

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

SUPPORTING STATEMENT PART A

Abstract

This includes narrative information explaining the purpose, scope, and benefit(s) of this data collection request. Suggested word length limit - 250 words only.

NVLAP uses a web-based application submission system for all new and renewal applicant laboratories. This NVLAP Interactive Web Site (NIWS) system was developed to simplify the application process and provide a secure means for the applicant laboratory to submit their documentation.

NVLAP-accredited laboratories are recognized as conforming to ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, which allows for and promotes trade by U.S. industries, resulting in positive benefits to the U.S economy.

The information collected is required for NVLAP to fulfill its mission as set forth in Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR), as well as to be compliant with the international standard ISO/IEC 17011, *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies*.

This information is collected, maintained, and used in a way that is consistent with application NIST CIO Information Quality Guidelines and Standards.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

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. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

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. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

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 impacts small businesses or other small entities, describe any 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 consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

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 would cause an information collection to be conducted in a manner: requiring respondents to report information to the agency more often than quarterly; requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it; requiring respondents to submit more than an original and two copies of any document; requiring respondents to retain records, other than health, medical, government contract; grant-in-aid, or tax records, for more than three years; in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study; requiring the use of a statistical data classification that has not been reviewed and approved by OMB; that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

No special circumstances apply to this information collection.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

A 60-Day Federal Register Notice to solicit public comments was published on September 30, 2021, on pages 54167-54168, Vol. 86, No. 187. NIST received no comments.

A 30-Day Federal Register Notice to solicit public comments was published on December 17, 2021, on pages 71618-71619, Vol. 86, No. 240.

NVLAP accreditation is granted annually for each accredited laboratory, based on review of the submission information. Upon completion of the accreditation process, with the issuance of the accreditation documents, every laboratory is provided with a survey in which to provide feedback regarding their experience with all aspects of the accreditation process, including the use of the NIWS. All feedback is reviewed once per year, at a minimum, during NVLAP's annual Management Review.

9. Explain any decision to provide any payment or gift 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 the assurance in statute, regulation, or agency policy. If the collection requires a system of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

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. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Provide estimates of the hour 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
650	1 response annually	3.0	1,950	Laboratory Manager	\$48	\$93,600

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

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

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 costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

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	\$ 92,500

license	
Technical support	\$45,000
Total cost	\$137,500

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

With this submission, the estimated number of respondents has been decreased from 750 to 650, which also decreased the previous burden hours from 2,250 to 1,950.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

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 that 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 topics of the certification statement identified in "Certification or Paperwork Reduction Act Submissions."

There are no exceptions to the certification statement.