Internal audits

- Periodic, predetermined schedule and procedure to verify that lab’s operations comply with its management system and NVLAP Handbook 150

- Audit cycle is normally within one year
  - May audit different elements or sections of the management system on a monthly, quarterly, etc., schedule throughout the year
What assessor should look for

- **NIST Handbook 150 Checklist, 4.14.1**
  
  - **Note to assessor:** Attach a copy of the full internal audit schedule.
What assessor should look for

• Internal audit is done by the organization itself

• Audits by other parties (NVLAP, regulatory bodies, customers, etc.) are not a substitute for the lab’s internal audit
What assessor should look for

- Audits shall be carried out by trained and qualified personnel
- Address all elements of the management system and testing/calibration activities
- If audit not complete, why not?
What assessor should look for

- Assessors must review the laboratory’s internal audit report
  - Look for corrective actions
  - Verify implementation
  - Evidence that customers were notified, if necessary
What assessor should look for

- Nonconformities found in internal audits provide valuable information for improvement of the laboratory’s management system and should be used as input to management reviews.
Management reviews

• A regular systematic evaluation by top management of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy and quality objectives.
What assessor should look for

- **Who is top management?**
  - Members with responsibility for design and implementation of management system
  - Members with responsibility for technical operations
  - Have authority to ensure that all actions from the review are carried out and monitor effectiveness
What assessors should look for

• Date of the most recent management review

• Management review schedule
  • Typically the period for conducting the management review is once every 12 months

• Review should include all elements of NIST Handbook 150, 4.15.1
What assessors should look for

- Suitability of policies and procedures
- Reports from managerial and supervisory personnel
- Outcome of recent internal audits
- Corrective and preventive actions
What assessor should look for

• Assessments by external bodies (NVLAP, etc.)

• Results of proficiency testing / interlaboratory comparisons

• Changes in the volume and type of work
What assessor should look for

- Customer feedback
- Complaints
- Recommendations for improvement
What should assessors look for

- Are management reviews conducted separately from internal audits?
- Agendas of reviews – are they documented and do they address the items in 4.15.1?
- Are reviews only a paper exercise? Are metrics used?
What should assessors look for

- Do the results of management review feed into the laboratory planning system and include the goals, objectives and action plans for the coming year?
- Is responsibility for recording findings and actions described in the lab’s procedure?
- Does the record show who was involved; what was discussed; what actions were planned or taken, by whom and when?
What should assessors look for

• Have any tools been developed to track actions (e.g., timelines, logs)?

• Are labs conducting management reviews and don’t realize it?

(Management review includes consideration of related subjects at regular management meetings.)
Additional resources

- These documents give guidance to laboratories on how to establish and implement a program for audits and reviews
  
  - APLAC TC002: Internal Audits for Laboratories (rev. 3 issued 05/06)
  
  - APLAC TC003: Management Review for Laboratories (rev. 3 issued 05/06)