

Because you care
about CONSUMERS' HEALTH



ISO/IEC 17025 Accreditation: The Big Picture and Getting Started

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- Accreditation versus Certification
- Top view of an accreditation program
- The values of being accredited
- Getting started



Let's Get Started!!



Accreditation versus Certification



- Certification is analogous to getting a driver's license.
 - Written Test
 - Practical Test
 - One-Time Assessment



- Accreditation is analogous to being monitored after getting the license
 - Perform same steps as certification
 - Continuously track performance with objective data
 - Document continued competency
 - Always looking to improve





A procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks





I International
S Organization for
O Standardization

ISO 9000 Quality Management Standard

Say What You Do, And Do What You Say





“General Requirements for the Competence of Calibration and Testing Laboratories”

- An evolution of the ISO 9000 Quality Management System standard
- Management and Technical requirements





- An Internationally recognized accreditation standard of quality for laboratories
- Mutually Recognized
 - Asian Pacific Laboratory Accreditation Coop
 - European Coop for Accreditation
 - InterAmerican Accreditation Coop



Section 4: Management Requirements



- 4.1 Organization
- 4.2 Quality System
- 4.3 Document Control
- 4.4 Review of Requests, Tenders and Contracts
- 4.5 Subcontracting of Tests and Calibrations
- 4.6 Purchasing Services and Supplies
- 4.7 Service to the Client
- 4.8 Complaints
- 4.9 Control Of Nonconforming Testing and/or Calibration Work
- 4.10 Improvement
- 4.11 Corrective Action
- 4.12 Preventive Action
- 4.13 Control of Records
- 4.14 Internal Audits
- 4.15 Management Reviews

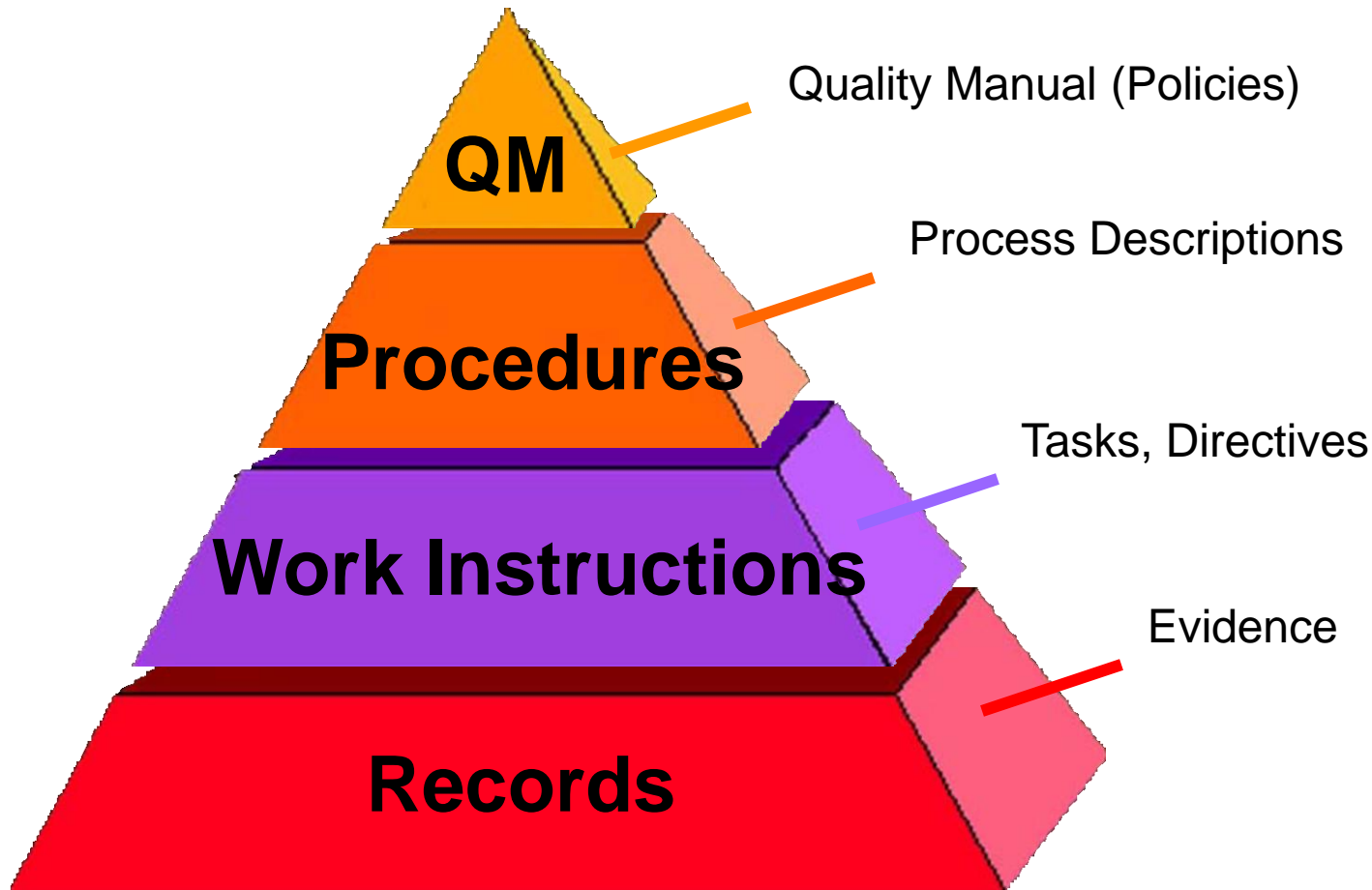
15 sections



- 5.1 General
- 5.2 Personnel
- 5.3 Accommodation and environmental conditions
- 5.4 Test and calibration methods and method validation
- 5.5 Equipment
- 5.6 Measurement Traceability
- 5.7 Sampling
- 5.8 Handling of test and calibration items
- 5.9 Assuring the quality of test and calibration results
- 5.10 Reporting the results

10 sections

ISO 17025 Quality Management System



A Slice Through the Pyramid



Situation: Someone needs training on an assay

Policy: Refer to policies that address training

QM

Procedure: Lists the key elements of training
-how, what, why, who, record requirements

Procedures

Actions: Individual training requirements
-lists details (extraction, analysis, etc.)

Work Instructions

Evidence: Raw data, statistics, final sign-off

Records





■ Phase I

- Make the Commitment Your Lab Will be Accredited
 - Assign all resources
 - Compose the Quality Manual
 - Internal Gap Analysis
 - Develop Strategy
 - Suggest hiring an expert consultant

■ Phase II

- Establish Plan to Fill Gaps
- Initiate any Proficiency Tests not already being undertaken
 - Must have 1 complete set by application date
 - Most PT programs have scheduled dates
- Full Gap Analysis
- Readiness Audit





- Phase III
 - Apply for Accreditation
 - Accrediting Body Audits Your Laboratory
 - Remote
 - On-Site
 - Closure of Corrective Actions
 - Certification of Quality System
 - Conducted by Accrediting Body

- Phase IV - Maintenance of Accreditation
 - Includes continuing participation in the appropriate PTs



Compliance to a recognized standard, operational consistency and efficiency, and customer confidence.

■ Consistency

- Tasks are done the same way every time
- Ensures ongoing product (result) quality

■ Efficiency / Effectiveness

- Clear expectations for completing tasks
- Clear, well-organized information

■ Customer Confidence

- Demonstration of competence



Additional Reasons



- Supports international growth strategies
 - International acceptance of data
- Customer driven
- Alignment with FDA, USDA, competitors
- Data defensibility
- Promotes continuous improvement efforts
- A positive cultural upgrade
 - As the practices become a way of life, issues are truly resolved and learnings are captured



