Internal Auditing

ISO/IEC 17025 Section 4.14

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Some commonly asked questions

- When should I start auditing?
- What do I audit and how often?
  - The whole quality system? Every year?
  - All my methods? Every year?
- Vertical or horizontal audits?
  - What are these?
  - Which should I use?
- Who should audit?
  - Does the internal auditor always have to be independent of the area being audited?
- How formal should internal audits be? Should I have opening & closing meetings?
- What do my audit records have to look like?
  - Paper? Electronic? Checklists? Notes? Pictures?
  - How about an Ipad/tablet?

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When should I start conducting internal audits?

- As soon as possible
- First audits may not cover the entire ISO/IEC 17025 Standard.
- Compliance may be difficult to assess initially, but the questions that arise will improve your knowledge, understanding, and move you forward.

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Challenges for first internal audits

Criteria in place

Time allowed to become compliant with criteria

"Trained" internal auditors

Tools (checklists, forms, etc)

Confidence

4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.

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What do I audit and how often?

- ISO/IEC 17025, 4.14.1 says "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 International Standard. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities."

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What do I audit and how often?

- What
- All elements of management system (all your quality SOPs)
- Testing activities (technical SOPs – not necessarily every one)
- Verify compliance with this International Standard (ISO/IEC 17025)

- How often
- Periodically (Note, not annually)
- Predetermined schedule
- It is up to you, *but*, widespread noncompliance can call your schedule and frequency into question.
- Check with your AB for their guidance

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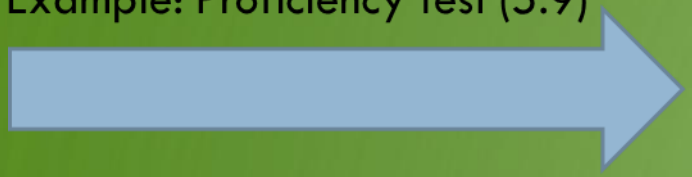
Tip: NC uses a 2 year schedule and representative methods.

Horizontal vs Vertical Audits

Horizontal

- Look at a particular requirement, activity, or process in detail across areas

Example: Document Control (4.3)
Example: Proficiency Test (5.9)



Feed Micro Organic

Vertical

- Trace a single sample from receipt through disposal

Sample Receipt (5.8)
Sample Preparation (5.7)
Personnel (5.2)
Environmental Conditions (5.3)
Method Selection, Verification, Validation, Measurement Uncertainty (5.4)
Equipment (5.5)
Measurement Traceability (5.6)
Technical Records (4.13)
Quality Control (5.9)
Reporting (5.10)

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Who should be an auditor?

- ISO/IEC 17025 4.14.1 states "audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited."

- Multiple viewpoints are beneficial.
- A larger internal auditor pool can only help:
  - Spread out the workload
  - Bring deeper understanding to all the lab sections
  - Facilitates sharing of ideas/improvements across lab sections

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What makes an internal auditor trained and qualified?

- Training is determined by the lab.
- This requirement expects training in how to conduct an audit.
- Online courses, books, seminars, certifications, OJT.
  - Based on ISO 19011Guidelines for Auditing Management Systems
- Have a record of authorization to perform internal audits

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Structure of Internal Audit

Audit Prep

- Read SOPs
- Prepare checklist, form, questions, etc.
- Look back at prior audits & findings if available

Opening Meeting

- Informal or formal
- Explain scope, method or process being audited
- Schedule specific time w/lab
- Foster team approach between auditor & lab

Conduct Audit

- Be transparent with auditees
- Discuss concerns as they arise
- Compile notes & findings into final report
- Share with area supervisor, discuss nonconformities

Mimicking the process of external assessments gives everyone practice and helps them know what to expect at the external assessment.

Closing Meeting

- May be more formal
- Include affected lab personnel
- Discuss positive findings
- Discuss suggestions for improvement or PA
- Explain nonconformities, including requirement not met

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What should my audit records include?

- ISO/IEC 4.14.3 states "The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded."

- This is the minimum.
- Practically speaking, more information is helpful.
- Looking back, you will likely want to know more detail about what processes, documents, or records you reviewed/observed.
- Be able to support completion of your schedule.

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Suggested audit records – compliance with ISO/IEC 17025

- Verify compliance with this International Standard (ISO/IEC 17025)
  - Create a checklist for ISO/IEC 17025
  - Check with your AB – they may have one already created that they will share.
  - Include objective evidence (documents/records/interviews) supporting compliance as well as non-compliance
  - Be sure your SOPs address all the items the Standard expects them to.

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Suggested audit records – compliance with your own QMS

- Make sure you have records to show that you verified compliance with your own Quality Management System SOPs (common deficiency)
  - Make a checklist as you develop your QMS SOPs
  - Or, use the Comments feature in MS Word
  - Cite examples of forms, reports, file locations

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9.2.1 Lab management determines goals with respect to additional education, training, and skills during the Management Review and Performance Management Process

1 Schedule

9.3.1 Safety training is conducted through the Division Safety Program and is scheduled by the Safety Officer for new and existing employees.

9.3.2 Quality management system training is conducted by the QA Section for existing employees when revisions are made or a need for additional training is identified by the Quality Systems Manager. New employees receive training on all quality system documents relevant to their duties, including completion of the signature list, and should be completed within 90 days of the hire date.

9.3.3 Technical training for test methods, work instructions, and other laboratory duties as assigned is scheduled by the supervisor. Performance and competency are evaluated at least semi-annually in state mandated Work Plan Performance Reviews. New employees must complete essential training relevant to assigned duties before the end of the probationary period. Training should be completed on a sufficient sampling of methods or tasks for the supervisor to be confident in the employee's competence to perform intended duties. Lab supervisors made a determination of competency prior to the end of the 2 year probationary period.

2 Training Process

Employees are trained on all quality management system documents, test methods, work instructions, and skills as relevant to the employee's assigned duties. The

Comment [tns1]: Is this scheduling guide suitable for FDPD laboratory?

Yes or No

Comment [tns2]: Is essential training for employees being completed before probationary period?

Yes or No

Comment [tns3]: Is the following training process being followed and completed as written here?

Suggested audit records – testing activities

- Create a checklist for each technical SOP, or a generic checklist
- Create an uncontrolled copy of a technical SOP for the auditor and allow them to make notes as they audit.
- Develop a shorthand for recording notes of observations so you can decipher the notes in the future.
- Clearly record which steps were observed.
- Include copies of logbook pages, worksheets, instrument printouts (or excerpts from printouts), final reports

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TEST METHOD AUDIT MATRIX

AUDIT ID CODE:	AUDITOR NAME:	AUDITOR *R & U* ENTRY DATE:	AUDIT
TEST TECHNOLOGY:	TEST METHOD NUMBER & NAME:		

ISO/IEC 17025:2005 *(ALACC Criteria March 2010)* Section: **5.4.6** Measurement U

5.3; 5.5 Accom. & Environment; Equipment	**5.4** Procedure/ Operating Instructions	**5.6.** Traceability Verification/ Calibration/ Ref. Standards/ Ref. Materials	**5.7; 5.8** Sampling; Handling/ Prep	**5.9** Quality Checks	**5.9** PT performan Accred. vend
O I P E	O I P E	O I P E	O I P E	O I P E	O I P
	Performed as written: ☐				*Type:* IN-HOUSE P *Instructions:* TM PT *Info in DB:* ☐

Paperless audit records

- Expect to supply internal audit records to outside parties (FDA, AB)
- Audit records quickly become a mixture of stapled, paper clipped, single-sided, & double sided records, typed and handwritten
- Challenging over the years to keep audit records orderly
- Tablets can be the auditor's best friend! (even if your WiFi isn't state of the art)

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Using an iPad for internal audits

- Create audit documents at your desk
- Upload to the cloud via email or Dropbox
- Load onto iPad via email or Dropbox
- Open in iAnnotate
- Conduct audit
  - Use stylus to write notes
  - Use typewriter feature
  - Create blank pages for additional notes
  - Take photos and embed
- Send to your network via email or Dropbox

Enables you to keep Standards and other references at your fingertips wherever you go in the lab. (ISO/IEC 17025, SOPs, AOAC, PAM, etc)

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Tips and Tricks

- Photos - help the auditor be sure of their observation, help the auditee be certain what to correct
- Set a deadline for publishing the internal audit schedule – earlier is better
- Use your knowledge of your lab when determining the schedule – you know where areas of concern are
- Use prior years' findings to support the schedule for the coming year
- Establish a link between audits and nonconformities/corrective actions to enable you to quickly cross-reference
  - Beneficial with external assessments as well as ensuring you don't have repeat problems

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Final Thoughts

Audit findings are presented in an Internal Audit Report. Deficiencies must be written in terms of the standard or requirements of the Quality Management System, otherwise a finding is a comment or recommendation only.

- Audits are Management's eyes on the lab.
- Audits are a tremendous learning opportunity for everyone.
- Audits are an opportunity to praise.
- Audits are fun!
- External audits – relax! There are no prizes for 0 findings

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