

ISO 17025 Accreditation/Quality Management Systems Panel Discussion

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Laboratory Methods & Service Committee

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ISO/IEC 17025 LABORATORY ACCREDITATION OVERVIEW

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Moderator*



Acknowledgement:

*Many thanks to Kristi McCallum, Colorado Department of Agriculture
for providing her slides for the overview presentation*



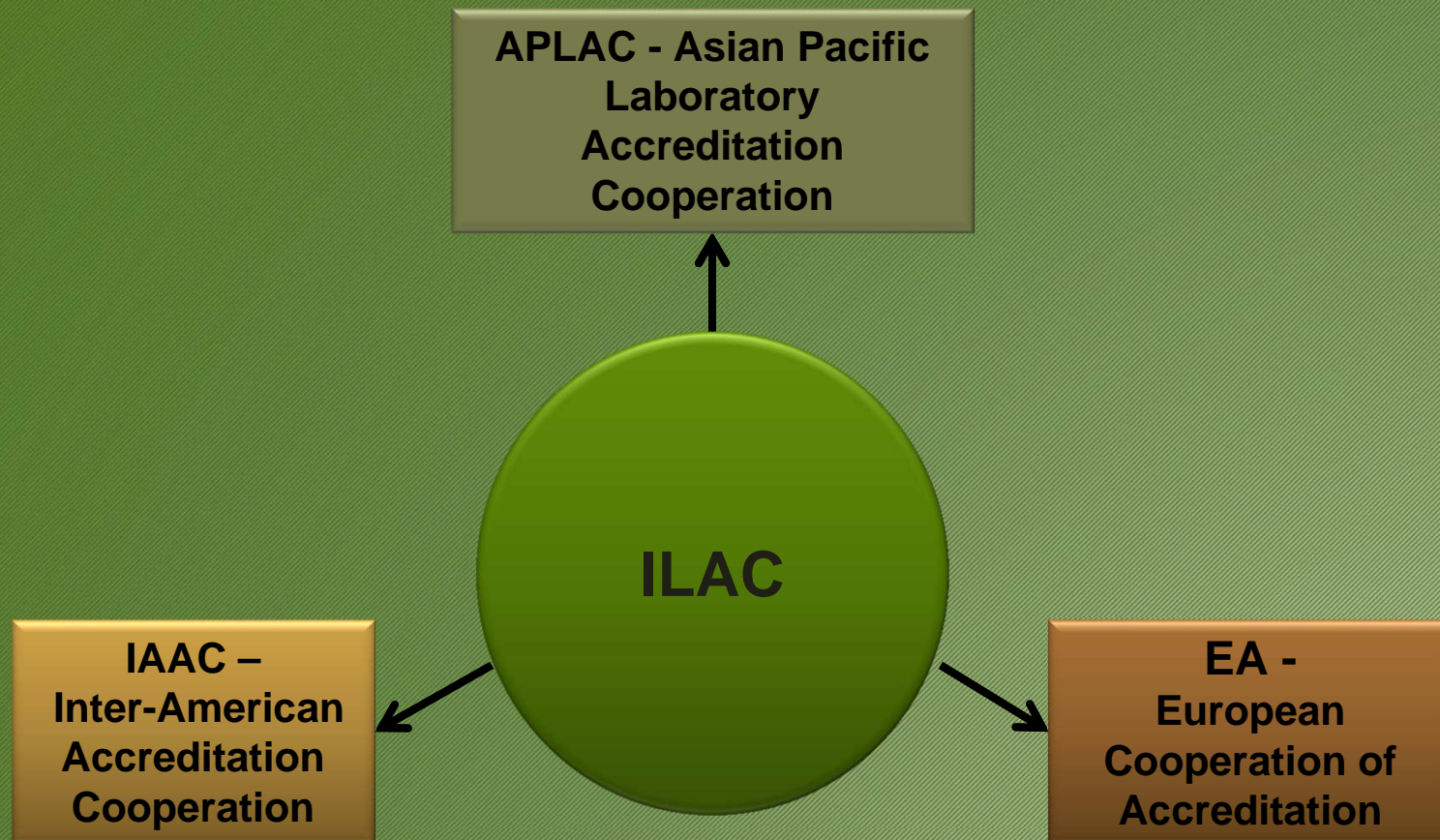
What is Accreditation?

- 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



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
- Must obtain a copy of the ISO/IEC 17025:2005 Standard available from <http://www.iso.org>
- 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

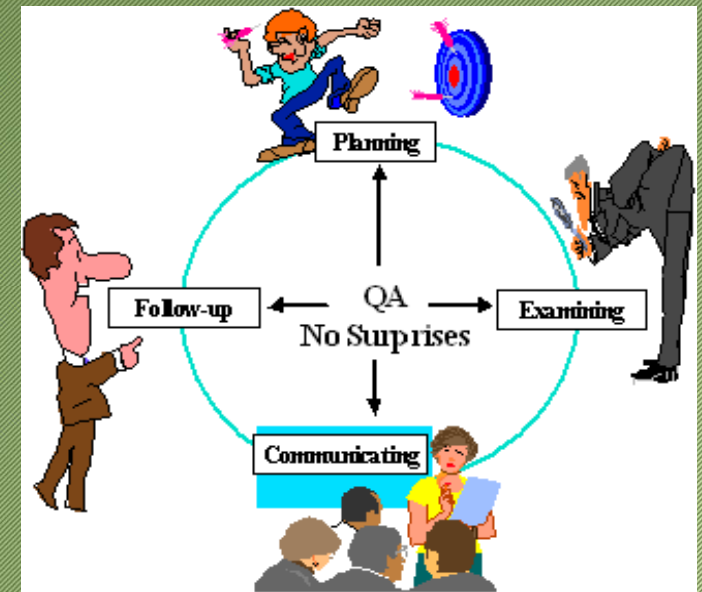
- Written policies and procedures



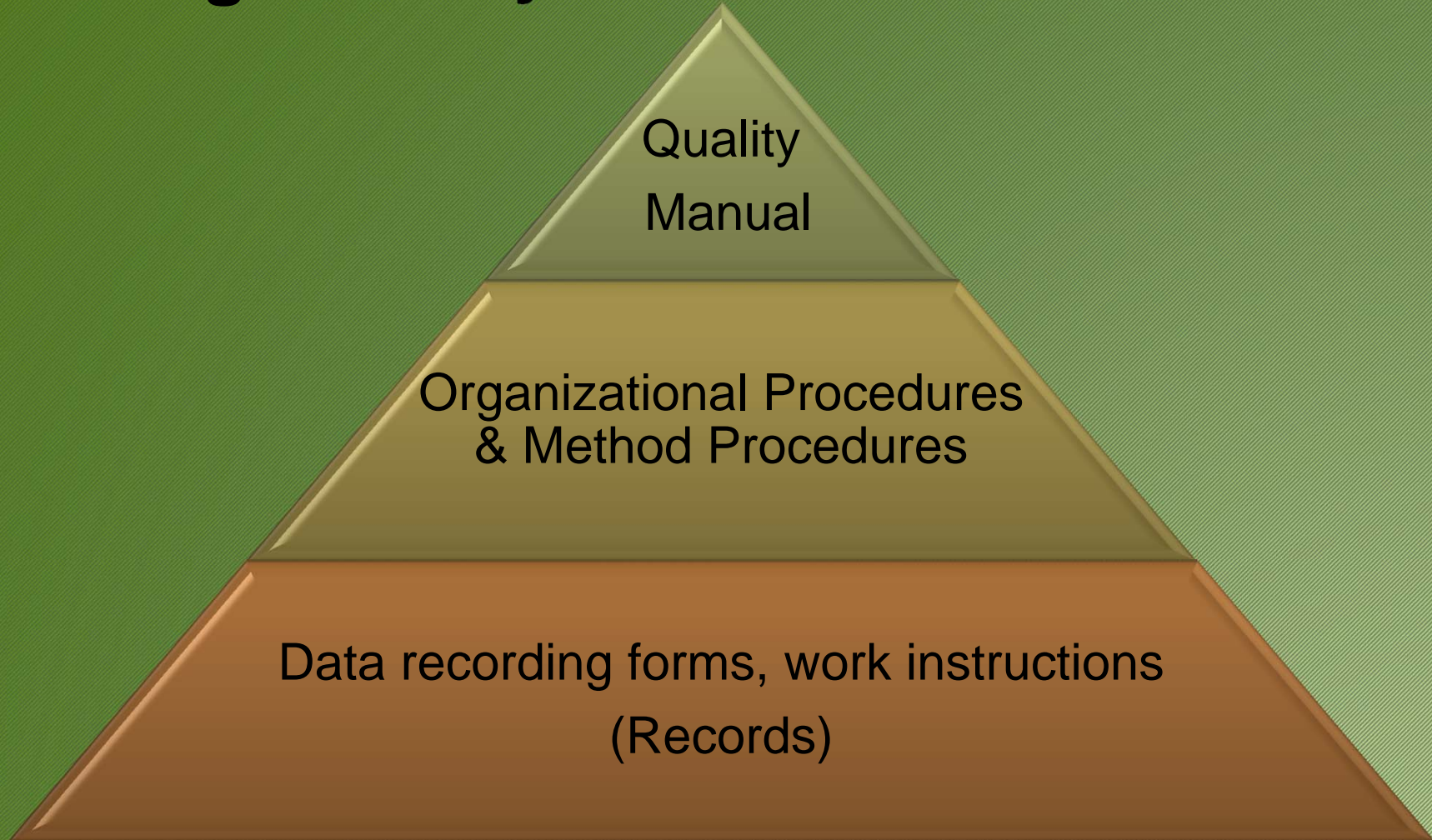
- Implementation



- Audit system to ensure it is working



Management System Document Structure



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

