ISO 17025 Accreditation/Quality Management Systems Panel Discussion

AAFCO 2014 Annual Meeting
Laboratory Methods & Service Committee
Sacramento, CA
July 26, 2014
ISO/IEC 17025 LABORATORY ACCREDITATION
OVERVIEW

Presented by Brenda Snodgrass
Oklahoma Dept. of Agriculture, Food & Forestry
Moderator

Acknowledgement:
Many thanks to Kristi McCallum, Colorado Department of Agriculture for providing her slides for the overview presentation
What is Accreditation?

• The procedure by which an authoritative body certifies that an entity or person is competent to perform a certain procedure or task

• Laboratories are accredited for specific test methods or calibrations performed

• ILAC (International Laboratory Accreditation Cooperation) sets the standard (example: ISO/IEC 17025). The standard is a set of requirements used to assess quality and competency.

• ILAC developed Mutual Recognition Agreements (MRA) with three Regional Cooperation Bodies. Under the MRA, these Regional Cooperation Bodies must ensure that laboratories accredited to ISO/IEC 17025 comply with the standard.

Information obtained from https://www.ilac.org/
ILAC Mutual Recognition Agreement Regions

APLAC - Asian Pacific Laboratory Accreditation Cooperation

IAAC – Inter-American Accreditation Cooperation

EA - European Cooperation of Accreditation

AAFCO - Association of American Feed Control Officials
United States Accrediting Bodies

- ANSI-ASQ National Accreditation Board and their associated brands ACLASS, FQS, and ANAB
- The American Association for Laboratory Accreditation (A2LA)
- Laboratory Accreditation Bureau
- Perry Johnson Laboratories
- American Industrial Hygiene Association
- International Accreditation Service
- National Voluntary Laboratory Accreditation Program (NVLAP) – Government agency that only accredits a few narrow disciplines
- American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB)
First things first…..

- **Must have management on board!** Your lab cannot become accredited without the support of senior management
- Very strict copyright laws pertain to all ISO Standards, including checklists which includes verbatim language of the Standards
- Must have a clearly defined Management System in place
- Must have a Quality System Manual in place
- Define the scope of accreditation (what methods are used and fields of testing)
Quality Management System (QMS)

- Must meet the requirements of ISO/IEC 17025, Section 4.2

- Consists of the Organizational Policies, Quality System Manual and Standard Operating Procedures (SOPs) for all management system policies and procedures and technical procedures
  - Section 4 includes the QMS Management Requirements
  - Section 5 includes the QMS Technical Requirements
Top 3 Things for a Functioning Management System

• Written policies and procedures

• Implementation

• Audit system to ensure it is working
Management System Document Structure

- Quality Manual
- Organizational Procedures & Method Procedures
- Data recording forms, work instructions (Records)
Management Procedures Include

• Organization - Organization chart, how your organization is managed; confidentiality and ethics policies & procedures
• Customer - Customer contracts, contract reviews, customer surveys
• Sub-contracting of analyses
• Purchasing
• Non-conforming analysis, complaint handling, corrective/preventive actions
• Internal audits
• Document control
• Management reviews and quality improvement processes
Technical Procedures Include

- Personnel - training, proficiency assessment
- Building and environmental conditions
- Analytical methods - suitability of method and method validations/verifications
- Measurement uncertainty and traceability
- Equipment - calibration/verification, maintenance
- Sample Handling - receipt, chain-of-custody, handling of test sample, sample storage, sample preparation
- Reporting Results - data reporting, data review, data handling, data storage
Technical Requirements

- Method Verification & Method Validation
- Personnel Competency
- Equipment
- Standard Reference Materials
- Measurement Traceability
- Sample Handling
- Reporting