


**ISO/IEC-17025:2005
LABORATORY ACCREDITATION:**

Process and points to consider


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44th Florida Pesticide Residue Workshop
July 24, 2007

Topics



- What is Accreditation?
- Preparing for assessment
- On-site assessment actions
- Types of deficiencies and root cause
- Following assessment

Facts about A2LA



American Association for Laboratory Accreditation:

- Established in 1978
- Largest *multi-discipline* laboratory accreditation system in the U.S.
 - Major focus: **Accredit testing and calibration laboratories for specific tests/calibrations**
 - **More than 1843 labs currently accredited**
 - **Over 160 currently seeking accreditation**
 - **Includes more than 100 laboratories outside the US**
- Non-profit, public service, non-governmental membership organization

Benefits of Accreditation



- **International recognition of technical competence**
 - Leads to comparable outcomes worldwide
 - Recognition validated via peer evaluation process
- **Legally defensible system**
 - Competent staff
 - Valid and appropriate methods
 - Suitable quality assurance to demonstrate control
 - Traceability of measurements
- **Marketing advantage.**
 - Re-enforcing customer's confidence
 - Goods tested in this country will be accepted in countries overseas




QMS Accreditation

LAB

Helps prevent slip ups!

Laboratory Accreditation



Defined as a procedure by which an authoritative body* gives formal recognition that a *Conformity Assessment Body* fulfills specified requirements and is **competent** to carry out specific tasks.

- Usually using **ISO/IEC 17025**

*(e.g. A2LA, NVLAP, NATA, UKAS, etc.)

Accreditation Ten Second Tutorial

Doing what you say you are doing

And being able to prove it!

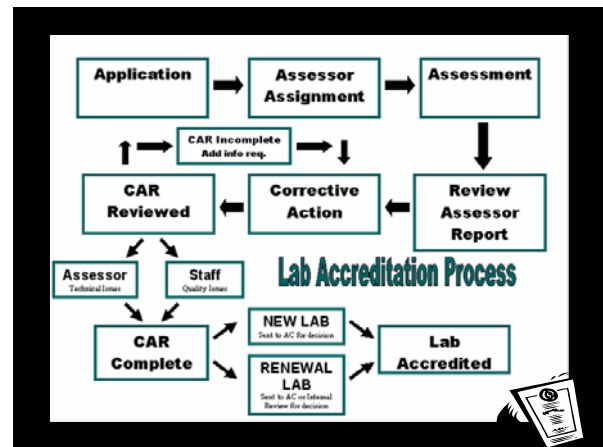
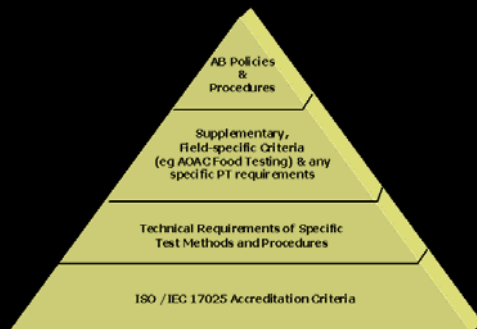


Three Critical Thoughts



- Does the laboratory “say” what they do?
 - Is there written documents (policies, procedures, arrangements) that meet the requirements of ISO 17025?
- Does the laboratory “do” what they say?
 - Are they in compliance with their own quality system, test methods and ISO 17025?
- And can they “prove” it with their records?
 - Ranging from having training records to standards preparation to work books to client reports to audit reports and everything in between?

Accreditation Requirements



What is Needed to Start?

- Application
- Quality Manual
- Completed ISO 17025 Assessor Checklist
- Scope: Identify desired tests/technologies
- Measurement traceability activities
- Initiate Proficiency Testing activities:
 - Commercial (AOAC, API, etc)
 - Well-organized ILCs (Private, AAFCO, SSCS, etc)



Preparing for Accreditation

- Study and understand requirements
- Involve the technical staff in ensuring the lab’s compliance
- Review all technical procedures and quality manual with technical staff
- Perform thorough internal audits

The On-Site Assessment



- Interviews with technical staff to verify knowledge of technical procedures and lab policies
- Witness testing activities being performed
- Inspection equipment and facilities
- Field visits (if applicable)
- Evidence that quality manual is a living document that meets accreditation criteria

What is Audited

- Quality System
 - management or administrative activities
 - organization, control of quality records,
 - evaluates “shall ensure” clause implementations
 - strict adherence to documented procedures
 - purchasing of consumable materials
 - management of calibration system
 - Internal audits, Management review,
 - CAR/PAR process



What is Audited

- Technical
 - scientific judgement
 - performance of test
 - sampling activities
 - preparation of reagents
 - strict adherence as well as technical correctness
 - gain information about training and supervision
 - determine status of equipment
 - review of PT Results



Deficiency (nonconformity)



- A departure from or an instance of noncompliance with a condition or criterion for accreditation
 - ISO/IEC 17025:2005
 - Method
 - Specific Program requirement
 - Policies & procedures

Causes of Deficiencies

includes:

- Lack of top management support
- Lack of system
- Lack of training of staff
- Lack of time
- Lack of resources
- Lack of motivation



Typical Deficiencies: Equipment



- Calibration and supporting documentation is lacking Not included in calibration schedule at all or not calibrated at appropriate intervals
- Equipment is substandard, out-of-tolerance, and/or as not been calibrated or verified at suitable intervals Not maintained properly - no maintenance procedures or schedule established
- Substitute equipment is used without acceptable evidence that it performs as specified for the standard

Typical Deficiencies: Accommodation*

- Temperature and humidity requirements are not being satisfied
- Incompatible activities are not separated
- Environmental conditions not monitored / recorded



*Std. does not address S&H issues

Typical Deficiencies: Personnel

- Objective evidence (Training records) is not available attesting to the competence of the personnel
- On the job practice has become careless and has departed from prescribed procedures



Typical Deficiencies: Quality System

- Lack of complaints procedure
- Lack of adequate document control
- Lack of purchasing procedures
- Not following through on corrective actions
- Inadequate internal audit / management review:
 - Lacking evidence of procedures
 - Not performed at required frequency
 - Does not cover all required elements
 - Findings not documented or addressed



Typical Deficiencies: Methods



- Out-of-date (superseded) methods in use
- Not following procedures as written; not identifying deviations on test reports
 - Doing more = OK
 - Doing less = Not OK
- Estimates of measurement uncertainty not calculated
- No validation of in-house test procedures or software

Investigating Causes of Deficiencies



One has to look below the surface...

Our Disaster Recovery Plan Goes Something Like This...



Root Cause Analysis (RCA)

A structured evaluation method that identifies the root causes for an undesired outcome and the actions adequate to prevent recurrence. Root cause analysis should continue until organizational factors have been identified, or until data are exhausted.

– RCA helps determine:

- What happened.
- How it happened.
- Why it happened.
- Allows learning from past problems, failures, and accidents.



Types of CAUSES

Cause (Causal Factor): Event or condition that results in an effect. Anything that shapes or influences the outcome.

Proximate Cause: The event(s) that occurred, including any condition(s) that existed immediately before, which directly resulted in its occurrence and, if eliminated or modified, would have prevented the undesired outcome. Also known as the direct cause(s). Can be both equipment and human based

Root Cause: One of multiple factors (events, conditions or organizational) that contributed to or created the proximate cause and subsequent undesired outcome and, if eliminated, or modified would have prevented the undesired outcome. Typically multiple root causes contribute to an undesired outcome.



Root Cause Analysis

Desired Outcome:

At a minimum corrective actions should be generated to eliminate proximate causes and eliminate or mitigate the negative effects of root causes.

When multiple causes exist, there is limited budget, or it is difficult to determine what should be corrected:

- Quantitative analysis can be used to determine the total contribution of each cause to the undesirable outcome
- Fishbone diagrams (or other methods) can be used to arrange causes in order of their importance
- Those causes which contribute most to the undesirable outcome should be eliminated or the negative effects should be mitigated to minimize risk.



Root Cause Analysis - Steps

1. Identify and clearly define the undesired outcome.
2. Gather data: Identify facts surrounding the undesired outcome
 - Create a timeline: Illustrate the sequence of events in chronological order horizontally across the page
 - Use a fault tree or other method/tool to identify all potential causes.



Root Cause Analysis - Steps (cont.)

1. Decompose system failures down to a basic events or conditions (Further describe what happened)
2. Identify specific failure modes (Immediate Causes)
3. Continue asking "WHY" to identify root causes.
4. Check your logic and your facts. Eliminate items that are not causes or contributing factors.
5. Generate solutions that address both proximate causes and root causes.



ISO 17025 4.10 Corrective Action

- Policy, procedures and authorities for nonconformances in :
 - work activities
 - departure from policies and procedures
- Cause analysis - root cause
- Eliminate the problem, prevent recurrence
 - degree appropriate to magnitude and risk

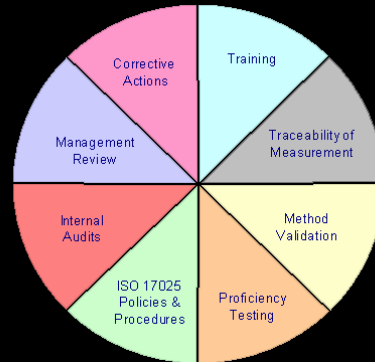


ISO 17025
4.9 Control of Non-Conforming Testing

- Policy and procedures for nonconformance in testing. Procedure shall include
 - responsibilities and authorities are defined and taken
 - evaluation of significance
 - remedial actions
 - recall of nonconforming work released to clients
 - responsibility for resumption of work
- Possibility of recurrence - Corrective Action 4.10



Functioning Quality System



In Summary

- Accreditation = International recognition of technical *competence*.
- Ten Second Tutorial: Do, Say, Prove.
- Root cause investigation is systematic and focuses on events, conditions or organizational factors for corrective action opportunities.
- Functional Quality system involves all elements of laboratory operations working in harmony.



Questions / Comments



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