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. This accreditation is available to commercial laboratories, manufacturers' in-house laboratories, university laboratories, and federal, state and local government laboratories; and granted following successful completion of the process. The process includes –

1. submission of an application;

2. on-site assessment;

3. resolution of identified nonconformities;

4. proficiency testing; and

5. technical evaluation.

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 following set of application forms:

1) General Application;

2) one or more Program-Specific Application forms (dependent upon the program area(s) selected for accreditation);

NVLAP currently offers accreditation in 19 programs: Acoustical Testing Services; Asbestos Fiber Analysis; Biometrics Testing; Calibration Laboratories; Carpet and Carpet Cushion; Chemical Calibration: Filter NTRMs; Commercial Products Testing; Construction Materials Testing; Efficiency of Electric Motors; Electromagnetic Compatibility and Telecommunications; Energy Efficient Lighting Products; Fasteners and Metals; Homeland Security: Radiation Detection Instruments; Information Technology Security 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 web site (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 accreditation decision 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 monthly in an on-line directory on the NVLAP web site, http://www.nist.gov/nvlap (Click on *NVLAP-Accredited Laboratories Directory* on the home page.) . 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.

The NVLAP Interactive Web Site (NIWS) 67 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 public URL for this web site is found at <http://ts.nist.gov/Standards/Accreditation/NVLAP-NIWS.cfm>. Attachment D is a screenshot of the user instructions for completing the on-line application for accreditation. Using 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.

NVLAP is developing the fourth release of the NIWS software. The system is currently open to six accreditation programs. NIWS version 4.0 will add another six programs, yielding a total of twelve programs for which laboratories can apply on-line. Laboratories in these twelve programs account for approximately 82% of total accreditations. When the last group of programs is added to the system in 2010, the total number of accreditations that could potentially be applied for on-line will be 100% (or 850 accreditations).

It is a laboratory's choice whether or not it wants to apply using the NIWS system or through traditional mail, e-mail, or faxing methods. Assuming that 40% of 850 accreditations are processed through the on-line system, then 340 responses are estimated to be collected electronically.

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

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, some of NVLAP's newer programs were developed to directly support components of the Homeland Security Department (e.g., biometrics testing and radiation detection instrumentation).

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 17, 2009, on pages 41371-41372, Vol.74, 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 under OMB Control No. 0693-0031 is currently being programmed by NIST IT staff and will be implemented soon. Information collected through this instrument will specifically address how well the NIWS system is meeting user needs. NVLAP depends heavily upon customer input regarding the user friendliness and correct functioning of this system.

NVLAP publishes a feedback page on its web site (click on *Provide Feedback to NVLAP* on the home page) 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 yet 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.

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, 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 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.

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 in 2010, the total number of applications that can be submitted annually on-line will be around 850. The estimates used in the table are based upon the assumption that 40% of the 850 applications will actually be submitted on-line. It is hoped that this number will increase each year as users become more comfortable with the on-line option.

Estimated hour burden:
Number of respondents = 850
Frequency of response = 1 (annually)
Hours per response = 2 hours and 30 minutes (weighted average)
Annual burden requested = 850 responses X 2 hrs and 30 mins each = 2,125 hours

Total Annual Burden Hours = 2,125

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 forms	340	1 hr. 15 min.	510	1 hr. 15 min.	Laboratory/ Quality Assurance Manager	$43.00	$45,688
Typing and mailing forms	340	0	510	30 min.	General Clerk	$17.00	4,335
Copying and filing	340	15 min.	510	30 min.	General Clerk	$17.00	5,780
Accounting	340	30 min.	510	30 min.	Accounting Clerk	$20.00	8,500
Total Cost	340		510				$64,303

** 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. If approximately 60% of participating laboratories elect to mail their applications (a conservative estimate that is expected to gradually decrease), the worse case scenario for their postage costs is **$622.20** ($1.22 per response X the estimated 510 laboratories).

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

NVLAP operates on a cost-reimbursable basis from accreditation fees paid by participating laboratories. 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 paper applications to all renewing laboratories in order 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 NIST overhead of 2 X)	
Paperwork Reduction Act compliance (12 hours @ $128 per hour)	$ 1,536
Application maintenance (32 hours @ $128 per hour)	4,096
Application processing (850 applications @ 20 min. each @ $66 per hr.)	18,700
Clerical support: copying applications, filing (80 hours @$36 per hour)	2,880
NIWS development and maintenance (IT support)	163,000
Total Labor Costs	$190,212
Non-Labor Costs	
Copier and paper costs: est. 15,000 impressions @ $ .06 each	$ 900
Postage: 850 pieces (est. 3 oz. ea.) @ $ 1.22 each	1,037
Total Non-Labor Costs	$ 1,937
TOTAL ESTIMATED ANNUALIZED COST	$ 192,149

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

The current OMB inventory will be decreased by 100 hours due to the planned availability of the web-based application system to all NVLAP programs in 2010, and preparing and photocopying paper forms.

The cost of mailing postage was not included in the previous submission but has been included for this request.

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.