

Slide 1

ASCLD/LAB- *International*

ISO 17025:2005
ASCLD/LAB Supplemental Requirements 2006

Slide 2

What is ISO?

- ISO = International Organization of Standardization
- ISO – from the Greek word ISOS, meaning “equal”
- ISO develops standards
- ISO has been around nearly 60 years
- Registration, accreditation and certification bodies use the standards
- These bodies form regional groups around the world

Slide 3

Regional Cooperations

- IAAC = Inter-American Accreditation Cooperation
ASCLD/LAB is a “full member” of IAAC
- APLAC = Asia/Pacific Laboratory Accreditation Cooperation
- There are other regional cooperations

- Regional cooperations have formed an international cooperation

Slide 4

International Cooperation

- ILAC = International Laboratory Accreditation Cooperation
- Most countries have only one accrediting body
- The U.S., Germany, and Japan (and a few others) have numerous accrediting bodies
- In the U.S., we have a group attempting to become recognized by ILAC or IAAC as a "national" cooperation

Slide 5

National Cooperation

- NACLA = National Cooperation for Laboratory Accreditation

ASCLD/LAB is an active member of NACLA

- Accrediting bodies operate in accordance with ISO 17011 – a different set of ISO standards from the laboratories we accredit

Slide 6

ASCLD/LAB- *International*

Differences from the ASCLD/LAB Legacy Program

Slide 7

Basic Vocabulary Differences

- Assessments (as opposed to inspections)
- Assessors (not inspectors)
 - Lead Assessors
 - Technical Assessors
 - Technical Experts

Slide 8

Program Differences

- Conformance with ISO/IEC 17025 and Supplemental Requirements (most current version of each)
- Offering accreditation of Breath/Alcohol calibration programs
- Optional "Pre-Assessment" visits to do a "gap analysis"

Slide 9

Program Differences

- Grading of non-conformities
- Level 1 non-conformities must be corrected prior to accreditation
- Level 2 non-conformities may be addressed on or before the next annual surveillance visit

Slide 10

Program Differences

- Quality Review Panel reviews results of assessment while the team is still on-site (prior to the closing meeting)
- Laboratory has 30 days to develop corrective action plans and have those reviewed and accepted by the Lead Assessor

Slide 11

Program Differences

- Annual, on-site surveillance visits are conducted
- Surveillance visits are much less comprehensive than a full assessment, focusing on core quality issues (new personnel, training, proficiency testing records, etc.)

Slide 12

Program Differences

- Technical Advisory Committee (TAC) is available to ASCLD/LAB during the assessment and accreditation process to provide consultation on technical questions
- Cost of program is about the same, except for optional pre-assessment visit and surveillance visits

Slide 13

Requirement Differences

- Technical management clearly identified in all disciplines, not just in DNA
- Appointment of "key deputies" – answers the question: Whose is in charge when _____ is away?

Slide 14

Requirement Differences

- Management system documents must be "controlled" :
 - Who approved them?
 - Effective date?
 - Revision status clear to all users
 - Page numbered
 - Clearly marked as "obsolete" (or equivalent) when no longer authorized for use

Slide 15

Requirement Differences

- "Contracts" (agreements to do work in whatever form they take in your lab) – must be reviewed and a record of the review retained:
 - Do you have the right resources to do the work?
 - Are you capable of performing the testing requested?
 - Is there a problem that needs to be resolved with the customer?

Slide 16

Requirement Differences

- If you use subcontractors, you must ensure they are “competent” – and keep a record of how you made that determination
- Evaluate suppliers of “critical consumables, supplies and services” – and keep a record of that evaluation (an example of a critical service might be having a vendor certify balances)

Slide 17

Requirement Differences

- Show evidence of seeking feedback (both positive and negative) from your customers – and analyzing that feedback during management reviews
- Corrective actions in the laboratory must begin with a “root cause” analysis

Slide 18

Requirement Differences

- Case records must be sufficient to establish an “audit trail” – we fully track at least case per discipline through your entire quality system during each full, on-site assessment
- Your own internal auditors must be “trained and qualified” as auditors (how you do that and what you require is up to you – but you must have records)

Slide 19

Requirement Differences

- Management review records must reflect consideration and evaluation of all 11 elements listed in ISO 17025 (Clause 4.15.1)
- Personnel must be "authorized" (**in writing**) to work in the laboratory – the authorization must make it clear what type(s) of testing each person is authorized to do

Slide 20

Requirement Differences

- If a testing method new to your laboratory was developed and validated somewhere else, you may introduce and use that method in your laboratory after completing and documenting a "performance verification" (a full validation is not required – assuming you are making no significant changes)

Slide 21

Requirement Differences

- Estimation of uncertainty of measurement is required for **quantitative** tests:
 - Phase 1: applies only to measurements that are reported (**measurements that matter**)
 - Phase 2: Will apply to all measurements that effect outcome of results (whether reported or just recorded in the case record)

Slide 22

Requirement Differences

- Equipment must be uniquely identified (one reason is to help with building an audit trail – what instrument was used for what test?)
- Establish and be able to show objective evidence that measurement standards are traceable to the International System of Units (Système international d'unités)

Slide 23

Requirement Differences

- If sampling plans are used in the laboratory, the documented plan must be available at the location where sampling occurs
- ILAC exception for "reporting" requirements in ISO 17025 is endorsed by ASCLD/LAB – you have 3 options:

Slide 24

Reporting Options

- Include everything ISO requires in your laboratory reports
- Issue reports as you do now – but issue an attachment which contains additional information required by ISO
- Issue reports as you do now – and ensure that all other information required by ISO is available somewhere in the case record

Slide 25

Requirement Differences

- "Opinions" and "interpretations" must be clearly marked as such in laboratory reports

The remaining differences are from the Supplemental Requirements

Slide 26

Requirement Differences

- When an independent check on a critical finding is carried out (we call this a **verification**), it shall be conducted by an individual having expertise gained through training and experience, and a record of the review shall be made to indicate that the critical finding has been checked and agreed to, by whom, and when the check was performed. (this language is from ILAC G19)

Slide 27

Requirement Differences

- Education requirements are set by the laboratory for Firearms/Toolmarks, Latent Prints, Questioned Documents, Crime Scene and Digital & Multimedia disciplines - *ASCLD/LAB-International assessors will assess to determine compliance with what you require*

Slide 28

ISO 17025:2005

- Management Requirements
- Management System
- Document Control
- Review of Requests, Tenders and Contracts
- Subcontracting of Tests
- Purchasing Services and Supplies

Slide 29

ISO 17025:2005

- Service to the customer
- Complaints
- Control of Nonconforming Testing
- Improvement
- Corrective Action
- Preventive Action
- Control of Records

Slide 30

ISO 17025:2005

- Internal Audits
- Management Reviews
- Personnel
- Accommodation and Environmental Conditions
- Test methods
- Estimation of Uncertainty of Measurement

Slide 31

ISO 17025:2005

- Control of Data
- Equipment
- Measurement Traceability
- Reference Standards
- Reference Materials
- Sampling
- Handling of Test Items

Slide 32

ISO 17025:2005

- Assuring the Quality of Testing
- Reporting the Results
