

# NVLAP Assessor Training

## Internal Audits and Management Reviews

## Pre-assessment...

- A laboratory presents you with a completed NVLAP Handbook 150 Checklist as evidence of their internal audit. The checklist includes detailed comments and identified several nonconformities.
- Is that an acceptable internal audit?



## Pre-assessment...

- A laboratory presents you with a beautiful report for a recent internal audit with no nonconformities identified. You cite 25 nonconformities during the assessment.
- Is there a nonconformity related to their internal audit process?



## Pre-assessment...

- A laboratory's management review procedure lists all the items Handbook 150 requires be covered in a management review. The records do not have each item listed, but include a statement that all items were covered.
- Is there a nonconformity?



# Objectives

- Break down clauses 4.14 (internal audits) and 4.15 (management reviews) into assessable points
- Promote consistency of interpretation across programs
- Describe best practices for how to record outcome of assessment of these clauses

## 4.14.1 Internal audits

**4.14.1** The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this handbook. The internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

**NOTE** The cycle for internal auditing should normally be completed in one year.

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shall **periodically**, and in accordance with a **predetermined schedule and procedure**...

- Procedure to describe how they do audits
  - ✓ Verify during document review
- Predetermined schedule
  - Doesn't have to be annual
  - ✓ Record in your report dates for audit(s) you reviewed

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...verify that its operations continue to comply with the requirements of the **management system and this handbook...**

- They have to verify they **continue** to comply with Handbook 150, so could use a NVLAP checklist, but...
- Handbook 150 checklist is not sufficient to cover the whole management system
- External audits (e.g. NVLAP on-sites) cannot substitute for internal audits, but can be considered in scheduling

## 4.14.1 Internal audits

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The internal audit program shall address all elements of the management system, including the testing and/or calibration activities.

- Whatever they describe in management system, they audit
- Auditing testing/calibration activities includes verifying that they **follow** methods or procedures, not just that they have the right documents
- Some LAPs have specific requirements for evaluating performance of tests

## 4.14.1 Internal audits

It is the responsibility of the quality manager to plan and organize audits as required by the schedule and **requested by management.**

- Management should be requesting audits when corrective action casts doubts on the laboratory's compliance with its management system or accreditation requirements. (4.11.5)

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## 4.14.1 Internal audits

Such audits shall be carried out by **trained and qualified personnel** who are, wherever resources permit, **independent** of the activity to be audited.

- Lab establishes training and qualification requirements (5.2.2)
- Auditors of testing/calibration activities should be technically knowledgeable
- Independence not always possible

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NOTE The cycle for internal auditing should normally be completed in one year.

## 4.14.2 Internal audit corrective action

**4.14.2** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.

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...shall take timely corrective action...

- “Never” is not timely
- Implement procedures under 4.11, including root cause analysis

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... shall notify customers in writing if investigations show that the laboratory results **may** have been affected.

- Written notification to customers may be email
  - ✓ Verify records of customer notifications
- Only has to be **possibility** results were affected, not definite proof

## 4.14.3 Internal audit records

4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

shall

- No requirement for checklists
- Could be summary reports
- Corrective action records must meet requirements of 4.13.1
- ✓ List the records you reviewed

## 4.14.4 Internal audit follow-up

4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

shall

- Follow-up “audit activities”
- Not immediately upon completion of corrective action
- Records must meet requirements of 4.13.1
- ✓ List the records you reviewed

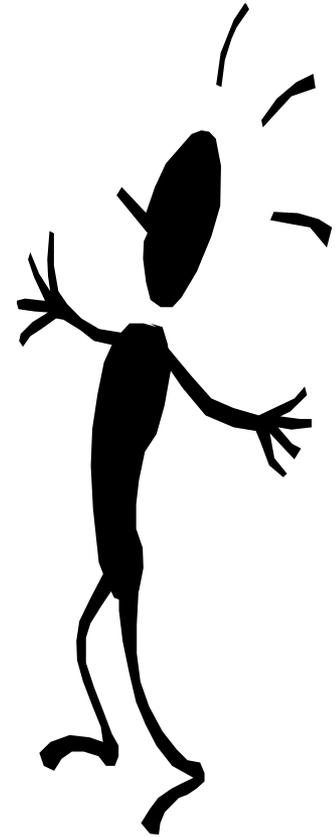
## Post-assessment...

- A laboratory presents you with a completed NVLAP Handbook 150 Checklist as evidence of their internal audit. The checklist includes detailed comments and identified several nonconformities.
- Is that an acceptable internal audit?



NO

- A NVLAP Handbook 150 Checklist may be a useful tool, but doesn't cover the entire management system and testing/calibration activities.
- Can (should) be used to verify continued compliance with Handbook 150



## Post-assessment...

- A laboratory presents you with a beautiful report for a recent internal audit with no findings identified. You cite 25 nonconformities during the assessment.
- Is there a nonconformity related to their internal audit process?



## It depends...

- At least a comment, especially for a renewal assessment
- Consider where the problem is:
  - ✓ Procedure?
  - ✓ Schedule?
  - ✓ Training of auditors?
- Avoid trying to find a root cause



## 4.15.1 Management reviews

**4.15.1** In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- the suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- the results of interlaboratory comparisons or proficiency tests;
- changes in the volume and type of the work;
- customer feedback;
- complaints;
- recommendations for improvement;
- other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

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NOTE 3 A management review includes consideration of management meetings.

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- reports from managerial and supervisory personnel;
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**...top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements**

- Covers all activities
- ✓ Record what management review records you assessed

## 4.15.1 Management reviews

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The review shall take account of...

- Good practice for the lab to have all the listed items in an agenda, or records that show all items were addressed

– changes in the volume and type of the work;

**NOTE 3** A management review includes consideration of related subjects at regular management meetings.

- Some of the items may be covered and documented through other meetings.

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## 4.15.2 Management records

**4.15.2** Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

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**Findings** from management reviews and the **actions** that arise from them shall be recorded.

- Only required to record outcomes, not inputs
- Actions must meet requirements of 4.11
- Records meet requirements of 4.13.1
- ✓ Record in assessor report any corrective or preventive action records you assessed that were related to management review

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- Same management that conducts review ensures actions are carried out
- Appropriateness is up to lab, but agreed timescale can be assessed
- ✓ Verify that timescales are being met

## Don't forget 4.2.2 (like I did...)

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review.

- One more item to add to laundry list in 4.15.1
- ✓ Verify that lab “takes account of” the quality policy in management review

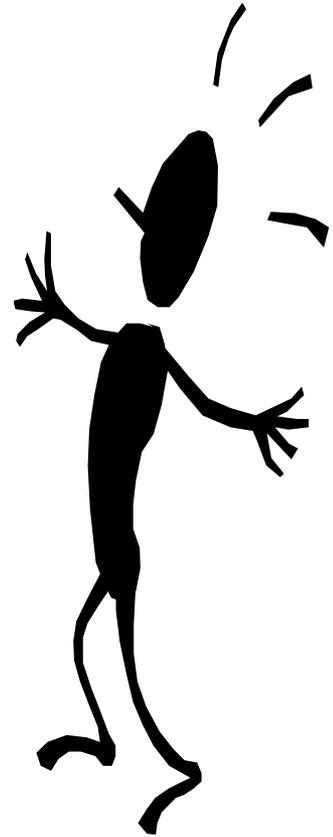
## Post-assessment...

- A laboratory's management review procedure lists all the items Handbook 150 requires be covered in a management review. The records do not have each item listed, but include a statement that all items were covered.
- Is there a nonconformity?



# NO

- 4.15.1 requires the lab to “take account of” the listed items.
- 4.15.2 only requires records of findings and actions. The statement that all items were covered constitutes a finding.



## Conclusions...

- We rely on the laboratory's management system, including internal audits and management reviews, to support compliance between assessments.
- The language of the standard allows some flexibility in how the laboratory realizes these important processes.
- When assessment records clearly indicate what audit and review activities were assessed, it facilitates NVLAP's review of records submitted by laboratories between on-sites.