

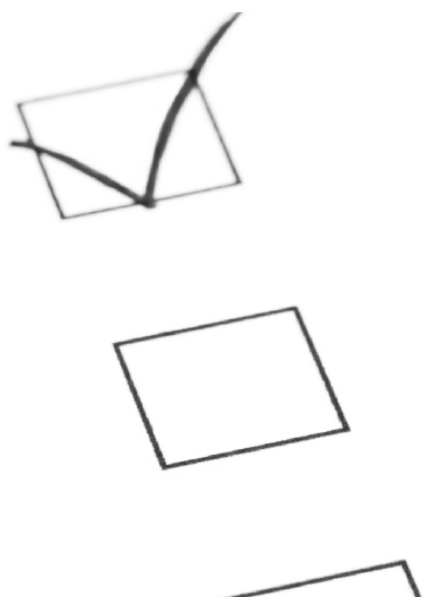
2011 CALA BIENNIAL ASSESSOR TRAINING

Assessing IT in Laboratories

Session 8

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Building Laboratory
Excellence

Vers l'excellence
dans les laboratoires



Session Goals

- Provide an overview of A96 - CALA Policy on the use of Computers in Accredited Laboratories
- Identify the relevant ISO/IEC 17025 clauses with respect to computerized systems.
- Identify areas to consider when assessing computerized laboratory systems.

POLICY STATEMENTS

- Accredited laboratories shall have appropriate controls and procedures in place for the collection, storage, manipulation, reduction and transmission of electronic data and results.
- Accredited laboratories shall have appropriate controls and procedures in place for the development, approval, storage, retrieval, access and archiving of electronic documents and records.

POLICY STATEMENTS

- Accredited laboratories shall implement controls and procedures dealing with information technology support to laboratory operations that meet the requirements given in ISO/IEC 17025 for paper-based documents, records, data and results.
- Accredited laboratories shall develop, document and implement procedures to formally document the validation of all software and information technology solutions employed to support laboratory operations

Integrity and Control of Electronic Data, Documents and Records

- *Accredited laboratories shall develop and implement procedures to prevent the inadvertent and/or unauthorized amendment of computer software, electronic records, documents and data. The procedures shall stipulate the steps to be taken to formally amend computer software, electronic data, documents, and records. [4.3, 4.13]*

Common Approaches

- Controlled access to software, electronic records, documents and data.
- Create multiple roles that read-only or read-write.
- Specify the persons who are normally granted access.
- Use of user ID and/or passwords.
- Use of read-only storage media.
- Clear and simple procedures to modify software, documents, records and data that provide the tracking information for amendments.
- Back ups of current versions, so as to allow restoration to current condition, if current storage media discontinues normal retrieval access.

Applicable Clauses from ISO/IEC 17025

- 4.3.1 - “ The laboratory shall establish and maintain procedures to control all documents”.
- 4.3.3.4 - “Procedures shall be established to to describe how changes in documents maintained in computerized systems are made and controlled”.

Scenario 1

- You are assessing a laboratory which maintains its documents in electronic format. In reviewing the SOP for internal audits, it was observed that the document did not contain the name or signature of the person approving it. However, the system records list the revision and indicates it was approved by the QM on March 21, 2010.

Scenario: 1

- N/C: NA.
- Clause: ISO/IEC 17025, 4.3.1, 4.3.2
- CALA Documentation: P07 4.3.2.2 It is not necessary for procedures to be signed by the approvers to indicate that they are approved. Some electronic systems control the approval of documents without signatures
- Grade: NA

Validation of Electronic Systems

- *Accredited laboratories shall develop and implement procedures to formally document the validation of computer systems (software and applications) in support of laboratory operations. Such validation shall be commensurate with each type of computer-based solution used in the laboratory and its intended purpose and scope. [5.4, 5.5]*

Types of Software Products

- COTS – Commercial off the shelf. This is software purchased without modification and will not be modified by the lab. Examples of this are Microsoft Word/ Excel or dedicated instrument interface.

However, the lab must have evidence that any formula written for use in spreadsheet calculations perform as expected.

Types of Software products

- **MOTS** – Modified off the shelf. Software modified or customized for specific applications. The purchased portion is considered COTS, however, the modified portion is considered CUSTOM and full validation is required.
- **CUSTOM** – Software that is lab written or vendor written. Full validation is required.

Common approaches

- Software Validation in Accredited Laboratories, Gregory Gogates, Sept. 2001
- ASTM E2066 Standard Guide for Validation of Laboratory Information Management Systems
- EPA 2185 Good Automated Laboratory Practices, 1995

Applicable Clauses from ISO/IEC 17025

- 5.4.7.1 - “Calculations and Data transfers shall be subject to appropriate checks in a systematic manner”
- 5.4.7.2a - “computer software developed by the user is documented insufficient detail and suitably validated....”
- 5.5.2 - “Equipment and its software....shall be capable of achieving the accuracy required....”
- 5.5.11 - Where calibration gives rise to correction factors the lab shall have procedures to ensure that copies (e.g. in computer software) are correctly updated”.

Scenario 2

- You observe that the laboratory uses a LIMS which flags data outside the control limits. The LIMS is also used track trends such as several points on the same side of the mean, points outside the warning limits etc. However, an actual control chart is not displayed.

Scenario: 2

- N/C: NA.
- Clause: ISO/IEC 17025, 5.9
- CALA Documentation: P07 5.9 QC data must be recorded in such a way that trends can be identified. Control charting and tabulating of data are the most common techniques used
- Grade: NA
- Rationale: While control charts provide a visual cue, it may not be the only appropriate way of recording trends. In such a case, the assessor would need to verify the the validation data demonstrates that the system is working effectively in capturing the trends.

Confidentiality/Security of information - Access Control

- *Accredited laboratories shall develop and implement procedures to provide adequate protection for software, electronic records, documents and data in order to prevent access and viewing by unauthorized persons. Such protection shall be commensurate with each type of record, document or observation/data point collected, stored, or maintained by the laboratory. [4.3, 4.13, 5.4, 5.5]*

Common Approaches

- Controlled access to software, electronic records, documents and data.
- Specify the persons who are normally granted access.
- Use of passwords or digital signatures.
- Tracking of access to software, electronic records, documents and data.
- Use of increased levels of security, such as Public Key Infrastructure (PKI), or other types of encryption, in the transmission and receipt of electronic records, documents and data.
- Use of firewalls to control external access.

Applicable clauses from ISO/IEC 17025

- 4.1.5c - “....shall have policies and procedures to ensure the protection of clients confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results”.
- 4.13.1.4 - “The lab shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment to these records”.
- 5.4.7.2b - “procedures are established for protecting data; such procedures shall include.....”.
- 5.3.4 - “Access to and use of areas affecting the quality of tests and/or calibrations shall be controlled”.

Retrieval of Electronic Data, Documents and Records

- *Accredited laboratories shall develop and implement procedures to provide adequate facility for the continuing retrieval of electronic records, documents and data in order to permit access and reference to such records, documents and procedures for as long as the laboratory may require such access and reference. [4.3, 4.13]*

Common Approaches

- Secure and controlled off-site storage.
- Use of formats that are likely to be used in the future such as Adobe Acrobat (*.pdf) format.
- Use of media, such as CD-ROM, DVD-ROM, memory cards and USB drives that are likely to be used in the future.
- Use of an appropriate method of indexing archived data to facilitate ease of retrieval.

Applicable clauses from ISO/IEC 17025

- 4.13.1.2 – “All records shall be legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss”

Scenario 3

- You observe that the laboratory backs up its data on 3.5 inch floppy disks. The lab has a stated record retention policy of 15 years.

Scenario: 3

- N/C: NA.
- Clause: ISO/IEC 17025, 4.13.1.2 All records shall beare readily retrievableRecord retention times shall be established.
- CALA Documentation: P07 4.13.1.2 and A96 section 3.4
- Grade: C
- Rationale: While the choice of storage media is a legitimate concern, this cannot be raised as a nonconformance without objective evidence the data was not readily retrievable. The lab would be expected to maintain the necessary hardware to access the information if required.

Maintenance of Electronic Systems (Computers/Software)

- *Accredited laboratories shall develop and implement procedures to effect the maintenance of electronic systems (software and applications), which may include software, firmware and/or hardware, so as to prevent non-conforming operation of the electronic system. [5.5]*

Common approaches

- Operation by trained and qualified personnel.
- Preventive maintenance schedules for hardware.
- Monitor the continuing validation of the IT solution throughout its life cycle in the laboratory. See Figure 1 of *“Software Validation in Accredited Laboratories”*.
- Inclusion of IT solutions within laboratory calibration program, as required

Applicable clauses from ISO/IEC 17025

- 5.4.7.2c - “the lab shall ensure that: computers and automated equipment are maintained to ensure proper functioning.....”.
- 5.5.2 - “Equipment and its software ... shall be capable of achieving the accuracy required... Before being placed into service equipment shall be calibrated or checked to establish it meets lab requirements”.