# NVLAP Assessor Training

## Nonconformities

# 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.

# Comment/Nonconformities

Do not write comments that indicate a nonconformity – write the nonconformity.

Comment – HB 150 sec. 4.11.1 – The lab did not follow its corrective action process for nonconformities cited at the last NVLAP assessment. All corrective actions were reviewed and approved by NVLAP.

# Specified Requirements

Specified requirements are defined in:

- NIST Handbook 150
- Program-specific handbooks
- Regulatory agency requirements
- Test methods identified on the scope of accreditation
- 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.

Nonconformities are not based on speculation about what may happen in the future.

# 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

# Consulting

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

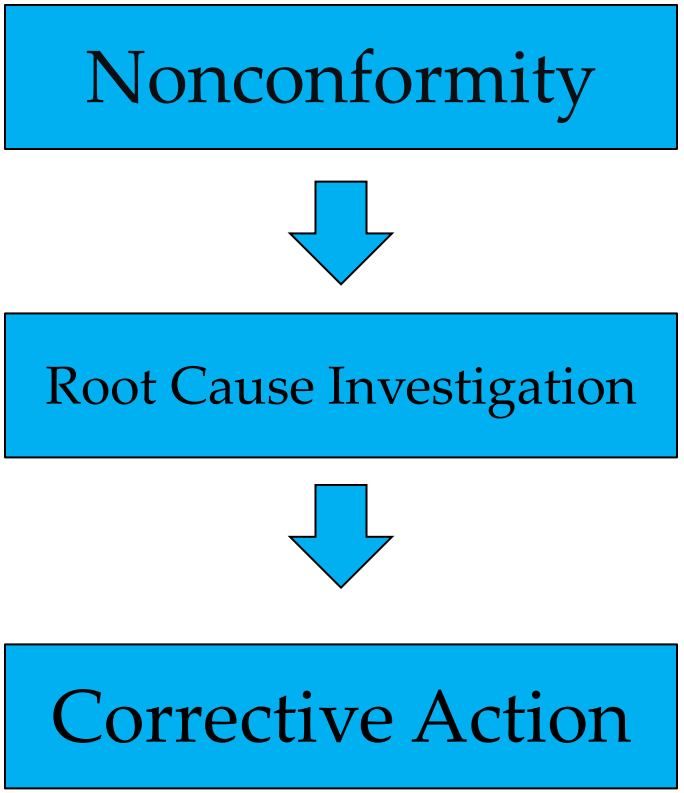
(ISO/IEC 17011, 7.8.1 The assessment team shall analyse all relevant information and evidence gathered during the document and record review and the on-site assessment. This analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the CAB with the requirements 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

NC#2 - HB 150, 4.3.2.3 – Internal test procedures issued by the lab do not include the issuing authority. The lab needs to add this to its document control procedure.

# Root Cause

Corrective action is based upon root cause investigation. It is the responsibility of the lab to perform this investigation and assign corrective action, not the assessor.



# Existing Corrective Action

If you identify a nonconformity and the lab has already addressed it through corrective action, it is not necessary to include it in the report.

# 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.

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

# Examples

# ASTM C177 & C518 – Test reports do not include a clear indication of the end of the test report.

- ASTM C177 and C518 do not require this. Cite against HB 150 sec. 5.10.2c.
- When possible, cite against specific clauses of standards.

HB 150 sec. 4.5.1 – The lab needs to address in quality manual in the event it needs to subcontract.

- Do not use mandatory language.
- Section 4.5 does not require a policy or procedure.
- Based on speculation.

HB 150 sec. 4.7.2 – The lab is not seeking feedback from customers. (The lab implemented its corrective action process and developed a customer survey. **This NC is considered closed.**)

4.7.2 requires the lab seek feedback. Developing a survey is not seeking feedback. NC should not be closed.

Comment – HB 150 sec. 4.4.1 – This is a captured calibration lab and only performs calibration for production. It does not have a procedure for review of contracts. The lab plans to conduct commercial calibrations and needs a procedure.

- 4.4.1 has no caveats. This is a nonconformity.
- Comments and mandatory language do not go together.
- This is based on future events.

# Questions?