# 2019 NALMA / LAC Conference
# Grapevine, Texas, Sep 9, 2019

# Laboratory Audits – What to Expect

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# AUDIT

An official inspection of an individual's or organization’s activities, typically by an independent body.







# ASSESSMENT

The evaluation or estimation of the nature, quality, or ability of someone or something.





# Laboratory Audits:

- Usually conducted as part of a recognized certification or accreditation system.

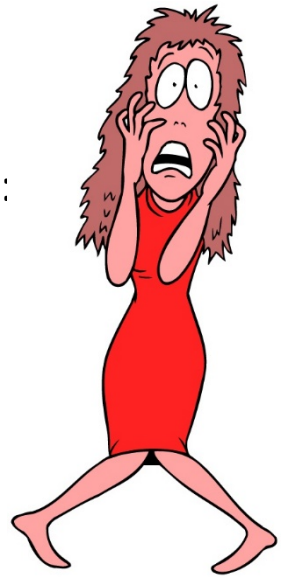
- Conducted against a documented standard:
  - ISO 17025
  - QCS / CDCB Auditing Guidelines

- Conducted every two years or whenever extraordinary circumstances indicate the need:
  - Addition of new test methods and/or equipment;
  - Relocation or renovation of facilities;
  - Significant staff turnover;
  - Response to customer complaints or concerns;
  - Failure to demonstrate acceptable analytical performance.





# Laboratory Audits:



- Are data collection activities designed to assist managers and staff in:
  - satisfying documented procedures;
  - maintaining certification;
  - identifying training needs;
  - identifying potential opportunities for improvement.

- Are not meant to:
  - quantify nonconformances, deficiencies, or QC failures;
  - review every single record, report, or test result for the entire audit cycle;
  - be stressful.

# Laboratory Auditor:

- The auditor is not your enemy. He is there to help you and your staff to maintain certification, to improve, and to better meet the rigorous demands of your clients.





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During the visit, the auditor will consider a number of different criteria:

1. The standard
   - CDCB Auditing Guidelines for Laboratories,
   - ISO 17025

2. Internal procedures
   - Standard operating procedures
   - “Say what you do…Do what you say.”

3. Good laboratory practices (GLP)
   - Good laboratory practices are accepted methods to carry out activities or operations. GLP is part of the quality assurance that ensures that organizations consistently produce and control results to a high quality standard.

4. Human resources, experience, training, technical competence

5. Any additional requirements mandated by certification agencies, clients, or partners.





There are three basic auditing activities:

1. Observe routine testing and quality control activities;

2. Interviews of key managerial and technical staff;

3. Review of documented procedures and lab records.

Every audit is different and the time spent on each of these activities will depend on specific circumstances.

Often two activities will be done simultaneously (i.e. observe and interview).





# OBSERVATION:

- Staff competence;
- Sample control and handling;
- Equipment condition, maintenance, calibration, operation;
- Testing procedures;
- Quality control;
- Response to nonconformances (bad samples, failed QC,etc.)
- Data collection, recording;
- Opportunities for improvement.





# INTERVIEWS:

- This is an information gathering exercise NOT a test.
- Don’t hunt for the “right” answer or the answer you think the auditor wants to hear.  Just answer the question.
- Auditors key on red-flag responses like:
  - The standard says…
  - We are supposed to…
  - You probably want us to…





# DOCUMENT REVIEW:

- Are all critical aspects of sample handling and analysis, staff training, equipment maintenance, and quality control documented in standard operating procedures?
- Are the procedures up-to-date, complete, reviewed and revised as necessary?
- Is there a master list of procedures showing when each was last reviewed and/or revised?





# RECORDS REVIEW:

- Are technical records authentic, complete, organized, retained and backed up to ensure they are protected from loss?
- Are nonconformances and QC failures followed up appropriately?
- Are all staff members recording results in the same manner (i.e. consider the sign +/- for IR zero checks)?
- Is there appropriate traceability (date, machine ID, reagent batch, operator, etc.)?





Authenticity of Records:

- On rare occasions, auditors identify records that do not appear to be authentic.

- Red-flags (paper records)
  - All worksheets completed in the same handwriting or using the same pen;
  - Worksheets have no corrections or additional notes;
  - None of the papers from the lab environment show signs of moisture, staining, etc.
  - Unrealistic data.

- Red-flags (electronic records)
  - Repeating of data (cut and paste);
  - Inability of staff to access the data templates;
  - Time-stamps on digital files do not match the referenced date;
  - Unrealistic data.

**It is very difficult to fool an experienced auditor.**





# INTERNAL AUDITS:

- Internal audits are conducted by staff members as part of a good quality management system.
- They are formal, with reports and associated recommendations reviewed and acted upon by upper management.
- They are based on standard operating procedures. “Are we following our procedures as documented?”
- They are scheduled such that every procedure is audited once in a specific time-frame.





# CONCLUSIONS:

- While the audits are a mandatory component of the certification or accreditation process, they also represent a key opportunity for improvement. They should not be cause for concern in any well-run organization.

- The auditor is a key partner, not a rival in the process and is interested in assisting your organization in maintaining its status.

- If there are major deficiencies, the auditor will identify these and, under most certification or accreditation systems, the organization will be given the opportunity to correct them.





# Questions?