



Assessing Compliance for Software and Computer Requirements in QSM 5.0

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Objectives of This Workshop

The primary purpose of this workshop is to understand and assess the laboratory's compliance to the requirements of QSM 5.4.7.2 (d-k).

- Understanding the requirements
- Asking the right questions
- Records

Requirements for LIMS

- A procedure to ensure:
 - All LIMS users have a unique ID and password. (QSM 5.4.7.2 (d))
 - Update the user's password at least once per year. (QSM 5.4.7.2 (d))
 - Periodic inspections of the LIMS (at least annually) (QSM 5.4.7.2 (f))
 - *Performed by the Quality Manager*
 - *Records of Inspections*
 - *Report to Management*
 - *Issues and Corrective Actions*

Requirements for LIMS

- Operating system privileges and file access safeguards are implemented to restrict the user of the LIMS data to users with authorized access; (QSM 5.4.7.2 (k)(ii))
 - How do you assess compliance for privileges?
- Client notification for changes in LIMS software or hardware with any impact to electronic data – prior to change (QSM 5.4.7.2 (g))

Security Awareness Training

- Security Awareness Training (initial and annual) (QSM 5.4.7.2 (e))
 - Records of training
- The standard specifically states LIMS users must have security training annually (QSM 5.4.7.2 (k)(iii))

Spreadsheet Requirements(QSM 5.4.7.2 (h))

- Records of verification initially and if any changes due to updates or software
- Formula cells are write-protected
- If the spreadsheet is printed, the all information for the calculated result is required

Required SOPs

- Software development methodologies based on the size and type of software (QSM 5.4.7.2 (i)(i))
- Testing and QC Methods (QSM 5.4.7.2 (i)(ii))
 - Acceptance Criteria
 - Tests
 - Who will conduct the tests?
 - Records of the test results, reviews, and approvals
 - Continuing verification

Required SOPs

- Change Control Methods
 - Requestor, Authorization, Requirements, Testing, QC, Approval, Implementation and Prioritization of Change Requests QSM 5.4.7.2 (i)(iii)
 - Records should exist for this process and are required by QSM 5.4.7.2 (j)
- Software Version Control – ability to associate the version of software with the data generated/processed QSM 5.4.7.2 (i)(iii)

Required SOPs

- Maintaining a historical file of software, software procedures, and versions
- Defining the acceptance criteria, testing, records, and approvals for changes to LIMS hardware and communication equipment 5.4.7.2 (i)(vi)

Records (QSM 5.4.7.2 (j))

- Software description and functional requirements
 - How do you define functional requirements?
 - Why are these important?
- Listing of Algorithms and Formulas
- Test and QA Records
- Installation, Operation, and Maintenance

Electronic Data Security Measures

- User Names and Passwords
- Operating System Privileges and Safeguards
- LIMS users receive annual computer awareness security training
- System Events Monitored – logon failures
- Virus Protection
- System Back-ups (published schedule)

Electronic Data Security Measures

- Testing of the backups
 - Performed
 - Recorded
- Limited Access to Servers

Questions?

Thank you!!