NVLAP Assessor Training

Nonconformities

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

NVLAP®

Definitions

Nonconformity – nonfulfillment of a specified requirement

Comment – an observation that cannot be justified as a nonconformity; an area for improvement; a preventive observation; an observation for the benefit of lab management; a note for future assessors

Implications

Nonconformities – All nonconformities must be adequately resolved for continued accreditation and must be addressed through the lab's corrective action process.

Comments – Comments have no standing in the accreditation process. No action is required of the lab.

Specified Requirements

Specified requirements are defined in:

- NIST Handbook 150;
- Program-specific handbooks;
- Regulatory agency requirements;
- Test methods identified on the scope of accreditation;
- The laboratory's management system.

Valid Nonconformities

If you cannot write a nonconformity statement in the words of a specified requirement, dig deeper.

If you still cannot write a nonconformity statement in the words of a specified requirement, you do not have a nonconformity!

If in doubt, get advice from NVLAP.

(ISO/IEC 17011 7.8.2 - Where the assessment team cannot reach a conclusion about a finding, the team should refer back to the accreditation body for clarification.)

Invalid nonconformities waste everyone's time!

Disagreements

If the lab disagrees with the validity of a nonconformity, listen. If you still believe the nonconformity is valid, advise the lab that it may appeal the validity of the nonconformity to the NVLAP program manager and move on.

Reasonable people sometimes disagree.

Nonconformity Statements

Nonconformity statements must be clearly written. They will be read by you, the lab, the program manager, future assessors, and possibly an evaluator, a technical expert, an internal auditor, and APLAC/IAAC evaluators.

Nonconformity Statements

Nonconformities statements should include:

- A numbering system (helpful);
- A citation of the document and section cited against;
- A clear and precise description of what the lab is not doing that is required or what it is doing that is forbidden;
- Specific reference to evidence observed to support the nonconformity;
- Identification of the assessor citing the nonconformity if multiple assessors are involved.

It is not necessary to copy the text of the specified requirement unless it has multiple components and you want to be clear.

Example 1

GOOD

NC#3 - HB 150 5.8.1 – TWR – The laboratory did not provide a procedure on protection and storage of customer equipment.

BAD

HB 150 5.8.1 – TWR – The lab does not address all of the requirements.

Consulting

Do not be prescriptive when writing nonconformity statements. You cannot tell a lab how to resolve the nonconformity.

(ISO/IEC 17011 7.8.1 The assessment team shall analyse all relevant information and evidence gathered during the document and record review and the on-site assessment. This analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the CAB with the requirements for accreditation. The team's observations on areas for possible improvement may also be presented to the CAB. **However, consultancy shall not be provided.**)

Example 2

GOOD

NC#2 - HB 150 5.5.10 – The lab is performing weekly intermediate checks on micrometers. The lab could not provide a procedure for these checks. (TWR)

BAD

HB 150 5.5.10 – The lab must include this in its quality manual. (TWR)

Multiple Violations

Cite multiple violations of the same requirement in a single nonconformity statement. Identify each violation sequentially if necessary. This commonly happens in traceability nonconformities.

Example:

NC#4 HB 150 5.6.2.1.1, B.3.3&4 – TWR – The following assets did not have accredited calibrations or a record of the suitability of the calibration provider:

a) signal generator 1T406;

b) DVM 1T304;

c) bilog antenna s/n 534022.

Closing Nonconformities On Site

- Closing nonconformities during the course of the assessment is permitted and offers some advantages.
- The laboratory must implement its corrective action process. We must not encourage shortcuts.
- Record the nonconformity like any other and indicate it has been closed during the assessment.
- Submit supporting evidence of closure with the assessment report. This is subject to review.