NVLAP Assessor Training

Assessment Techniques

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

NVLAP®

Outline

- Purpose of the Types of Assessments
- Instructions to the Assessor
- Conducting the Opening Meeting
- Collecting and Verifying Information
- Horizontal vs. Vertical Assessment
- Completing the Report(s)
- Time Management
- Conducting the Closing Meeting
- Case Study

Assessment - Definition

- *Process undertaken by an accreditation body to assess the competence of a CAB, based on a particular standard(s) and/or normative documents and for a defined scope of accreditation (ISO/IEC 17011:2004)*

Types of NVLAP Assessments

- Initial
  - NIST Handbook 150:2006
  - Program-specific handbooks/requirements
- Renewal
  - NIST Handbook 150:2006
  - Program-specific handbooks/requirements
- Monitoring/Scope Expansion
  - Few designated items
  - Full review

Laboratory Assessment Instructions for Assessor

- Do not commit monies prior to receipt of the purchase order
- Goal - conduct assessment within the first 6 months of the renewal cycle.

Laboratory Assessment Instructions for Assessor

- Lead Assessor – Pre-assessment Document Review and Agenda to lab at least 2 weeks prior to assessment
- Lead Assessor - contact lab rep, and the other assessor(s), 2-5 days prior to on-site to confirm dates and final logistics

Importance of the document review

- Requirement of APLAC/ILAC
- Request currency of management documents
- Request the Cross-Reference, if LAP requires
- Understand the lab's processes
- Evaluate the documented systems against accreditation requirements.
- Allows time for lab to correct potential NCs

Importance of the document review (continued)

- Identifies the in-house calibration needs
- Provides a foundation for record review
- Affords for the opportunity for the on-site to be completed in timely manner
- Identify clearances, safety, hazards, etc.
- If potential NCs are serious enough to consider not proceeding with the on-site assessment, contact your NVLAP PM immediately

Typical On-Site Assessment Agenda

- Day 1
  - 8:30 Team arrival at lab
  - 8:30-9:30 Opening meeting
  - 9:30-10:00 Laboratory tour
  - 10:00 Assessment begins
    - Management requirements: John James
    - Technical
      - Thermodynamic – Susan Jones
      - Force/Torque – Frank Brown

Typical Agenda - continued

- 11:45-12:00 Assessor progress meeting (if necessary)
- 12:00-1:00 Lunch
- 1:00-4:30 Continue assessment
- 4:30-5:00 Day 1 - briefing
- 5:00 End Day 1

Typical Agenda – continued

- Day 2
  - 8:30 Team arrival at lab
  - 8:30-12:00 Continue assessment process
    - Management requirements: John James
    - Technical
      - Thermodynamic – Susan Jones
      - Force/Torque – Frank Brown
  - 12:00-1:00 Lunch

Typical Agenda - continued

- Day 2
  - 1:00-2:00 Finalize/follow-up
    - Technical
      - Thermodynamic – Susan Jones
      - Force/Torque – Frank Brown
  - 2:00-4:00 Report completion
  - 4:00-5:00 Closing meeting
  - 5:00 Assessment complete

Agenda – Determining Sample of Test/Cals

- Look at previous assessment report
  - Specifically which methods were witnessed
    - **TMRS** (if used in LAP)
      - *OT – Observed Test (includes the three options listed below)*
      - *W/TT – Walked/Talked Through (includes listening and examining apparatus)*
      - *LDP – Listened to Description of Procedures*
      - *EA – Examined Apparatus.*
  - Observe (OT) different methods from previous assessment(s), if appropriate.

Conducting an Opening Meeting

- Introduction of personnel
- Audit purpose (initial/renewal assessment)
- Review/verify agenda
- Identify assessment requirements
  - HB 150
  - HB 150-xx (program-specific)
  - Verify the requested scope of accreditation

Opening Meeting – (continued)

- Explain the assessment process
  - Confidentiality between parties
  - Methods of collecting information
    - Interviews
    - Observation
    - Documentation/record review
    - Witness of testing/calibration activities
  - Representative sampling process
    - Not a sampling of the actual requirements
  - Process for when nonconformities are identified
  - Identify reporting documents

Opening Meeting – (continued)

- Logistics
  - Assessor base
  - Quality manager -> lead assessor (typical)
  - Tech. manager -> tech assessor(s) (typical)
  - Lunch arrangements
- Verify restrictions
  - Clearances, escorts, clothing, hazards, etc.

Facility Tour

- Identify “state of quality”
- Observe the environment
- Accommodations
- Observe the overall atmosphere
- Allows lab to showcase

Typical Assessment Activities (ISO 19011:2011, Fig. 2)

Before Arrival

6.2 Initiating the audit

6.2.1 General

6.2.2 Establishing initial contact with auditee

6.2.3 Determining the feasibility of the audit

6.3 Preparing audit activities

6.3.1 Performing document review in preparation for audit

6.3.2 Preparing audit plan

6.3.3 Assigning work to the audit team

6.3.4 Preparing work documents

On-Site

6.4 Conducting the audit activities

6.4.1 General

6.4.2 Conducting the opening meeting

6.4.3 Performing document review while conducting the audit

6.4.5 Communicating during the audit

6.4.5 Assigning roles and responsibilities of guides and observers

6.4.6 Collecting and verifying information

6.4.7 Generating audit findings

6.4.8 Preparing audit conclusions

6.4.9 Conducting closing meeting

6.5 Preparing and distributing audit report

6.5.1 Preparing the audit report

6.5.2 Distributing the audit report

Depart

6.6 Completing the audit

6.7 Conducting audit follow-up

(If specified in the audit plan)

Collecting and Verifying Information
(ISO 19011, Figure 3)

Source of information

Collection by sampling
(record review, observation, interview)

Assessment evidence

Evaluating against criteria

Findings

Reviewing

Assessment conclusions

Record Review

- Sampling
  - Customer contracts
  - Purchasing documents of services and supplies
  - Customer feedback
  - Complaints
  - Corrective action & preventive action
  - Internal audits & management review
  - Personnel qualification/training (5.2)
  - Test/calibration reports and certificates
  - Quality control data/PT results

Record Sampling

- How do you select a sample of the records?
  - There's no defined rule
  - No statistical requirement of how many
- The sample size should be relevant
- The sample size should be representative
- Generally the sample size is small
- Look at the last report

Assessment Tools

- Observations - a sampling
  - Test methods
  - Calibrations
  - Walk through a process
    - Follow a sample/artifact from receiving into the lab
    - Follow a sample/artifact during a test
      - Observe representative tests
    - Follow a sample/artifact through certificate/report (vertical)
    - Follow the feedback process

Assessment Tools

- Interviews
  - Supervisors/management
  - Technical staff
    - (Bench metrologist, technologist, technician)
  - Supporting staff
    - Administrative
    - Purchasing
    - Shipping/receiving

Horizontal Assessment

- An evaluation of a process, activity, or requirement across two or more units

(working your way through the assessment checklists)

Horizontal Assessment - example

NVLAP LAB CODE: ____

4.1.5 The laboratory shall:

____ a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

____ b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

____ c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

____ d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

____ e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

____ f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

Vertical Assessment

- An in-depth review of a particular function. This type of assessment technique would monitor the use of all relevant procedures as they are used to support the function.
- Review of records that are created in the process.

Vertical Assessment - "Beginning to End"

- Example 1 – Witness test and then review test report
  - 5.10 (Reporting)
  - 4.4 (Contract Review)
  - 5.2 (Personnel)
  - 5.5 (Equipment)
  - 5.7 (Sampling)
  - Annex A (NVLAP symbol use)
  - Annex B (Traceability)

Vertical Assessment - "Assess the Process"

- Example 2 – Review a contract (4.4)
  - 4.7 (Service to Customer)
  - 4.13 (Control of Records)
  - 5.4 (Method Selection)
  - 5.5 (Equipment)
  - 5.8 (Test/Calibration Items)
  - 5.9 (Quality Assurance/PT)
  - 5.10 (Reporting)

Horizontal Assessing

- Benefits: Ability to evaluate that a certain function is being effectively implemented across a "grouping"
- Challenges: May not provide sufficient insight on how the different parts of the system interoperate

Vertical Assessing

- Benefits: Provides insight on how the different parts of the system interoperate

- Challenges: May lead into areas outside of the scope of the assessment; the proverbial "rabbit hole"

Horizontal vs. Vertical (which one should I use on-site?)

Both

A “hybrid” approach will in almost all cases provide you the overall "best value” assessment (in-depth evaluation vs. time allotted).

Time Management

- Putting the necessary time into the pre-assessment document review
- Knowing when to move on
- Refrain from jumping from location to location

Completing the Assessment Report

- Use the checklist during the assessment. The checklists provide a road map to keep the assessment on track.
- You may work on it at the hotel.
- Finalize it during the last few hours of the assessment.

Conducting a Closing Meeting

- *A meeting shall take place between the assessment team and the CAB prior to leaving the site. At this meeting, the assessment team shall provide a written and/or oral report on its findings obtained from the analysis (see 7.8.1). An opportunity shall be provided for the CAB to ask questions about the findings, including nonconformities, if any, and their basis.*

  (ISO/IEC 17011, 7.8.3a)

Conducting a Closing Meeting

- Begin meeting with appreciation of the lab's conduct and hospitality throughout the assessment
- Identify the method of reporting and explain how the assessment findings will be presented
- Explain that the assessor's role is *the messenger.* The laboratory has the opportunity to challenge findings directly to NVLAP.

Conducting a Closing Meeting

- Deliver the assessment report (typically through review of the cited nonconformities & comments along with the narrative report)

  ("findings" can be either positive or negative)

- Allow lab opportunity to ask questions about the report
- Explain the process of how the lab is to handle the comments and nonconformities (i.e., 30 days, recommendation of follow-up assessment)

Conducting a Closing Meeting

- Deliver positive feedback from throughout the assessment
- Finish up by again thanking the lab staff for their cooperation and flexibility throughout the assessment

Case Study #1 - Question

- During the on-site assessment, you identify that the lab has not validated their new software testing tool
- The lab responds by saying they identified this issue also during their internal audit and have opened a corrective action
- **Do you still cite this as a NVLAP nonconformity?**

Case Study #1 - Answer

- Answer:
  - Perhaps
  - Does the finding cast doubt on the effectiveness of the testing/calibration activity?

Case Study # 2 - Question

- On Day 1 of the assessment, you identify an NC to the lab that their equipment calibration certificates are not being verified upon equipment return (HB 150, 4.6.3)
- The next morning, the lab comes to you with a record of "checked compliance" for 1 of their 3 oscilloscopes and asks you to close the NC on-site.
- **Do you comply?**

Case Study #2 - Answer

- Answer:
  - No, you do not.
  - The reason is that the NC has been identified and is now part of the assessment report. A laboratory shall address NCs by following their corrective action procedure, which is to begin with identifying the root cause (HB 150, 4.11).
- Your response: Please provide me with your corrective action information.

[*END*]