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 an application;
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 (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.

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 (see relevant excerpts in Attachment B) 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.

The collection system consists of the NVLAP General Application form plus one or more Program-Specific Application forms, which are dependent upon the program area(s) selected for accreditation. NVLAP currently offers accreditation in 20 programs:

Acoustical Testing Services;
Asbestos Fiber Analysis;
Biometrics Testing;
Calibration Laboratories;
Carpet and Carpet Cushion;
Chemical Calibration:
Filter NTRMs;
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.

These applications are publicly available on NVLAP's website (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 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 supplied by the laboratories on the applications (laboratory name, address, phone and fax numbers, URL, contact name, etc.) is published weekly in an on-line

directory 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, 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.

A laboratory may apply for accreditation through one of two ways (see Attachment D):

1. the NVLAP Interactive Web Site (NIWS);

2. PDF application forms.

NVLAP Interactive Web Site (NIWS)

The NIWS is a web-based application designed to enable a laboratory to securely submit its application via the Internet. An applicant laboratory may use this system if all required supporting documents, including the laboratory quality manual, are in an electronic format that can be uploaded to NVLAP's information system. The NIWS was developed 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 public URL for this website is <http://www.nist.gov/nvlap/nvlap-niws.cfm>. Attachment E is a screenshot of the user instructions for completing the on-line application. 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.

This system is currently available to laboratories enrolled in 15 fields of accreditation (see list of available fields at the NIWS launch page), representing 78 % of active accreditations. NIWS software release 4.4, expected to go live in November 2012, will add two more programs, Calibration Laboratories and Ionizing Radiation Dosimetry, bringing the total to 96 %. By the end of FY 13, 100 % of NVLAP's programs are projected to be accessible through the NIWS (approximately 850 accreditations).

It is a laboratory's choice whether or not to apply using the NIWS system or through traditional methods (e-mail, fax, or mail). Assuming that 50% of 850 accreditations are processed through the on-line system, then 425 responses are estimated to be collected electronically every year.

PDF application forms

A laboratory that does not elect to use the NIWS has the option of downloading PDF application forms from the NVLAP website and sending them to NVLAP, or updating pre-filled forms provided by NVLAP to renewing laboratories.

NVLAP is exploring options for moving these laboratories to a PDF form system accessible through the NIWS. Moving to such a system would eliminate the need for NVLAP staff to enter data received from laboratories. This, in turn, would result in a reduction in the amount of pre-processing time by NVLAP administrators compared to paper-based PDF and renewal applications.

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 fulfill its mission or 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 programs) could no longer meet federal regulations. Also, NVLAP's newer programs were developed to 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; 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 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 Federal Register Notice to solicit public comments was published on August 14, 2012, on pages 48503-48504, Vol. 77, No. 157. No comments were received as a result of this Federal Register Notice.

NVLAP conducts an ongoing transactional survey, Accreditation Services Customer Survey (OMB Control 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.

A second transactional survey (also OMB Control No. 0693-0031) collects information from users of the NIWS system. Questions were designed to assess satisfaction with instructions for applying on-line, overall ease of using the NIWS, likelihood to use the NIWS again, and time spent in filling out application forms and payment information. Open ended questions are included, too (i.e.,"How can NVLAP improve the NIWS?"). NVLAP depends heavily upon customer input regarding the user friendliness and correct functioning of this system.

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 applications are 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.

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. When the last group of laboratory accreditation programs is added to the NIWS, the total number of applications that can be submitted annually on-line will be approximately 850. The estimates used in the table are based upon the assumption that 50 % of the 850 applications will actually be submitted on-line.

Estimated hour burden:
Number of respondents = 850
Frequency of response = 1 (annually)
Hours per response = 2 hours and 23 minutes (weighted average)
Annual burden requested = 850 responses X 2 hrs and 23 mins each = 2,026 hours
Total Annual Burden Hours = **2,026**

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

Activity	Applications Submitted On-line		Applications Submitted by Other Means		Salary Category*	Wage Rate	Total
	# of Respon-dents	Annual Labor Hrs.	# of Respon-dents	Annual Labor Hrs.			
Reporting							
Reviewing instructions, compiling information, reviewing/completing submission	425	1 hr. 15 min.	425	1 hr. 15 min.	Laboratory/ Quality Assurance Manager	$44.00	$46,750
Preparing and sending forms	425	0	425	30 min.	General Clerk	$18.00	$3,825
Copying and filing	425	15 min.	425	30 min.	General Clerk	$18.00	$5,738
Accounting	425	30 min.	425	30 min.	Accounting Clerk	$20.00	$8,500
Total Cost							$64,813

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

13. <u>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)</u>.

Estimated annual cost burden to respondents 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. Many laboratories submit their applications via e-mail instead of the postal service; however, even if 50 % of participating laboratories elected to

mail their applications, the worse case scenario for their postage costs would be **$552.50** ($1.30 first class mail per response X the estimated 425 laboratories).

14. <u>Provide estimates of annualized cost to the Federal government</u>.

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 and recordkeeping.

The share of the NVLAP budget associated with information collection is difficult to isolate; in essence, all NVLAP activities are driven by the collection. However, NVLAP can provide specific cost estimates (see Table 2) of providing pre-filled applications to all renewing laboratories to give them options for submitting the information, providing labor to develop and maintain the NVLAP Interactive Web Site (NIWS), and the administrative processing of the forms and data.

Table 2. Estimates of annualized cost to the Federal government	**Amount**
Labor Costs (all hourly rates include an overhead factor of 1.8 X)	
Paperwork Reduction Act compliance (12 hours @ $118 per hour)	$ 1,416
Application maintenance (32 hours @ $118 per hour)	3,776
Application processing (850 applications @ 20 min. each @ $66 per hr.)	18,700
Clerical support: copying applications, filing (80 hours @ $41 per hour)	3,280
NIWS development and maintenance (IT support + server charges)	96,500
Total Labor Costs	$123,672
Non-Labor Costs	
Copier and paper costs: est. 15,000 impressions @ $ .10 each	$ 1,500
Postage: 850 pieces (est. 3 oz. ea.) @ $ 1.30 each	1,105
Total Non-Labor Costs	$ 2,605
TOTAL ESTIMATED ANNUALIZED COST	$126,277

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

The current OMB inventory will be decreased by 99 hours to account for an adjustment in usage (from 50 % to 40 %) of the on-line system (NIWS), and cost burden decrease of $69 due to fewer mailed applications.

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 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.

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.