVLAP staff with questions, searching for and gathering information, and preparing documents for submission. Respondents were advised to exclude any time spent performing customary and usual business practices.

Table 1. Estimates of annualized cost to respondents for hour burdens.

# Respondents	# Responses per Respondent	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)	Salary Category*	Average Hourly Wage Rate*	Total Annual Respondent Cost
750	1 response annually	3.0	2,250	Laboratory Manager	\$48	\$108,000

* U.S. median expected salary as reported on<<http://monster.salary.com/>>.

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in Question 12 above).

The six laboratory representatives who provided estimates for the average burden per response were also asked if there were any additional financial costs associated with applying for accreditation; i.e., those attributable to only the NVLAP application process and not to customary and usual business practices. All six respondents replied there were no costs beyond the labor burden hours.

In summary, (a) there are no capital or start-up costs associated with this collection, and (b) the costs of operations and maintenance associated with the collection are negligible and part of the normal cost of doing business.

14. Provide estimates of annualized cost to the Federal government.

NVLAP does not operate using appropriated funds; it is a fee recovery program, which charges fees for its services under the OMB Circular A-25. Since the laboratory fees cover the direct and indirect costs of application, assessment and evaluation, there is no cost to the Federal government for NVLAP information collection. However, there are Federal costs incurred regarding the items below.

Table 2. Estimates of annualized cost to the Federal government

Description	Annual Cost
Off-the-shelf product license	\$ 92,500
Technical support	\$45,000
Total cost	\$137,500

15. Explain the reasons for any program changes or adjustments.

With this submission, the estimated number of respondents has been decreased from 800 to 750; which also decreased the previous burden hours from 2,400 to 2,250.

With the launch of the electronic, web-based application system, all applicants, regardless of the field of accreditation, are now required to use this system to submit the application information to NVLAP and to select their scopes of accreditation from a database using search filters. The number of test and calibration methods vary based on the accreditation program. The number ranges from less than 5 methods to more than 5000 methods, per program.

16. For collections whose results will be published, outline the plans for tabulation and publication.

After accreditation is granted, a laboratory's name, address, phone and fax numbers, e-mail and URL addresses, contact person, and scope of accreditation are published in the online NVLAP directory of accredited laboratories. The information provides a service to customers in business and industry, including regulatory agencies and purchasing authorities, who are seeking competent laboratories to perform testing and calibration services.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

NVLAP displays the OMB Control number and expiration date for OMB approval appropriately in the NVLAP Interactive Web System (NIWS). A screen shot of the NIWS Log-in screen has been uploaded into ROCIS as a supplemental document.

18. Explain each exception to the certification statement.

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

No statistical methods will be used for this collection of information.