Internal Audits - Who Does Them and How?

Marcia Valbracht, State Hygienic Laboratory at the University of Iowa

Valerie A. Knox, CMQ/OE, CQA, Quality System Manager, Food and Drug Administration (FDA), Jefferson, AR
Terms, Acronyms & Definitions

• **Audit (assessment):** The on-site verification activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements. An audit can apply to an entire organization or might be specific to a function, process or production step.

• **Correction:** The immediate fix to the problem.

• **Corrective Action (CA):** The fix that will eliminate the root cause and prevent its reoccurrence.

• **Documents:** “say” what you are going to do.

• **Nonconforming record (NCR):** A permanent record—made in writing—for accounting and preserving the knowledge of a nonconforming condition for the purposes of documenting facts or events.

Photo credit: State Hygienic Lab
Terms, Acronyms & Definitions

• **Nonconformity**: The nonfulfillment of a specified requirement or a failure to meet a professional standard

• **Preventive Action**: Action taken to remove or improve a process to prevent potential future occurrences of a nonconformance

• **Quality Audit**: A systematic, independent examination and review to determine whether quality activities and related results comply with plans and whether these plans are implemented effectively and are suitable to achieve the objectives

• **Quality Management System**: The quality, administrative and technical systems that govern the operations of the laboratory

• **Records**: “Proof” of what you are doing

• **Root Cause**: A factor that caused a nonconformance and should be permanently eliminated through process improvement and/or corrective action

• **Root Cause Analysis**: Need to dig deeper to find out “WHY”
Learning Objectives

• The participant should be able to
  – Outline a process for training staff to perform an Internal Audit
  – Discuss how audits are used in laboratories
  – Describe the elements of checklists used in the auditing process

Process approach to Internal Auditing

Verify compliance

Write a report
Why do Internal Audits?

• Provide assurance to management that the management system is implemented as intended
• Training purposes-learn the requirements of accreditation bodies (standards)
• Find non-conformances before they effect the quality of data
• To improve our processes
• Get ourselves ready for external audits
2 Types of Internal Audits

Horizontal
Systemic Audit = all elements of the Quality System
Per ISO/IEC 17025:2005 “cycle should be 1 year”

Vertical
Process Audit – small area/piece of the QS
Usually special purpose or verification/follow up
# Vertical Audit

## Audit Details

<table>
<thead>
<tr>
<th>Sample/SOP ID:</th>
<th>Product:</th>
<th>Date Sample Received:</th>
<th>Date Sample Reported Out:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analysis/Method audited:</strong></td>
<td>Workgroup/Area:</td>
<td>Date Audit started:</td>
<td>Date Audit completed:</td>
</tr>
<tr>
<td><strong>Auditor:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Audit Areas

<table>
<thead>
<tr>
<th>Audit Area</th>
<th>Clause</th>
<th>Records/methods/procedures/processes/personnel questioned</th>
<th>Compliant?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Does the worksheet clearly describe the sample &amp; condition when received by the Analyst?</td>
<td>4.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is information on worksheet compatible with request?</td>
<td>4.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are dates of receipt, analysis, &amp; data reporting included in report?</td>
<td>5.10.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upon receipt are abnormalities or departures from normal or specified conditions, as described in the test, recorded?</td>
<td>5.8.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does analysis electronic data match that recorded on worksheet? (i.e. FACTS, LIMS)</td>
<td>4.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the electronic record complete &amp; does it accurately reflect what is documented on the worksheet?</td>
<td>4.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit Area</td>
<td>Clause</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>---------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are corrections properly annotated with single cross out, initials, and date?</td>
<td>4.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the identification retained throughout the life of the item in the laboratory?</td>
<td>5.8.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are subsamples clearly identified and tracked on worksheet?</td>
<td>5.8.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was sample stored under correct environmental conditions?</td>
<td>5.8.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was amended report clearly identified as a separate report with reference to the original?</td>
<td>5.10.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is Sample Custodian properly trained, competent, &amp; authorized?</td>
<td>8.8.4   AOAC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is Method used recorded on Worksheet &amp; in electronic record?</td>
<td>4.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the authorized method used?</td>
<td>5.4.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a procedure for the method used?</td>
<td>5.4.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the procedure used included on a Document Master List?</td>
<td>4.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the procedure validated?</td>
<td>5.4.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were spikes, controls, +/- or system suitability performed?</td>
<td>5.9.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was QC data monitored &amp; within acceptable parameters?</td>
<td>5.9.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was unsatisfactory QC recorded?</td>
<td>5.9.2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Audit Area</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is traceability of reference material/standards used available?</td>
<td>5.6.3</td>
</tr>
<tr>
<td>Was proficiency testing for the technology used performed within the last year?</td>
<td>5.9.1</td>
</tr>
<tr>
<td>Have the last 4 proficiency tests for this technology been rotated among different analysts?</td>
<td>5.9.1</td>
</tr>
<tr>
<td>Is the worksheet signed by the lead analyst and all others involved in the analysis?</td>
<td>4.13</td>
</tr>
<tr>
<td>Have all analysts completed training and been authorized to perform the portion they signed for?</td>
<td>5.2</td>
</tr>
<tr>
<td>Are records for calibration, verification, service, &amp; maintenance for equipment available and complete?</td>
<td>5.5</td>
</tr>
<tr>
<td>Were supplies, reagents, media purchased or internally prepared, evaluated for suitability, prior to use.</td>
<td>4.5</td>
</tr>
<tr>
<td>Can one item used in the analysis be traced back to stock and purchasing records?</td>
<td>4.6</td>
</tr>
<tr>
<td>Does the worksheet &amp; FACTS show final disposition of sample?</td>
<td>5.8</td>
</tr>
</tbody>
</table>
ISO/IEC 17025:2005

Section 4.14

• “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 & this Standard.” The program shall address all elements of the management system, including test/calibration activities.
Purpose of Standards

- Standard: A document in a specific discipline/technical area developed through expert consensus
- Sets the criteria for a quality management system
- Ensures customers get consistent, good quality products and services, which in turn brings business benefits

Photo credit: State Hygienic Lab
Audits should be based on “Standards Analysis”
To identify current problems and risks; improve performance and increase customer satisfaction
Section 4.14 continued

• “Such audits shall be carried out by trained & qualified personnel

• who are, wherever resources permit,

• independent of the activity to be audited.”
An Auditor Must...

- Be open minded and mature
- Be able to consider alternative ideas or points of view
- Possess sound judgment
- Have good analytical skills
- Be ethical-fair
- Be truthful, sincere, honest, and discreet
- Be observant
- Be decisive
- Be timely
- Be self reliant; tenacious
- Be objective
- Be able to communicate effectively
Lead Auditor Responsibilities (Usually the Quality Manager)

- Plans & schedules
- Forms the team
- Provides documents and reviews with team
- Assigns standards segments to team
- Assists with the audit
- Reviews the audit
- Discusses obstacles and challenges with leadership
- Helps with audit report
- Manages meetings
Auditor Responsibilities

• Reviews prior documents and audit reports
• Performs the audit
• Asks objective questions (e.g., “What is your process?”)
• Reviews documents
• Seeks lead auditor help when necessary
• Completes audit form & summary
• Reviews non-conformances with management
• Submits review documentation to lead auditor for review
• Attends meetings
• Discusses findings and answers questions
Overview of Conducting the Audit

• Schedule the opening and closing meeting
  – Review scope, objectives
• Follow staff as they perform testing
  – Ask questions about the SOP/procedure
  – Does the SOP have enough detail?
• Follow checklist per accreditation requirements
  • AIHA, ISO, EPA, CLIA, TNI, OSHA, UI

• Check the records
  – Training files
  – Logbooks
• Write audit report

Photo credit: www.elevationtohuman.com
Plan the Audit

- Develop audit strategy
  - Research prior audits (internal/external)
  - Were corrective actions taken?
  - Are they still being followed and are they effective?
- Review procedures and documents
Understand Management & Staff

• Research the department and area
  – How many employees?
  – How many tests?
  – Is there a problem area?

• Who is: management, supervisors, lead staff?

• Who are the employees who may be interviewed?
Ensure background training matches
Scope of Audit assigned

Administrative person
- Purchasing/contract records
- Records (Format/availability/completeness)

Method validation records
- Analyst
- Equipment

Sample Handling
- Laboratory aid/technician
What makes an “audit trail”?

- Sample receipt, handling, and storage
- Sample preparation and analysis
- Equipment qualification & maintenance
- Equipment performance (function/verification)
- Calibration(s)
- Traceability (reference standards/materials and to analysts/technicians at each step of process)
- Analyst Training
- Proficiency Test Results
Remember-Assess the system, not who did it. Ask, “What system weakness allowed this non-conformance to occur?”

Steps of Audit/Assessment:

- Converse with staff
- Ask open ended questions
- Observe activities
- Review records & reports
- Review documents (procedures)
- Make copies of non-conformances
- Are they in the Document Control system?
- Have they been authorized and reviewed in a timely manner?
- Copy and maintain documented evidence
- Are there hand amendments?
Review a Sampling

• Not necessary to review every record!

Sample ID

Sample Receipt Area

Chain of Custody

Storage/disposition

QC
Not familiar with a process?

“Open-ended” questions establish facts (who, what, when, where, why, how, or please show me)

“Closed” questions more direct; used to clarify information (i.e., Did I understand that calibration is required only when QC is unacceptable?)
During the Interview

• Keep
  – The conversation 2-way
  – Questions open-ended
  – Notes

• How to phrase questions
  – How, what, where, why, when…
  – What is your process…
  – Where can we find…
  – Could we have a look at…
  – Can we review…
  – Show me…
  – What happens when…
  – How have you met…
  – So, can you tell me of your…
  – What is your role in…
  – Walk me through…
  – You seem busy. How do you deal with…
  – Can you tell me more of how that occurs…

Photo credit: fanpop.com
During the Interview

• Review
  – Training files
  – Procedures
  – Records (temperature charts, logbooks, etc.)

• Look for Conformances
  – But track any found non-conformance

• The phrases “essential requirement” and “shall” are mandatory

• Recommendations and NOTES are “good practice/best practice”
How to Determine a Non-conformance

1. Procedures/protocol does not address requirement
2. Procedures not followed
3. Repeat non-conformance
Audit report

1. Begin with what was positive in the audit
2. Provide checklist with findings (include dates of audit)
3. Never specify names of individuals
4. Provide summary of findings (mention documents, equipment, etc.)
5. Submit overall conclusions and recommendations
Examples of Terminology to use

- There is no evidence...
- There is insufficient evidence...
- The procedure for ____ is not fully implemented
- Not all...
- Current practice does not reflect...
- Current documentation...

There is no evidence...

There is insufficient evidence...

The procedure for ____ is not fully implemented

Not all...

Current practice does not reflect...

Current documentation...
Terminology to Avoid

- Do not use past tense
  - See previous slide

- Avoid providing solutions
  - This prevents opportunity to perform RCA

- Never specify names
  - Specify system or process non-conformance

Photo credit: Microsoft Office images
Example: Training Records-Competence

ISO 17025, 5.2.1:

- “Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.” (includes support staff)

Non-ISO, but other accreditating bodies add (or policy may state)

- “Successful training (in-house courses are acceptable) in specific methodologies used in the laboratory shall be documented.”

Non-ISO, but other accreditating bodies add (or policy may state)

- Analysts shall have demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. Their performance must be documented.

ISO 17025, 5.2.5:

- “The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel.”
Scenario—during the audit

**Auditor:** How do you provide and document education for employees?  
**Manager:** Our staff are in-serviced when assigned to a new area. The employee is deemed competent and authorized to work before they work alone.  
**Auditor:** Can I see documentation?  
**Manager:** Yes.  
**Auditor:** Reviews records, policies and procedures to determine compliance.  
**Auditor:** Reviews employee training records revealing inconsistent education.  
**Policy/procedures stated:** Competency assessment is required before employee can work independently.
Scenario Steps after audit

- Auditor records the requirement #
  - ISO 17025: 2005 #5.2.5

- Is this a deficiency (shall) or a suggestion for improvement (should)?
  - Shall

- State the requirement
  - The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel.

- Comments (phrase your citation—how was this a non-conformance?)
  - Deficiency
  - Comment: There is no documentation that the employee was deemed competent and authorized to perform the task prior to performing task.
Internal Audit Process

Start Here

Department/section identified for annual audit

Internal audit performed

Report given to department/section

Auditor reviews corrective actions and responds

Department responds to audit with corrective actions

Department/section responds if necessary

Final report reviewed by management

Follow-up
I would like to acknowledge and thank Valerie Knox, FDA, for her contributions to this presentation. Her program can be seen in its entirety by registering at APHL’s website here:

**Internal Audits APHL 651-16 SS**

For more APHL training resources see:
[https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/ISOIEC-17025-Accreditation-Training-Resources.aspx](https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/ISOIEC-17025-Accreditation-Training-Resources.aspx)

Thank you.