NVLAP Assessor Training

Working for NVLAP

National Institute of Standards and Technology
U.S. Department of Commerce

Our Vision

To be a world-class accreditation body recognized nationally and internationally for raising the bar and setting the standard for excellence in accreditation.

Scope of presentation

- Part 1: Your responsibilities as a representative of NVLAP
- Part 2: What you need to know about the federal government procurement process, if you are a contractor
- Part 3: Assessor monitoring & recordkeeping

Requirements for Accreditation Bodies

- NVLAP complies with ISO/IEC 17011:2004, *General requirements for accreditation bodies accrediting conformity assessment bodies*

  (i.e., testing & calibration labs).
- NVLAP's compliance and subsequent recognition through Mutual Recognition Arrangements (MRAs) provide confidence to purchasers of laboratory services and regulators & facilitate cross-border trade.

17011 Requirements for Assessors

- The accreditation body (AB) shall require all personnel to commit themselves formally . . . to comply with the rules defined by the AB.
- The commitment shall consider aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with CABs (i.e., labs) to be assessed. (ISO/IEC 17011:2004, 6.1.4)

How do we meet this requirement?

The **NVLAP Declaration** addresses:

- compliance with NVLAP policies, procedures, and rules
- confidentiality
- consultancy
- impartiality
- conflict of interest and prior associations with labs

NVLAP Declaration and other forms used by assessors are located on the NVLAP web site

NVLAP®

NVLAP DECLARATION
(for NVLAP staff, assessors, and technical experts)

This is to acknowledge that I understand my responsibilities as a representative of the National Institute of Standards and Technology (NIST) and the National Voluntary Laboratory Accreditation Program (NVLAP) in carrying out my duties.

I hereby commit myself to the following:

- I agree to comply with the policies, procedures, and rules set forth by NVLAP while working for or on behalf of NVLAP.

  I agree to maintain my awareness of NIST Handbook 150, ISO/IEC 17025, ISO/IEC 17011, and other appropriate requirements documents.

- I agree to maintain confidentiality of all information relating to applications, assessments, and accreditations of laboratories. I will hold in strict confidence all information, proprietary or otherwise, obtained during on-site assessments of laboratories. I agree to maintain this confidentiality even after I am no longer working for or on behalf of NVLAP.

  I understand that I may reveal information about individual laboratories only to NVLAP, the laboratory itself, and members of a NVLAP assessment team or NVLAP review panel.

- I agree not to offer consultancies or services to laboratories that might compromise my impartiality during any phase of the accreditation or decision-making process.

- For each laboratory about which I obtain information, I agree to be free of any commercial or financial interests or other pressures or conflicts of interest that might cause me to act in other than an impartial or nondiscriminatory manner.

  For each laboratory about which I obtain information, I agree to keep NVLAP informed, in a timely manner, of any activities, affiliations, or relationships that might compromise my adherence to commitments made in this declaration. This includes informing NVLAP of any prior association with any laboratory to be assessed or evaluated.

For employees of the Executive Branch of the U.S. Federal Government:

- I am aware of the rules for employee responsibilities and conduct as set forth in The U.S. Code of Federal Regulations, 5 CFR Part 2635, *Standards of Ethical Conduct for Employees of the Executive Branch*.

Signature _____ Date _____

Printed Name _____

NVLAP DECLARATION 1 REV. 2006-04-13

Consultancy and Impartiality

- What is consultancy?
  - *Participation in any of the activities of a laboratory subject to accreditation (ISO/IEC 17011:2004, 3.11)*
- Examples:
  - preparing or producing manuals or procedures for a lab
  - giving specific advice or training towards development & implementation of a lab's management system and/or operational procedures
  - telling a lab ***how*** to resolve a specific nonconformity
  - promoting specific vendors and/or their products or services.

More on Consulting & Impartiality

- Nothing shall be said or implied that would suggest accreditation would be simpler, easier, faster or less expensive if any specified person or consultancy were used (ISO/IEC 17011: 2004, 4.3.6).
- It's okay to provide generic (i.e., not lab-specific) advice/training to groups of labs.

Safeguarding Confidentiality

- NVLAP's policy is to protect the confidentiality of all information obtained during the assessment process.
- NVLAP may not disclose information about a particular lab without the lab's written consent (except where required by law).
- Confidentiality is essential!

Information to Keep Confidential

Confidential information includes:

- Assessment paperwork and electronic files
- Discussions about the assessment, whether they take place on-site or afterwards with team members or NVLAP staff
- Names of labs that you assess and when you assess them
- Proficiency testing results

How to Protect Information

- Breaches of confidentiality are serious!
- Precautions include:
  - Using an e-mail address that is not shared by others (including family members)
  - Keeping lab-related information out-of-sight and locked when not in use
  - Returning or destroying materials when they are no longer needed

Conflict of Interest

- It is the assessor's responsibility to advise NVLAP **before the on-site** of any real or perceived conflict of interest with an assigned laboratory (see Declaration).
- Examples include past connections with a lab, competitive position between assessor and lab, financial interest of family member.

Ethical Concerns – Q & A

- May the lab pay for my lunch?
  - Plan to pay for all meals; however, the provision of an inexpensive lunch is acceptable if it is the lab's customary practice for visitors.
- What should I do if the lab presents me with a gift?
  - A small gift or token of appreciation may be accepted if not excessive in value (e.g., company marketing items such as a pen or a mug).

Ethical Concerns – More Q & A

- Who do I contact if I am uncomfortable and not sure what to do?
  - Discuss with Lead Assessor, or call your NVLAP Program Manager.
- You can always tactfully decline what is being offered.
- Common sense and awareness of usual business practice within the culture is the best guide.

In a Nut Shell . . .

Avoid any situation that might be construed as undue or improper influence upon assessment findings

Procurement Process

Simply stated:

What you need to know if you're a contractor and want to get paid.

Contractor Requirements

- An individual, company, or Federal agency must obtain the following:
  - DUNS No. (Dun & Bradstreet)

    www.dnb.com
  - CAGE Code (Central Contractor Registration)

    www.ccr.gov

    Must be renewed annually!

Submitting a Bid

- NVLAP will contact you and ask you to do a job (e.g., on-site visit, assessment review, document review)
- On-site package will be mailed to you by CD
- If you are asked to do more than one job, submit the individual bids together so they can be placed on one purchase order (P.O.)

Total Bid for a Job

- Assessor Quote Form Tool

NVLAP Assessor Quote Form
(Microsoft Excel Worksheet)

Date:	9/3/2009
Assessor Name:	John Doe
Laboratory Name:	ABC Lab
NVLAP Lab Code:	500000-0

	Quantity (hours or miles)	Amount ($)
1. On-Site Assessment (hours)		
Preparation/document review	8.00	
Travel	8.00	
On-site visit	24.00	
Post-assessment review of nonconformity responses	4.00	
Subtotal (# hrs. X $68.90/hr.)	44.00	$3,031.60
2. Travel Expenses		
Airfare		$360.00
Car Rental		$275.00
Taxi/Limo		$50.00
Parking/Tolls		$50.00
Mileage (# miles X $0.55/mi.) *	100.00	$55.00
Subtotal		$790.00
3. Per Diem Expenses *		
Lodging		$400.00
Meals and Incidentals		$200.00
Subtotal		$600.00
4. Miscellaneous Expenses		
Phone, Internet, Postage		$50.00
Other:		$100.00
Subtotal		$150.00
TOTAL AMOUNT OF QUOTE		$4,571.60

* Visit <http://www.gsa.gov> for current lodging, per diem, and mileage rates.

Agreed Upon Price

- After an agreed upon price for the job, PM will start requisition process to obtain a P.O.
- NIST Procurement requires ***30 days*** to process an order
- E-mail authorization will include the job, P.O. number, & authorization amount
- NIST Procurement will e-mail copy of P.O.
- Authority to work comes from the P.O.

Authorization

- No work can be performed before the authorization is received.
- If you perform work without a Purchase Order, NVLAP cannot pay you!

Invoicing

- NVLAP Assessor Resources web page has an invoice form that you can use
- Payment authorization cannot be made without the deliverable (e.g., completed on-site report)
- If you have more than one job on a P.O., submit an invoice after each job is completed.

Getting Paid

- Submit invoice to NIST Accounts Payable
  - E-mail to invoice@nist.gov
  - Fax to 301-975-8283
- Accounts Payable issues payment 30 days from its receipt of the invoice
- Submitting the invoice to NVLAP may delay your payment

Assessor Monitoring

Back to ISO/IEC 17011 . . .

- 6.3.1 requires an AB to establish procedures for monitoring the performance & competence of assessors.
- 6.3.2 gives examples of monitoring methods and requires each assessor to be observed on-site regularly, ***normally every 3 years***.
- Also, an assessor candidate must be observed on-site before being judged "fully qualified."

How Does NVLAP Meet These Requirements?

- NVLAP has a procedure (APM 22.02) that addresses the monitoring & evaluation of the performance of persons who serve as assessors and technical experts for NVLAP, *including NVLAP and NIST staff members*.

Why is Monitoring So Important?

- Provides information for improved decision-making
- Identifies training needs and problems facing assessors
- Harmonizes the interpretation of requirements and assessor practices
- Ensures that assessments are carried out in a systematic manner according to NVLAP procedures

Assessors are the face of NVLAP!

Methods Used: On-site observations

- NVLAP monitors all active-status assessors through on-site observations every 3 years.
- Evaluators are NVLAP Program Managers (PMs), lead assessors, or other qualified persons designated by NVLAP.
- Assessor Performance Evaluation Form (APEF) is used to record feedback.
- Evaluator completes form within 15 days of end of assessment, ***shares feedback*** with assessor being evaluated, & returns the signed form to NVLAP.

Key Performance Measures

- Understanding NVLAP policies/procedures
- Understanding/application of NIST HB 150
- Organization of opening/closing meetings
- Assessment skills and techniques
- Technical skills
- Demeanor and interpersonal skills
- Communication skills
- Time management

Assessor Performance Evaluation Form

Program Manager

reviews form and, for negative comments, takes appropriate action:

- investigates comments for accuracy;
- discusses comments with assessor;
- takes corrective action as necessary and documents actions taken;
- notifies laboratory, if appropriate, of corrective actions taken.

NVLAP ASSESSOR PERFORMANCE EVALUATION

This form is used by NVLAP evaluators to record the results of observations of both fully qualified assessors and assessors-in-training at on-site assessments. The evaluation record should identify areas of good performance, as well as areas in need of improvement and further training. If a rating area does not apply to the category of assessor being evaluated, then enter "NA" in the Comments block.

This form must be completed by the evaluator within 15 days of the conclusion of the on-site assessment. The information on the form is shared with the assessor being evaluated, and the form is signed by both the evaluator and the assessor. The NVLAP Program Manager (if different from the evaluator) then reviews and signs the completed form and ensures that it is filed in the assessor's records.

Assessor Being Evaluated:	Evaluator:	
Lab Name:	NVLAP Lab Code:	
Date(s) of observation:	Start date	End date

Assessor's Role (check all that apply): ☐ Lead Assessor ☐ Technical Assessor ☐ Technical Expert

RATE THE ASSESSOR IN THE FOLLOWING AREAS:

	Poor (1)	Fair (2)	Good (3)	Very Good (4)	Excellent (5)
1. Understanding of NVLAP policies and procedures	☐ (1)	☐ (2)	☐ (3)	☐ (4)	☐ (5)
Comments:					
2. Understanding and application of NIST Handbook 150 requirements	☐ (1)	☐ (2)	☐ (3)	☐ (4)	☐ (5)
Comments:					

Methods Used: Review of reports

- Evaluation of on-site report is done by PM or by an on-site assessment reviewer.
- NVLAP Evaluation of On-Site Report form is used to record evaluation results and comments.
- PM takes appropriate action as described in previous slide.

Evaluation of On-Site Report Form

EVALUATION OF ON-SITE REPORT

To be completed by the Program Manager (PM) or the on-site assessment review evaluator(s) and signed by the PM

Name of assessor:	Program:
Was the assessor assessing the: management system ☐	technical competence ☐ or both ☐
Lab Name:	NVLAP Lab Code:
Date(s) of assessment: Start date	End date

Evaluation areas	*N/A (form not used in this report)*	*Current version?*		*Rate the quality of the report for questions 1-3*					
				Missing	*Poor*	*Fair*	*Good*	*Very Good*	*Excellent*
		Y	*N*	*0*	*1*	*2*	*3*	*4*	*5*
1. For forms a) through e), as applicable: Was current version used? Is the report complete?									
a) On-Site Assessment Summary	☐	☐	☐	☐	☐	☐	☐	☐	☐
b) Signature Sheet w/Narrative Summary	☐	☐	☐	☐	☐	☐	☐	☐	☐
c) NIST Handbook 150 Checklist	☐	☐	☐	☐	☐	☐	☐	☐	☐
d) Program-Specific Checklist	☐	☐	☐	☐	☐	☐	☐	☐	☐
e) Test Method Review Summary	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Is the report legible?					☐	☐	☐	☐	☐
3. Are nonconformities reported? If Yes, complete a) through d).	Yes ☐	No ☐							
a) Are nonconformities clearly stated?					☐	☐	☐	☐	☐
b) Are they declared against specific requirements?					☐	☐	☐	☐	☐
c) Is objective evidence identified?					☐	☐	☐	☐	☐
d) Are reported nonconformities valid?					☐	☐	☐	☐	☐

4. Reviewer's comments:

5. Program Manager's comments and actions taken:

Reviewer:	Date:	Program Mgr.:	Date:

Key measures:

- Completeness
- Use of current version
- Legibility
- Quality of non-conformity statements

Methods Used: Feedback from labs

- Every month NVLAP mails Assessor Questionnaires to labs that had recent on-sites.
- Lab is asked to complete a questionnaire for each assessor who participated in the on-site.
- Measures are similar to those used on APEF.
- PM evaluates comments and, for negative feedback (including ratings of 1 or 2), takes appropriate action.

Assessor Questionnaire

OMB No. 0693-0031
Expires: 2012-02-29

This survey is authorized under Executive Order 12862, "Setting Customer Service Standards." Your response is voluntary and all data collected will be considered confidential. Public reporting for this collection of information is estimated to average 5 minutes per response, including the time of reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this estimate or any other aspects of this collection of information, including suggestions for reducing the length of this questionnaire, to the National Institute of Standards and Technology, 100 Bureau Drive, Stop 1710, Gaithersburg, MD, 20899-1710 and the Office of Management and Budget Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Laboratory Name:	NVLAP Lab Code:
Assessor Name:	Assessment Date(s):

Please provide NVLAP with your evaluation of the assessor by rating the following performance areas. Complete a separate questionnaire for each assessor. For any question rated Poor or Fair, comment below.

		Poor	*Fair*	*Good*	*Very Good*	*Excellent*
1.	Familiarity with NVLAP accreditation procedures and requirements (NIST Handbook 150 series)	(1)	(2)	(3)	(4)	(5)
2.	Knowledge of relevant assessment methods and techniques: examining, questioning, evaluating and reporting	(1)	(2)	(3)	(4)	(5)
3.	Audit management skills: preparation, organization, and direction	(1)	(2)	(3)	(4)	(5)
4.	Technical knowledge of specific tests or calibrations for which accreditation is sought and, where relevant, of the associated sampling procedures	(1)	(2)	(3)	(4)	(5)
5.	Personal attributes: judgment, objectivity, maturity, interpersonal skills	(1)	(2)	(3)	(4)	(5)
6.	Oral and written communication skills	(1)	(2)	(3)	(4)	(5)
7.	Presentation of assessment findings and conclusions in a logical and orderly sequence and in appropriate depth (exit briefing and on-site assessment report)	(1)	(2)	(3)	(4)	(5)

8. Duration of assessment (number of hours at laboratory) _____

9. Comments (use back if needed) _____

Records of Assessor Monitoring

- 17011, 6.4.1 requires NVLAP to maintain records of assessor monitoring and to keep them up-to-date.
- Records are stored in individual assessor folders kept in a secure file room accessible to NVLAP staff only.
- Records are maintained for duration of active service.
- No Personally Identifiable Information (PII) is kept electronically.

Importance of Performance Records

The records we create demonstrate the effectiveness of our management system and provide the basis for the measurement and feedback essential for continual improvement.

In Closing . . .

We are glad you have chosen to be a part of the NVLAP accreditation team and are helping us to achieve our vision!

Information Contacts:

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