

U. S. Department of Energy



Consolidated Audit Program

Checklist 5

Laboratory Information Management Systems Electronic Data Management

Revision 3.8

January 2012

Audit ID:

Date:

Approved by:  DOECAP Manager, January 2012

Audit ID: _____ Laboratory: _____ Auditor: _____

Areas of Review During Audit

___ Personnel

___ Hardware

___ LIMS Data

___ Facilities

___ Software

___ Complaints

___ Security

A = Acceptable

U = Unacceptable

NA = Not Applicable

F = Finding

O = Observation

Referenced regulations are accessible at the following URLs:

- <https://doecap.oro.doe.gov/>

NOTE:

- When audit findings are written against *site-specific documents* (i.e., SOPs, QA Plans, licenses, permits, etc.), a copy of the pertinent requirement text from that document must be attached to this checklist for retention in DOECAP files.
- Fully document any deviation from the LOI and the requirements of QSAS 2.8
- Refer to Page 17 for the record of revision.

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Audit ID: _____ **Laboratory:** _____ **Auditor:** _____

Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
1.0	Personnel		
1.1	The LIMS and electronic data management support staff and users have adequate education, training and experience to perform assigned LIMS and electronic data management functions. <i>QSAS, Section 5.2.1</i>		
1.2	Job descriptions, qualifications and training for the LIMS and electronic data management support staff are current. <i>QSAS, Sections 5.2.4 and 5.2.5</i>		
1.3	QA personnel are separate from and independent of LIMS and electronic data management personnel. <i>QSAS, Section 4.1.5 j) 3)</i>		

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2.0	LIMS Data		
2.1	Periodic inspections of the LIMS operations are performed by the QA Unit to ensure the integrity of LIMS data. The QA Unit maintains records of inspections and submits reports to laboratory management noting any problems identified with LIMS data processing and stating the corrective actions taken. <i>QSAS, Section 5.4 DOE-4; 4.12.1.5 b</i>		
2.2	An SOP exists for the manual entry of raw data, from analytical measurements when there is not a direct interface to the LIMS, e.g., double key entry, single entry with secondary review, etc. <i>QSAS, Section 4.2 DOE-3</i>		
2.3	An SOP exists for making changes to electronic data. <i>QSAS, Sections 4.2 DOE-3 and 4.12.2.3</i>		
2.4	An SOP exists for how electronic data are processed and maintained by the LIMS. <i>QSAS, Section 4.2 DOE-3</i>		
2.6	An SOP exists for how electronic data are reported by the LIMS. <i>QSAS, Section 4.2 DOE-3</i>		
2.7	An SOP exists for the retention of electronic data, documentation, and records pertaining to the LIMS. <i>QSAS, Sections 4.2 DOE-3 and 4.12.2.4</i>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
2.8	Individuals responsible for entering and recording data into the LIMS are uniquely identified when the data are recorded, and the times and dates are documented. <i>QSAS, Section 4.12.2.1 and 4.12.1.5 a)</i>		
2.9	The instrument transmitting data to the LIMS is uniquely identified when the data are recorded, and the time and date are documented. <i>QSAS, Section 4.12.2.5.3 b) and c)</i>		
2.10	Documentation for changes made to data in the LIMS includes: <ul style="list-style-type: none"> • the original recorded required documentation; • clear evidence that a change was made; • the reason for the change; • the date of the change; • the person who made the change; and • the person who authorized the change. <i>QSAS, Sections 4.12 DOE-3, 4.12 DOE-4, 4.12.1.5.d) and f)</i>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
3.0	Software		
3.1	An SOP exists for software development methodologies that are based on the size and nature of the software being developed. <i>QSAS, Sections 4.2 DOE-3 and 5.4 DOE-4</i>		
3.2	An SOP exists for testing and QA methods to ensure that all LIMS software accurately performs its intended functions. The SOP includes: <ul style="list-style-type: none"> • acceptance criteria; • tests to be used; • personnel responsible for conducting the tests; • documentation of test results; • frequency of continuing verification of the software, and, • test review and approval. <i>QSAS, Sections 4.2 DOE-3, 5.4.7.2 a), and 5.4 DOE-4</i>		
3.3	An SOP for software change control methods exists that includes instructions for requesting, testing, approving, documenting, implementing changes; and establishing priority for change requests. <i>QSAS, Section 5.4 DOE-4</i>		
3.4	An SOP for software version control methods exists that documents the LIMS software version currently used. Data sets are documented with the date and time of generation and/or the LIMS software version used to generate the data set. <i>QSAS, Section 5.4 DOE-4</i>		

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3.5	An SOP exists for maintaining a historical file of software, software operating procedures, software changes, and software version numbers. <i>QSAS, Section 5.4 DOE-4</i>		
3.6	All SOPs and LIMS documentation are readily available in the facility where the software is used and where the procedures are performed. <i>QSAS, Sections 4.3.2.2 a) and 5.4.1.1 c)</i>		
3.7	Software Change Control documentation identifies: <ul style="list-style-type: none"> • persons requesting and authorizing software changes; • requirements to be met by the change; • measures for testing and QA; • methods for moving changed versions to the production environment; • change request forms/problem reports; and • priority of change requests. <i>QSAS, 5.4 DOE-4</i>		
3.8	Documents available in the laboratory to demonstrate the validity of software used in the LIMS include: <ul style="list-style-type: none"> • software description and functional requirements; • listing of algorithms and formulas; • testing and QA documentation; and • installation, operation, and maintenance records. <i>QSAS, Section 5.4 DOE-4</i>		

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3.9	The software historical files of all versions of software programs exist and include dates that software was placed into and removed from production. <i>QSAS, Section 4.12.2.4 b</i>		Requiring dates “placed into and removed from production” is hard to enforce without specifics in QSAS.
3.10	Equations used in spreadsheets have been verified and validated. <i>QSAS, Section 5.4 DOE-4</i>		
3.11	Spreadsheets are locked to avoid unauthorized changes and the versions are controlled. <i>QSAS, Section 5.4 DOE-4</i>		

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4.0	Security		
4.1	Individual user names and passwords have been implemented on the LIMS. <i>QSAS, Section 5.4. DOE-4</i>		
4.2	Passwords are changed regularly, at minimum of once per year. <i>QSAS, Section 5.4. DOE-4</i>		
4.3	Users are trained in computer awareness security, initially upon employment and thereafter on an annual basis. Documentation of the training will be maintained and available for review. <i>QSAS, Section 5.4 DOE-4</i>		
4.4	Operating system privileges and file access safeguards are implemented to restrict the use of LIMS data to users with authorized access. <i>QSAS, Section 5.4 DOE-4</i>		
4.5	System events such as logon failures or break-in attempts are monitored. <i>QSAS, Section 5.4 DOE-4</i>		
4.6	The LIMS is protected by application-specific safeguards. <i>QSAS, Section 5.4.7.2 d)</i>		
4.7	The LIMS is protected from the introduction of computer viruses. <i>QSAS, Section 5.4 DOE-4</i>		

Status Key: A = Acceptable, U = Unacceptable, NA = Not Applicable, F = Finding, O = Observation

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4.8	Emergency, backup, disaster recovery, and contingency plans exist for the LIMS. <i>QSAS, Sections 4.12.1.4</i>		
4.9	System backups occur on a regular and published schedule and can be performed by more than one person within an organization. <i>QSAS, Section 5.4 DOE-4 and QSAS 4.12.1.4</i>		
4.10	testing of the LIMS system backups is performed and documented to demonstrate that the backups contain all required data. QSAS, Section 5.4 DOE-4		<p><i>In 5.4 DOE-4 "periodic" is not in requirement. I am often told that a lab's staff has tested the backup files were tested once.</i></p>
4.11	Physical access to the LIMS servers is limited by security measures such as locating the system within a secured facility or room, and/or utilizing cipher locks or key cards. <i>QSAS, Section 5.4 DOE-4</i>		
4.12	Fire extinguishers designed to avoid damage to computer equipment must be available and mounted in visible, accessible areas. <i>QSAS, Section 5.4 DOE-4</i>		

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5.0	Hardware		
5.1	A description of the LIMS design and capacity is documented and maintained. <i>QSAS, Sections 5.5.3 and 5.5.5</i>		
5.2	An SOP exists for defining the acceptance criteria, testing, documentation, and approval required for changes to LIMS hardware and communications components. <i>QSAS, Sections 5.4 DOE-4</i>		
5.3	Documentation of the regularly scheduled maintenance for LIMS hardware and communications components is maintained and includes: <ul style="list-style-type: none"> • descriptions of operations performed; • names of persons who conducted them; • dates operations were performed; and • results. <i>QSAS, Sections 5.5.5 f) and g).</i>		
5.4	Documentation for repair of malfunctioning or inoperable LIMS hardware and communications components is maintained and includes: <ul style="list-style-type: none"> • a description of the problem; • corrective action taken; • acceptance testing criteria; and • testing performed to ensure proper performance prior to returning the LIMS hardware to production. <i>QSAS, Section 5.4.7.2 c and 5.5.2.1 a)</i>		

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6.0	Facilities		
6.1	The servers are located in a temperature-controlled environment with adequate ventilation. <i>QSAS, Section 5.4.7.2 c</i>		
6.2	The LIMS and associated communications components are protected through the use of surge protectors and connection to an uninterrupted power supply. <i>QSAS, Section 5.4.7.2 c</i>		
6.3	Environmentally adequate storage space is provided for the retention of LIMS data storage media and hard copy records. Long-term archival copies of LIMS backup media are stored in an offsite location with the same environmental control and security systems required of onsite storage facilities. <i>QSAS, Section 4.12.1.2;4.12.1.3; 4.12.2.4 e)</i>		

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7.0	Electronic Data Deliverables		
7.1	An SOP exists for creating electronic data deliverables. <i>QSAS, Section 4.2 DOE-3</i>		
7.2	An SOP exists for verifying that electronic data deliverables match hardcopy report forms (for clients requiring both). <i>QSAS, Section 4.2 DOE-3</i>		
7.3	An SOP exists for handling and documenting client-requested modifications to electronic data deliverable formats. <i>QSAS, Section 4.2 DOE-3</i>		
7.4	The hardcopy data reporting forms and electronic data deliverables are created from the same source. <i>QSAS, Sections 4.2.6 and 5.4.7.1</i>		
7.5	A corrective action plan exists for resolving discrepancies between electronic data deliverables and hard copy report forms. <i>QSAS, Section 4.10</i>		Though not called out specifically, electronic data deliverables and hardcopy would be included in the overall corrective action plan of a laboratory.

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Record of Revision for Checklist 5 Laboratory Information Management Systems and Electronic Data Management

Revision Number	Effective Date	Reason for Revision	Line of Inquiry
3.5	11/2009	Changed reference for SOP requirement for making changes to electronic data to 4.12.2.3.	2.3
3.5	11/2009	Changed reference for LOI to 4.12 DOE-4	2.9
3.5	11/2009	Add requirement that SOPs must be developed for the frequency of continuing verification of software.	3.2
3.5	11/2009	Users are trained on computer awareness security upon employment and thereafter, on an annual basis.	4.3
3.5	11/2009	Added periodic testing of LIMS backups to demonstrate that the backups contain all data and information.	4.10
3.6	11/2010	Added the requirement for the establishment of change control priority.	3.7
3.6	11/2010	Changed reference from 4.12.2.3 to QSAS, 5.4 DOE-4	3.7
3.7	11/2011	Added the following to the LOI Notes: Fully document any deviation from the LOI or the requirements for QSAS 2.7	Page 1
3.8	1/2012	Added the following to the LOI Notes: Fully document any deviation from the LOI or the requirements for QSAS 2.8	Page 1