

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 high quality 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 submission of an application and payment of fees, on-site assessment, resolution of identified nonconformities, proficiency testing, and technical evaluation. NVLAP-accredited laboratories are recognized worldwide as conforming to international standards for laboratory competence. 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 (Attachment A) 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. 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. Basic identifying information supplied by the laboratories on the applications (laboratory name, address, phone and fax numbers, URL, contact name, etc.) is published monthly in an on-line directory on the NVLAP web site, <www.nist.gov/nvlap>. 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.

The information collection is also required for NVLAP to be compliant with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17011:2004, *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies*. Compliance with ISO/IEC 17011 (see relevant excerpts in Attachment B) is required for NVLAP to be recognized internationally 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.

The collection system consists of the following set of application forms:

- 1) General Application;
- 2) Fee Calculation Worksheet (or Fee Statement for renewing applicants); and
- 3) Program-Specific Application, which is dependent upon the program area selected for accreditation.

NVLAP currently offers accreditation in 16 programs: Acoustical Testing Services; Asbestos Fiber Analysis; Calibration Laboratories; Carpet and Carpet Cushion; Chemical Calibration; Commercial Products Testing; Construction Materials Testing; Efficiency of Electric Motors; Electromagnetic Compatibility and Telecommunications; Energy Efficient Lighting Products; Fasteners and Metals; Information Technology Security Testing; Ionizing Radiation Dosimetry; Thermal Insulation Materials; Wood Based Products; and Voting System Testing. These applications are available on NVLAP's web site, <<http://ts.nist.gov/Standards/Accreditation/formprin.cfm>> (see Attachment C).

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.

The information collected will be used by NVLAP to assess laboratory conformance with applicable criteria (see Section 285.14, *Criteria for accreditation*, of 15 CFR Part 285). An administrative review is performed by the NVLAP operations staff to ensure completeness of the applications. NVLAP Program Managers perform technical reviews of the information to ensure accuracy and availability of requested services. To maintain its accreditation, a laboratory must apply for renewal every year; therefore, these reviews are conducted annually prior to renewing accreditation (see 285.10, *Renewal of accreditation*, of 15 CFR Part 285).

The accreditation decision is based upon NVLAP's review of information collected during the accreditation process and a determination of whether or not all requirements for accreditation have been fulfilled. The name and contact information of each accredited laboratory, along with the test methods or calibration parameters for which it is accredited, is posted on the NVLAP web site at <<http://ts.nist.gov/Standards/scopes/programs.htm>>.

This information is collected, maintained, 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 and to determine the system's effectiveness.

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.

NVLAP announced the opening of its new web-based application system—the NVLAP Interactive Web Site (NIWS) —in June 2006 (see announcement in Attachment D). The NIWS enables laboratories to apply for the first time or to complete their renewal applications over the Internet in order to simplify the application process, eliminate the redundancy of submitting the same information year-after-year, and shorten the time needed to provide the information to NVLAP. The login URL for this web site is < <https://rproxy.nist.gov/niwsapp/ext/login.jsp>>. Attachment E is a screenshot of the user instructions for completing the on-line application for accreditation. Using the NIWS, renewing laboratories may review their current application data on-line, make any changes needed to renew their accreditation, and upload supporting documents required by the application.

The first phase of NIWS deployment (present phase) has been to open the system to two of NVLAP's programs: the Electromagnetic Compatibility and Telecommunications Program (ECT) and the Acoustical Testing Program (Acoustics). Laboratories in these two programs account for approximately 225 of NVLAP's 850 accreditations. The next group of laboratories being added to the NIWS is the Asbestos Fiber Analysis program, consisting of approximately 330 accreditations. This will bring the total number of accreditations that could potentially be applied for on-line to 555 annually. If 40 % of these accreditations are processed through the on-line system, then roughly 222 (or 25 % to 30%) of all responses (850) will be collected electronically.

The programs will be added to the NIWS one-by-one as the production system continues to be modified and enhanced based upon user feedback and testing. In the meantime, any laboratory has the option of downloading Adobe PDF application forms from the NVLAP web site and e-mailing or faxing them to NVLAP, or updating the pre-filled forms (for renewal labs) provided by NVLAP.

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 4.3.3 of ISO/IEC 17011, which states: "Access [to NVLAP's services] shall not be conditional upon the size of the applicant Conformity Assessment Body (CAB) [laboratory] or membership of any association or group, nor shall accreditation be conditional upon the number of CABs 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 operate in accordance with 15 CFR Part 285. 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 not operate, and some enrolled laboratories could no longer remain in business.

If the collection is conducted less frequently, the result would be an increased risk that an accredited laboratory may depart from accreditation criteria; hence, the NVLAP accreditation would be of less value to its customers. Per ISO/IEC Guide 17011, 7.11.2, NVLAP must carry out periodic surveillance activities and reassessments at sufficiently close intervals to monitor the continued fulfillment by the accredited laboratory of the requirements for accreditation.

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

None of the special circumstances listed in the instructions apply to this information collection.

8. Provide a copy 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 Federal Register notice to solicit public comments was published on September 5, 2006, on page 52321, Vol.71, No. 171. Only one comment was received in response to this notice: "this minimum information collection really does nothing to keep these labs honest and safe for use by those who need accurate and honest science. it is simply the minimum and does nothing. send out secret investigators to test out the labs and see if they are in fact doing reliable, honest, accurate work, or if they take bribes. we find that bribes are altering the alleged 'science'

we get far far too often.” NVLAP took no action on this comment, as the comment was irrelevant to the information collection and too vague to merit a specific response.

NVLAP conducts an ongoing transactional survey, Accreditation Services Customer Survey (OMB Approval No. 0693-0031), which measures the satisfaction of accredited laboratories with the application process and the timeliness of the processing of an accreditation, as well as other service attributes. The survey instrument provides space for comments, which are reviewed upon receipt.

Users of the NIWS have been providing feedback as NVLAP fine tunes the new web-based application system. NVLAP has depended heavily on customer input regarding the user friendliness and correct functioning of the system.

NVLAP also publishes a feedback page on its web site to solicit comments from accreditation users on what they like about the program, what they would like to change, and what is not clear. This page provides an additional avenue for customers to offer their views on information collection.

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.

The completed applications are reviewed only by NVLAP staff and contractors. Technical contractors are required to sign a declaration stating that 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.

NVLAP’s policy regarding confidentiality is set forth in 15 CFR Part 285, Sec. 285.2, which states: “To the extent permitted by applicable laws, NVLAP will protect the confidentiality of all information obtained relating to the application, . . . 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*.

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.

The estimates shown below are conservative and are based upon the percentage of laboratories that chose to submit their applications on-line when the on-line application system was made available to them (roughly 40 %). The number of laboratories shown in Table 1 as “Labs Applying On-line” is based upon FY 07 projections and includes the ECT, Acoustics, and Asbestos accreditation programs. This number is expected to increase each year as users become more comfortable with the on-line option and as the remaining NVLAP programs are added to the NIWS. See Table 1 for an explanation of how the annualized burden was calculated.

Estimated hour burden:

- Number of respondents = 850 laboratories
- Frequency of response = 1 (annually)
- Hours per response = 1 hr., 37 min. (weighted average)
- Hours per recordkeeper = 1 hr. (average)
- Annual burden for respondents = 850 responses X (1 hr., 37 min. each) = 1375 hrs.
- Annual recordkeeping burden = 850 recordkeepers X (1 hr. each) = 850 hrs.
- Total Annual Burden = 2,225 hrs.**

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

Activity	Labs Applying On-line		Labs Not Applying On-line		Salary Category*	Wage Rate	Total
	# of Labs	Annl. Labor Hrs.	# of Labs	Annl. Labor Hrs.			
Reporting							
Reviewing instructions, compiling information, reviewing/completing forms	225	1 hr. 15 min.	625	1 hr. 15 min.	Laboratory/ Quality Assurance Manager	\$42.00	\$44,625
Typing and mailing forms	225	0	625	30 min.	General Clerk	\$16.00	5,000
Record-keeping							
Copying and filing	225	30 min.	625	30 min.	General Clerk	\$16.00	6,800
Accounting	225	30 min.	625	30 min.	Accounting Clerk	\$18.00	7,650

Total Cost	225		625				\$64,075

** 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 recordkeepers resulting from the collection (excluding the value of the burden hours in #12 above).

Estimated annual cost burden to respondents or recordkeepers excluding data in Table 1:

(a) There are no capital or start-up costs associated with this collection.

(b) Costs of operations and maintenance associated with the collection are negligible. Any office supplies (e.g., file folders and toner cartridges) purchased by a laboratory are part of its customary and usual business practices. If approximately 70 % to 75 % of participating laboratories elect to mail their applications (a very conservative estimate that is expected to decrease each year), the worse case scenario for their postage costs is \$ 527.00 (\$ 0.87 per response X an estimated 606 laboratories).

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

NVLAP receives no appropriated funds and operates on a cost-reimbursable basis from accreditation fees paid by participating laboratories. In this sense, there is no cost to the federal government for NVLAP information collection and recordkeeping because the laboratories pay fees to cover the direct and indirect costs of application, assessment and evaluation.

The estimated annual costs that NVLAP would not have incurred without the collection of information total \$23,000; however, it must be noted that these costs are very difficult to extract from the normal costs of operating the program. These estimates may be misleading given that NVLAP cannot operate without the collection of information. NVLAP still provides pre-filled paper applications to renewing laboratories in order to give them options for submitting the information. The cost of this may be broken down as follows in Table 2:

Table 2. Estimates of annualized cost to the Federal government	Amount
<i>Labor Cost (all hourly rates include NIST overhead of 2 X)</i>	
Paperwork Reduction Act compliance (12 hours @ \$114 per hour)	\$ 1,368
Application maintenance (32 hours @ \$114 per hour)	3,648
Application processing (850 applications @ 20 min. each @ \$49 per hr.)	13,883
Clerical support: stocking applications, filing (80 hours @\$35 per hour)	2,800

Table 2. Estimates of annualized cost to the Federal government	Amount
Total Labor Costs	\$ 21,699
<i>Non-Labor Costs</i>	
LaserJet copies (paper + toner): 7,000 impressions @ \$.02 each	\$ 140
Duplicating: 8200 impressions @ \$.05 each	410
Postage: 850 pieces (est. 3 oz. ea.) @ \$ 0.87 each	740
Total Non-Labor Costs	\$ 1,290
TOTAL ESTIMATED ANNUALIZED COST	\$ 22,989

Note: The NVLAP Interactive Web Site (NIWS) is funded through the surcharge that NVLAP pays towards NIST Technology Services (TS) overhead.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-I.

The current OMB inventory will be decreased by 113 hours due to NVLAP's action in providing the web-based application system. The difference is attributable to reduced labor burden involved in preparing and mailing paper forms.

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

Information submitted by applicant laboratories is treated in a confidential manner and is used internally during the accreditation process. 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 on-line 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 expiration date for OMB approval appropriately in all media (web-based application, PDF forms, and paper forms).

18. Explain each exception to the certification statement identified in Item 19 of the OMB 83-I.

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.