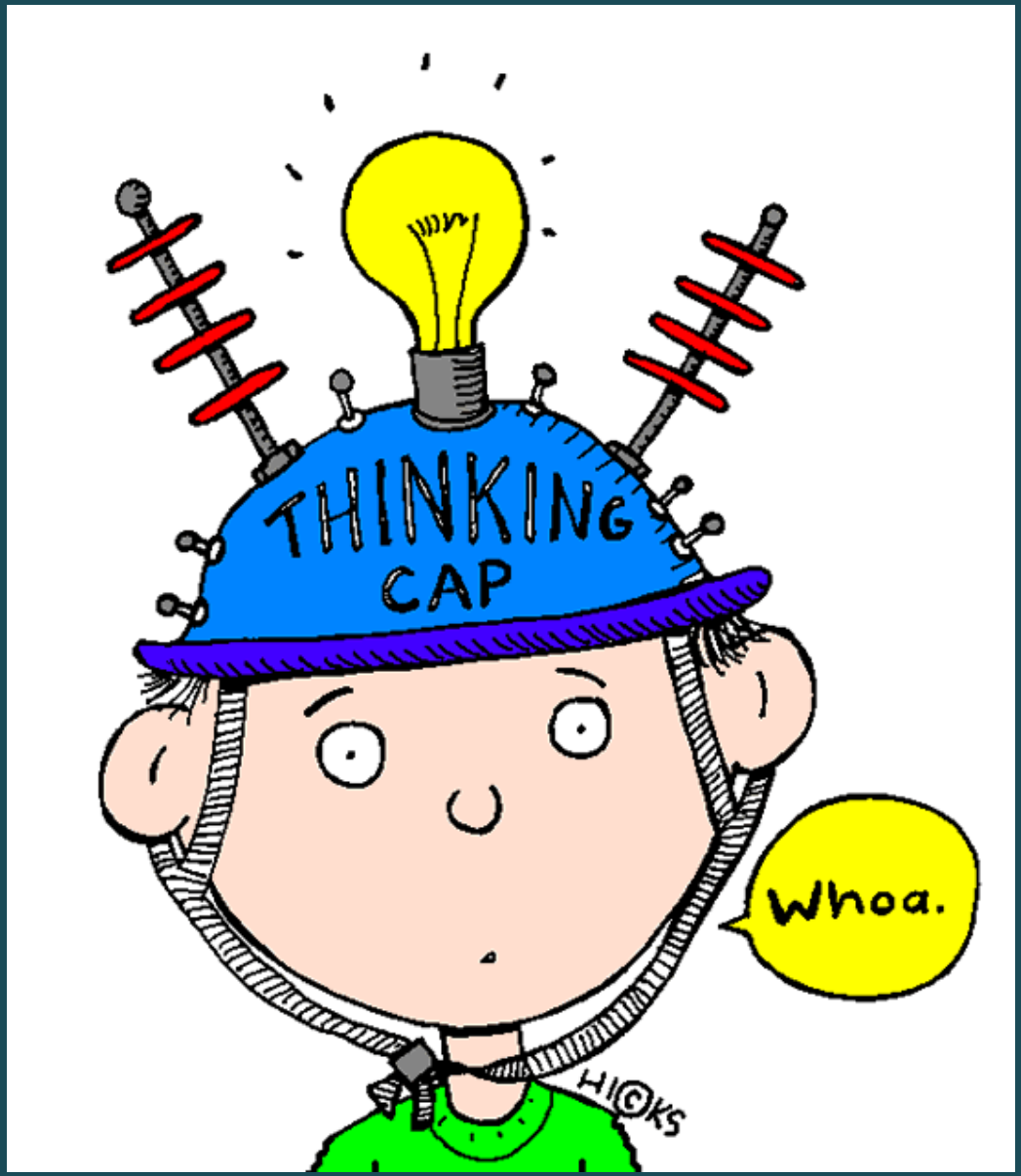
ISO Accreditation Requirements - Pattern Evidence Considerations

John Neuner, Program Manager
ASCLD/LAB-*International*
Impression and Pattern Evidence Symposium
August 2, 2010
Clearwater Beach, Florida

Talking about accreditation standards in a conference setting can be tough . . . especially after lunch !!

http://www.moonbattery.com/sleeping_student.jpg



http://wwcsd.net/~wernerv/images/thinkingcapwhoa_color.gif

I'll bet that most of you are well fed, refreshed, and ready to explore ways for ensuring greater quality in your work !!!

The approach for today …

With a focus on “impression and pattern evidence” disciplines:

- Selected ISO accreditation standards
- Selected supplemental accreditation standards
- A quick note about anticipated changes coming up

Disclaimer/Clarification:

Guidance documents, interpretations , and general applications of accreditation requirements will vary in some instances among accrediting bodies. Always check with your accrediting body to ensure a clear understanding of accreditation requirements.

The information presented today reflects the ASCLD/LAB application of ISO/IEC 17025:2005 accreditation requirements. Information from other accrediting bodies may vary for certain requirements discussed.

ISO/IEC 17025:2005

"*General requirements for the competence of testing and calibration laboratories*"

ISO standards are "general requirements"

ISO/IEC 17025:2005 is not discipline specific. There are no "pattern evidence " specific requirements in the ISO standards document .

The focus this afternoon will be on discussing certain "ISO " standards" as they relate to "impression and pattern evidence" practitioners.

ISO/IEC 17025:2005 standards fall in two general categories

- Section 4 - Management Requirements
- Section 5 - Technical Requirements

NOTE: Throughout the rest of this presentation, references to “17025” will mean “ISO/IEC 17025:2005”

ISO/IEC 17025:2005

Section 4 – Management Requirements

17025 – Section 4 – Management

- 4.1.5 (h) – The laboratory shall … have **technical management** which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations.
- Requirement is applicable in all disciplines, including impression and pattern evidence areas

17025 language lesson – What is a "test"

Test – the determination of one or more characteristics according to a procedure

ISO 9000:2000
“Quality management systems — Fundamentals and vocabulary”

17025 – Section 4 – Management

"**Contracting**" can lead to "**subcontracting**"

- 4.5 - Subcontracting of tests and calibrations
  - § Placed with a "competent" subcontractor
  - § Customer awareness of subcontracting
  - § Responsibility for subcontractor's work
  - § Maintaining records of subcontracting

17025 – Section 4 – Management

4.13.2 - Technical records (means more than "case notes")

- "… sufficient … to establish an audit trail …"
- "… sufficient … to enable the test … to be repeated under conditions as close as possible to the original"

ISO/IEC 17025:2005

Section 5 – Technical Requirements

17025 – Section 5 – Technical

5.1.2 – The laboratory shall take account of [several] factors in developing … methods, procedures, training, qualification of personnel and … selection of equipment:

- Human factors
- Accommodation and environmental conditions
- Test methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test items (“test items” = “evidence”)

17025 – Section 5 – Technical

- 5.2.5 – The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.

Accrediting bodies will vary on the application of this requirement – and the focus will likely increase in the future

17025 – Section 5 – Technical

- 5.4.2

  “Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated.”

  “Validation” does not have to occur in the laboratory. What if the method is already validated by someone else? (Answer is on slide 35)

17025 – Section 5 – Technical

- 5.4.6.2 – Testing laboratories shall have … procedures for estimating uncertainty of measurement …

  Using the right external calibration laboratory is a key element in some cases

17025 – Section 5 – Technical

- 5.6.2.1.1 - When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.

17025 – Section 5 – Technical

- Competence – ISO/IEC 17025:2005 accredited calibration laboratory by a competent accrediting body

- Measurement capability – accredited to calibrate in the measurement range important to you (e.g. truck scales, laboratory balances, etc.)

- Traceability – calibration is traceable to international measurement standards

17025 – Section 5 – Technical

5.6.3.1 Reference standards

- "… reference standards of measurement …"

5.6.3.2 Reference materials

- Generally "standards" other than measurement standards (SRM, CRM, etc.)

17025 – Section 5 – Technical

5.10 – Reporting the Results

- 5.10.1 – “The results of each test … or series of tests … carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively …”

ASCLD/LAB-*International* Supplemental Requirements

"Sector specific requirements" – Every accrediting body will have some

Supplemental Requirements (ASCLD/LAB)

Remember the note about methods already validated by someone else?

- 5.4.2.1 – Prior to implementation of a validated method new to the laboratory, the reliability of the procedure shall be demonstrated in-house against any documented performance characteristics of that procedure. Records of performance verification shall be maintained for future reference.

Supplemental Requirements (ASCLD/LAB)

- 5.6.3.2.1 – Reference collections of data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes … shall be fully documented, uniquely identified and properly controlled.

Supplemental Requirements (ASCLD/LAB)

Is this your reference collection?

http://fooshinc.com/wp-content/uploads/2010/06/pile-of-shoes.jpg

Supplemental Requirements (ASCLD/LAB)

Or is it more like this?

http://msnbcmedia1.msn.com/j/msnbc/Components/ArtAndPhoto-Fronts/COVER/080315/g-080315-cvr-dc-gun-ban.grid-6x2.jpg

Supplemental Requirements (ASCLD/LAB)

- fully documented – the important characteristics of the specimen are recorded (including source)
- uniquely identified – each specimen is appropriately labeled for traceability purposes
- properly controlled – the opposite of “out of control” (not necessarily under lock and key)

Supplemental Requirements (ASCLD/LAB)

- 5.9.4.1 – Technical reviews shall be conducted by individuals having expertise gained through training and casework experience in the category of testing being reviewed. In addition, the reviewer shall have sufficient knowledge of the discipline to verify compliance with the laboratory's technical procedures and that the conclusions reached are supported by the technical records.

NOTE 1 An individual conducting the technical review need not be an active analyst in the discipline (category of testing) or currently being proficiency tested in the discipline (sub-discipline).

Supplemental Requirements (ASCLD/LAB)

- 5.10.3.5 – When associations are made, the significance of the association shall be communicated clearly and qualified properly in the report.

  "… could have been made by" – What does that really mean and how it will be interpreted by your customer?

Anticipated Changes

- Each analyst (however named) and technical support personnel engaged in testing activities shall be proficiency tested at least once during each five-year accreditation cycle, in each category of testing appearing on the laboratory's Scope of Accreditation, in which the individual performs testing. To satisfy this requirement, the laboratory shall have a documented schedule for proficiency testing which is being followed by each examiner.

Anticipated Changes

- "ASCLD/LAB Guiding Principles" shall be in or referenced in the quality manual
- "ASCLD/LAB Guiding Principles" shall be reviewed with all employees annually
- Page numbering (or total number of pages) for "*examination records*" ß the correct ISO term
- Administrative reviews done by someone other than the author of the report
- Required elements of a technical review

Anticipated Changes

- Required elements of an administrative review
- Required elements of competency testing
- Required elements of laboratory test reports

Concluding Comments

- With one exception, conformance with accreditation requirements is not unique for the pattern evidence disciplines.
- The exception is specific requirements for examination records in the Latent Print discipline
- An important reminder – before applying for accreditation, always check with your accrediting body for further guidance, interpretations, applications and sector specific supplemental requirements

"Accumulate learning by study, understand what you learn by questioning."

Cha'n Master Mingjiao

Contact Information

John K. Neuner, Program Manager
ASCLD/LAB-*International*
919-773-2600

jneuner@ascld-lab.org

www.ascld-lab.org