U. S. Department of Energy

Consolidated Audit Program
Checklist 1

Quality Assurance Management Systems and General Laboratory Practices (with LIMS and AIHA)

Revision 4.4
March 2014

Audit ID:	Date:

Audit ID:	Laboratory:	Auditor:

Areas of Review During Audit

___Performance Testing	__ Management Requirements	__ Document Control
__ Requests, Tenders, and Contracts	___Subcontracting of Environmental Test	__ Purchasing Services and Supplies
__ Calibration Requirements	__ Service to the Client	__ Control of Nonconforming Work
__ Improvement and Corrective Actions	__ Preventive Action	__ Control of Records
___Internal Audits	__ Management Reviews	__ Data Integrity Investigations
___Technical Requirements (Joe Pardue)	__ Accommodation and Environmental Conditions	__ Sample Handling, Acceptance, and Receipt
__ LIMS (if needed)	__ AIHA (if needed)	

A = Acceptable U = Unsatisfactory NA = Not Applicable F = Finding
NO = Not Observed O = Observations

Referenced regulations are accessible at the following URLs:

- https://doecap.oro.doe.gov/
- http://www.aiha.org/Content/LQAP/documents/2008LabAccredPolicyRevision.htm*(for IH laboratory audit only)*

NOTE: Checklist 1 incorporates requirements of DoD/DOE Quality System Manual Rev. 5.0; TNI EL-V1-2009, ISO/IEC 17025:2005, and AIHA Laboratory Accreditation Standard.

- 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 or the requirements of QSM Rev. 5.0
- Refer to Page 73 for the record of revision.

Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
1.0	**Requirements for Participation (Performance Testing)**		
	Initial Inclusion		
1.1	Can the laboratory demonstrate a minimum of one year's participation in a nationally recognized PE program for all analytes to be reported under contracts supporting DOE work? (MAPEP or commercially available PE programs) *QSM Rev. 5.0, Module 1, Section 3.1.1;AIHA-LAP 6*		
1.2	Does the laboratory participate in MAPEP? **NOTE:** Participation in MAPEP is required for all laboratories that possess a radiological materials license and that perform inorganics, semivolatile organics, or radiochemical analyses for DOE. (This requirement does not replace the laboratory's participation in program specific PE programs or for PE required for *TNI STANDARD, EL-VI-2009,* NELAC accreditation) *QSM Rev. 5.0, Module 1, Section 3.1.2*		
1.3	If the laboratory provides volatile organic and wet chemistry analyses do they maintain proficiency in nationally recognized PE programs for all matrices that the laboratory provides data to DOE? **NOTE:** These analytes are not available from MAPEP *QSM Rev. 5.0, Module 1, Section 3.1.2*		
1.4	If the laboratory does not have a radiological materials license, do they participate in MAPEP for semivolatile analyses? *QSM Rev. 5.0, Module 1, Section 3.1.2*		

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1.5	Does the laboratory corrective action process encompasses its PE program and is it documented by: • clear identification of unacceptable PE values; and, • identification of the root cause for the failure and correction of the unacceptable value prior to reporting of the next PE sample? *QSM Rev. 5.0, Module 1, Section 3.1.2; AIHA-LAP2A.4.9.2, 2A.4.11.1, 2A.4.11.2*		
	Continued Participation		
1.6	Can the laboratory demonstrate continued proficiency in either MAPEP or external performance testing programs? *QSM, Rev. 5.0, Module 1, Section 3.2.1**;** AIHA-LAP 6*		
1.7	Does the laboratory document the cause(s) for failed PT results and develop corrective action(s) to address the causes within 21 calendar days from receipt of the results? *QSM, Rev. 5.0, Module 1, Section 3.2.2**;** AIHA-LAP2A.4.9.2, 2A.4.11.1, 2A.4.11.2*		

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2.0	**Management Requirements**		
	Organization (ISO/IEC 17025:2005(E)		
2.1	At a minimum, are the following laboratory management staff (however named) considered as key managerial personnel: a) Management (e.g., President, Chief Executive Officer, Chief Operating Officer, Laboratory Director); b) Technical managers (e.g., Technical Director, Section Supervisors); c) Quality managers; d) Support systems and administrative managers (e.g., LIMS manager, purchasing manager, project managers); e) Customer services managers *QSM, Rev. 5.0, Module 2, Section 4.1.5*		
2.2	Has the laboratory appointed deputies for key managerial personnel? *ISO/IEC Standard 2005, Clause 4.1.5 j)*		

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2.3	Does the laboratory's quality manager and/or his/her designee(s): a) serve as the focal point for QA/QC and be responsible for the oversight and/or review of QC data; b) have functions independent from laboratory operations for which they have QA oversight; c) evaluate data objectively and perform assessments without outside (e.g., managerial) influence; d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system; e) have a general knowledge of the analytical methods for which data review is performed; f) arrange for or conduct internal audits annually; g) notify laboratory management of deficiencies in the quality system; h) monitor corrective actions; i) implement, maintain, and improve the management system by using available tools such as audit and surveillance results, control charts, proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends? ***NOTE*:** Where staffing is limited, the quality manager may also be the technical manager. *QSM Rev. 5.0, Module 2, Section 4.1.7.1 i) and TNI EL-VIM2-2009, Section 4.1.7.1a) through h)*		
	Management		
2.4	Has the laboratory established, implemented and maintained a management system appropriate to the scope of its activities? *QSM Rev. 5.0, Module 2, Section, 4.2.1 and ISO/IEC/IEC 17025:2005(E), Clause 4.2.1*		

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2.5	Has the laboratory documented its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results? *QSM Rev. 5.0, Module 2, Section, 4.2.1 and ISO/IEC 17025:2005(E), Clause 4.2.1*		
2.6	Is the system's documentation communicated to, understood by, available to, and implemented by the appropriate personnel? *QSM Rev. 5.0, Module 2, Section, 4.2.1 and ISO/IEC 17025:2005(E), Clause 4.2.1*		
2.7	Are copies of all management system documentation provided to DOECAP in English? *QSM Rev. 5.0, Module 2, Section, 4.2.1 and ISO/IEC 17025:2005(E), Clause 4.2.1*		
2.8	Has top management provided evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1and TNI ELM2-V1, Section 4.2.8.1*		

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2.9	Is management responsible for: a) Defining the minimum qualifications, experience, and skills necessary for all positions in the laboratory; b) Ensuring that all laboratory technical staff has demonstrated capability in the activities for which they are responsible. Are these demonstrations documented; c) Ensuring the training of each member of the technical staff is kept up-to-date (on-going) by the following: • Each employee training file must contain a certification that the employee has read, understands, and is using the latest version of the management system records relating to his/her job responsibilities; • Training courses or workshops on specific equipment, analytical techniques, or laboratory procedures are all recorded; and • Review of analyst work by relevant technical managers on an on-going basis is recorded or another annual demonstration is performed by one of the following: a. Acceptable performance of a blind sample (single or double blind to the analyst); b. At least four consecutive laboratory control samples with acceptable levels of precision and bias. The laboratory determines the acceptable levels of precision and bias prior to analysis; or c. If the above cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst. d) Recording all analytical and operational activities of the laboratory; e) Ensuring adequate supervision of all personnel employed by the laboratory; f) Ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored; and g) Recording the quality of all data reported by the laboratory? *QSM, Rev. 5.0, Module 2, Section4.2.3 and ISO/IEC 17025 Clause 4.2.4*		

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2.10	Has the laboratory established and maintained a documented data integrity system? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1 and ISO/IEC17025 Clause 4.2.8.1*		
2.11	Are the four (4) required elements included within the data integrity system including; 1) data integrity training, 2) signed data integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1 and ISO/IEC 17025 Clause 4.2.8.1*		
2.12	Are the data integrity procedures signed and dated by top management? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1 and ISO/IEC 17025 Clause 4.2.8.1*		
2.13	Has management annually reviewed data integrity procedures and updated as needed? a) Does laboratory management provide a procedure for confidential reporting of data integrity issues in their laboratory? A primary element of the procedure is to assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern. b) In instances of ethical concern, does the procedure include a process whereby laboratory management is to be informed of the need for any further detailed investigation? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1 and ISO/IEC 17025 Clause 4.2.8.1*		
2.14	Does the laboratory have a documented program to detect and deter improper or unethical actions? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1 and TNI EL-VIM2-2009, Section, 4.2.8.1 a) and b)*		

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2.15	Are data produced according to the project-specific requirements as specified in the final, approved project-planning documents, such as the approved Quality Assurance Project Plan (QAPP), when these documents are provided to the laboratory? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1c) and TNI EL-VIM2-2009, Section, 4.2.8.1 a) and b)*		
2.16	Are the following minimum elements of an acceptable program for detecting and deterring improper or unethical actions implemented: i. Has an ethics policy been read and signed by all personnel; ii. Has initial and annual ethics training been conducted: iii. Have analysts recorded an explanation and signed off on all manual changes to data; and iv. Where available in the instrument software, are all electronic tracking and audit functions enabled? *QSM, Rev. 5.0, Module 2, Section 4.2.8.1c) and TNI EL-VIM2-2009, Section, 4.2.8.1 a) and b)*		
2.17	Is the quality manager responsible for maintaining the currency of the quality manual and reviews (or oversee review of) the quality manual at least annually? *QSM, Rev. 5.0, Module 2, Section 4.2.8.2;TNI EL-VIM2-2009, Section 4.2.8.2; and AIHA-LAP2A.4.2.2*		
2.18	Has the quality manual been updated if needed? *QSM, Rev. 5.0, Module 2, Section 4.2.8.2;TNI EL-VIM2-2009, Section 4.2.8.2; and AIHA-LAP 2A.4.2.2*		

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2.19	Does the quality manual contain or reference: a) all maintenance, calibration and verification procedures used by the laboratory in conducting tests; b) major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests; c) verification practices, which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal QC schemes; d) procedures for reporting analytical results; e) the organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts; f) procedures to ensure that all records required under this Standard are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force; g) job descriptions of key staff and reference to the job descriptions of other laboratory staff; h) procedures for achieving traceability of measurements; i) a list of all methods under which the laboratory performs its accredited testing; j) procedures for ensuring the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work; k) procedures for handling samples; l) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur; m) policy for permitting departures from documented policies and procedures or from standard specifications;		.

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2.19con't	n) procedures for dealing with complaints; o) procedures for protecting confidentiality (including national security concerns), and proprietary rights; p) procedures for audits and data review; q) procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training; r) policy addressing the use of unique electronic signatures, where applicable; s) procedures for procurement of standards; t) procedures for data management including validation, verification, and purging of electronic data and data systems; u) procedures for manual entry of raw data from analytical measurements that are not interfaced to LIMS and the verification and records of the accuracy of manually entered data; v) procedures for making changes to electronic data (including establishing the requirements for a hardcopy or electronic log to record all changes to electronic data that affect data quality); w) procedures for how electronic data are processed, maintained, and reported; x) procedures for ensuring that data review includes all quality-related steps in the analytical process, including sample preparation, dilution calculations, chromatography evaluation, and spectral interpretations (The SOP requires that records of data review be maintained and available for external review); y) a list of all current certifications and accreditations that the laboratory holds and the scope of certification or accreditation (with expiration date) for each; z) Health and Safety, (e.g., Chemical Hygiene Plan); and aa) Materials (Waste) Management? *QSM, Rev. 5.0, Module 2, Section 4.2.8.4a) through z) and TNI EL-VIM2-2009, Section 4.2.8.4 a) through r)*		

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2.20	Do internal data reviews consist of a tiered or sequential system of verification, consisting of at least three tiers, 100% review by the analyst, 100% verification review by a technically qualified supervisor or data review specialist, and a final administrative review? *QSM, Rev. 5.0, Module 2, Section 4.2.8.4 and TNI EL-VIM2-2009, Section 4.2.8.4 p, AIHA-LAP 2A.5.4.6*		
2.21	Does the analyst and verification review include at least the following procedures: i. Determination of whether the results meet the laboratory-specific QC criteria; ii. Checks to determine consistency with project-specific measurement performance criteria (MPCs) if available; iii. Checks to ensure that the appropriate sample preparatory and analytical procedures and methods were followed, and that chain-of-custody and holding time requirements were met; iv. Checks to ensure that all calibration and QC requirements were met; v. Checks for complete and accurate explanations of anomalous results, corrections, and the use of data qualifiers in the case narrative; and vi. Procedures for audits and data review? *QSM, Rev. 5.0, Module 2, Section 4.2.8.4 and TNI EL-VIM2-2009, Section 4.2.8.4 p, AIHA-LAP 2A.5.4.7*		
2.22	If the instrument does not have an audit trail, does the laboratory have procedures to record the integrity of the data? *QSM, Rev. 5.0, Module 2, Section 4.2.8.4 and TNI EL-VIM2-2009, Section 4.2.8.4 p*		
2.23	Does the final administrative review verify that previous reviews were recorded properly and that the data package is complete? *QSM, Rev. 5.0, Module 2, Section 4.2.8.4 and TNI EL-VIM2-2009, Section 4.2.8.4 p*		

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2.24	Does the quality manager or designee review a minimum of 10% of all data packages for technical completeness and accuracy? *QSM, Rev. 5.0, Module 2, Section 4.2.8.4*		
2.25	If electronic audit trail functions are available, are they in use at all times, and is associated data accessible? *QSM, Rev. 5.0, Module 2, Section 4.2.8.4 and TNI EL-VIM2-2009, Section 4.2.8.4 p*		
2.26	Does the laboratory maintain procedures that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods? a) Do these documents contain adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result? b) Are the relevant procedures readily accessible to all personnel? c) Does each procedure clearly indicate the effective date of the document, the revision number, and the signature(s) of the approving authority? d) Are any changes, including the use of a selected option, documented and included in the laboratory's method records? e) Does the laboratory have and maintain a procedure for each accredited analyte or method?		

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2.26 con't	f) Does each method include or reference the following topics where applicable: i. identification of the method; ii. applicable matrix or matrices; iii. limits of detection and quantitation; iv. scope and application, including parameters to be analyzed; v. summary of the method; vi. definitions; vii. interferences; viii. safety; ix. equipment and supplies; x. reagents and standards; xi. sample collection, preservation, shipment and storage; xii. quality control; xiii. calibration and standardization; xiv. procedure; xv. data analysis and calculations; xvi. method performance; xvii. pollution prevention; xviii. data assessment and acceptance criteria for quality control measures; xix. corrective actions for out-of-control data; xx. contingencies for handling out-of-control or unacceptable data; xxi. waste management;		

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2.26 con't	xxii. references; xxiii. any tables, diagrams, flowcharts and validation data xxiv. equipment/instrument maintenance; xxv. computer hardware and software; and xxvi. troubleshooting? i) Are all technical procedures (e.g., sample preparation, analytical procedures, sample storage, or sample receipt) reviewed for accuracy and adequacy at least annually, and updated if necessary? Do personnel having the pertinent background, recorded, and made available for assessment conduct such reviews? h) Does the laboratory develop, maintain, and implement procedures, however named, for Chemical Hygiene, Waste Management, and Radiation Protection (as applicable)? *QSM, Rev. 5.0, Module 2, Section 4.2.8.5, TNI EL-VIM2-2009, Section 4.2.8.5 a) through f)*		

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3.0	**Document Control**		
3.1	Do the procedure(s) adopted ensure that: a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed; b) documents are periodically reviewed for continuing suitability and compliance with applicable requirements; c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked; e) affected personnel are notified of changes to management systems documents and supporting procedures, including technical documents; f) reviews (internal or external) of management system documentation are maintained and made available for assessment; and g) any documents providing instructions to laboratory personnel (e.g., operator aids) are considered part of the management system and are subject to document control procedures? *QSM, Rev. 5.0, Module 2, Section 4.3.2.2 and ISO/IEC 17025, Clause 4.3.2.2*		

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4.0	**Review of Requests, Tenders and Contracts**		
4.1	Has the laboratory established and maintained procedures for the review of requests, tenders and contracts? Do the policies and procedures for these reviews leading to a contract for testing and/or calibration ensure that: a) the requirements, including the methods to be used, are adequately defined, documented and understood, b) the laboratory has the capability and resources to meet the requirements; c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements ? ***NOTE* 1**: The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way. ***NOTE* 2:** The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparison or proficiency testing and/or the running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc. ***NOTE* 3**: A contract may be any written or oral agreement to provide a customer with testing and/or calibration services. *ISO/IEC 17025, Clause 4.4.1*		
4.2	Are any differences between the request or tender and the contract resolved before any work commences? *ISO/IEC 17025, Clause 4.4.1*		
4.3	Is each contract acceptable both to the laboratory and the customer? *ISO/IEC 17025, Clause 4.4.1*		

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4.4	Are records of reviews, including any significant changes, maintained? *ISO/IEC/IEC 17025, Clause 4.4.2*		.
4.5	Are records maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract? ***NOTE*:** For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained. *ISO/IEC17025, Clause 4.4.2*		
4.6	Does the review of requests, tenders, and contracts also cover any work that is subcontracted by the laboratory? *ISO/IEC 17025, Clause 4.4.3*		.
4.7	Is the customer informed of any deviation from the contract? *ISO/IEC/IEC 17025, Clause 4.4.4*		
4.8	If a contract needs to be amended after work has commenced, is the contract review process repeated and amendments communicated to the affected personnel? *ISO/IEC 17025, Clause 4.4.5*		

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5.0	**Subcontracting of Environmental Test**		
5.1	When a laboratory *subcontracts* work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), is this work placed with a competent subcontractor? **NOTE**: A component subcontractor is one that, for example, complies with ISO/IEC 17025 for the work in question. *ISO/IEC 17025 Clause 4.5.1*		
5.2	Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing? *ISO/IEC 17025 Clause 4.5.2*	A	
5.3	Is the laboratory responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used? *ISO/IEC 17025 Clause 4.5.3*		
5.4	Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with ISO/IEC 17025 for the work in question? *ISO/IEC 17025 Clause 4.5.4*		.
5.5	When a laboratory subcontracts work, is the work placed with a laboratory that meets applicable statutory and regulatory requirements for performing the test and submitting the results of tests performed? *TNI EL-VIM2-2009, Section 4.5.5*		

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5.6	Is the laboratory performing the subcontracted work indicated in the final report? *TNI EL-VIM2-2009, Section 4.5.5*		
5.7	Does the laboratory make a copy of the subcontractor's report available to the client when requested? *TNI EL-VIM2-2009, Section 4.5.4*		
5.8	Does the laboratory ensure and document that subcontracted (sub-tier) laboratories meet the requirements of the QSM? *QSM, Rev. 5.0, Module 2, Section 4.5.6*		
5.9	Are subcontracted laboratories performing analytical services for the DOE approved by the appropriate DOE subcontractor representative? *QSM, Rev. 5.0, Module 2, Section 4.5.7*		
5.10	Do subcontracted laboratories receive project-specific approval from the DOE customer before any samples are analyzed? *QSM, Rev. 5.0, Module 2, Section 4.5.8*		
5.11	Do the requirements for subcontracting laboratories also apply to the use of any laboratory under the same corporate umbrella, but at a different facility or location? *QSM, Rev. 5.0, Module 2, Section 4.5.9*		
5.12	Does the subcontracted or outsourced management systems elements (such as data review) or outsourced personnel comply with the laboratory's overall management system, comply with requirements of the QSM, and are subject to review/approval by the DOE customer? *QSM, Rev. 5.0, Module 2, Section 4.5.10*		

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6.0	**Purchasing Services and Supplies**		
6.1	Does the laboratory have policy (ies) and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations? *ISO/IEC Clause 4.6.1*		.
6.2	Do procedures exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations? *ISO/IEC/IEC Clause 4.6.1*		
6.3	Do records for services and supplies that may affect the quality of environmental tests include the following, where applicable: a) Date of receipt; b) Expiration date; c) Source; d) Lot or serial number; e) Calibration and verification records; and f) Accreditation or certification scopes/certificates? *QSM Rev. 5.0, Module 2, Section 4.6.1*		
6.4	Does the laboratory ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned? *ISO/IEC 17025, Clause 4.6.2*		
6.5	Do these services and supplies comply with specified requirements? *ISO/IEC 17025, Clause 4.6.2*		

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6.6	Are records of actions taken to check compliance maintained? *ISO/IEC 17025, Clause 4.6.2*		
6.7	Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered? ***NOTE:*** The description may include type, class, precise identification, specifications, drawings, inspection instructions, and other technical data including approval of test results, the quality required and the management system standard under which they were made. *ISO/IEC 17025, Clause 4.6.3*		
6.8	Are these purchasing documents reviewed and approved for technical content prior to release? *ISO/IEC 17025, Clause 4.6.3*		
6.9	Does the laboratory evaluate suppliers of critical consumables, supplies and services that affect the quality of testing and calibration, and maintain records of these evaluations and list those approved? *ISO/IEC 17025, Clause 4.6.4*		

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7.0	**Calibration Requirements**		
7.1	Are records maintained of each item of equipment and its software significant to the tests/or calibrations performed and do the records include at least the following: a) the identity of the item of equipment and its software; b) the manufacturer's name, type identification, and serial number or other unique identification; c) checks that equipment complies with the specification ; d) the current location, where appropriate; e) the manufacturer's instructions, if available, or reference to their location; f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; g) the maintenance plan, where appropriate, and maintenance carried out to date; h) any damage, malfunction, modification or repair to the equipment? *ISO/IEC 17025 Clause 5.5.5 a) – h)*		
7.2	Are the following also implemented and documented: a) Date placed in service; b) Condition when received (e.g., new, used, reconditioned); c) Operational status; and d) Instrument configuration and settings? *QSM Rev. 5.0, Module 2, Section 5.5.5 i) – k)*		
7.3	Is check weighing performed daily using NIST-traceable weights? Do the balance checks bracket the range of use? Are daily balance checks documented? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table and TNI EL-V1M2, Section 5.5.13.1 a)*		

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7.4	Is Class 1 (formerly referred to as Class S) certified check weights calibrated every five years using recognized National Metrology Institute, such as NIST, traceable references, when available? ***NOTE:*** The date for recalibration of the check weights is stated on the certificate of calibration supplied by the accredited calibration firm. *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table and TNI EL-V1M2-2009, Section 5.5.13.1 b) and d)*		
7.5	Are all support equipment, including balances, calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table and TNI EL-V1M2-2009, Section 5.5.13.1 b) and d) AIHA-LAP Appendix H Table 5-1*		.
7.6	Does the laboratory maintain a copy of the Certificate of Calibration from an ISO/IEC accredited calibration laboratory? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table and TNI EL-V1M2-2009, Section 5.5.13.1 b) and d) AIHA-LAP Appendix H 5.2*		
7.7	Prior to use, are balances checked on a daily basis using two standards weights that bracket the expected mass? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table*		.
7.8	Are the acceptance criteria for a top-loading balance ±2% or ±0.02 grams whichever is greater? Are the acceptance criteria for an analytical balance ±0.1% or ±0.5 mg. whichever is greater? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table*		

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7.9	Are liquid in-glass thermometers verified against a NIST-traceable standard before the first use and annually? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 and TNI EL-V1-2009, Section 5.5.13.1 b), AIHA-LAP Appendix H, Table 5-1*		
7.10	Are electronic thermometers checked before use and on a quarterly basis? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 and TNI EL-V1-2009, Section 5.5.13.1 b)*		
7.11	Are mechanical volumetric pipettes checked daily before use and is the bias within ± 2% of the nominal volume? ***NOTE:*** For variable volume pipettes, the nominal value is the volume of use. *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table*		
7.12	Are glass microliter syringes checked upon receipt and upon evidence of deterioration? *QSM Rev. 5.0, Module 2, Section 5.5.13.1 Table*		
7.13	Are samples stored according to the conditions specified by the preservation protocol? *TNI-EL-V1M2, Section 5.8.9 a) and i)*		
7.14	Are samples that require thermal preservation stored under refrigeration that is +/-2°C of the specified preservation temperature unless regulatory or method specific criteria exist? *TNI-EL-V1M2, Section 5.8.9 a) and i)*		
7.15	For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable. *TNI-EL-V1M2, Section 5.8.9 a) and i)*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
7.16	Are refrigerator temperatures monitored daily and recorded in a logbook or via electronic media such as a data logger? Daily temperature monitoring of refrigerators and freezers is required for all samples that require temperature preservation. Daily monitoring for rad samples other than Tritium will not be required. The requirement for daily monitoring for sample storage refrigerators and freezers will not apply in the event that samples are not being stored from a DOE site. *QSM Rev. 5.0, Module 2, Section 5.5.13.1 f)*		
7.17	Does the laboratory have procedures for recording catastrophic failure of support equipment (e.g., refrigerators, freezers) and that addresses identification of affected samples and customer notification? *QSM Rev. 5.0, Module 2, Section 5.5.13.1.a)*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
8.0	**Service to the Client**		
8.1	**Clarification Only** The following is a clarification of *ISO/IEC Clause 4.7.1:* Examples of situations for which immediate clarification or feedback is sought from the customer include the following: a) The customer has specified incorrect, obsolete, or improper methods; b) Methods require modifications to ensure achievement of project-specific objectives contained in planning documents (e.g., difficult matrix, poor performing analyte); c) Project planning documents (e.g., Quality Assurance Project Plan (QAPP) or Sampling and Analysis Plan (SAP)) are missing or requirements (e.g., action levels, detection and quantification capabilities) in the documents require clarification; or d) The laboratory has encountered problems with sampling or analysis that may impact results (e.g., improper preservation of sample). *QSM Rev. 5.0, Module 2, Section 4.7.1*	NA	Clarification only - response not required.
	Complaints		
8.2	Does the laboratory have a policy and procedure for the resolution of complaints received from customers or other parties? *ISO/IEC 17025 Clause 4.8*		
8.3	Are records maintained of all investigations and corrective actions taken by the laboratory? *ISO/IEC 17025 Clause 4.8*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
9.0	**Control of Nonconforming Environmental Testing Work**		
9.1	Does the laboratory have policy (ies) and procedures that are implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer? *ISO/IEC 17025 Clause 4.9.1*		
9.2	Does the policy and procedures ensure that: a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified; b) an evaluation of the significance of the nonconforming work is made; c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work; d) where necessary, the customer is notified and work is recalled; e) the responsibility for authorizing the resumption of work is defined? ***NOTE:*** Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management and technical operations. Examples are customer complaints, I n strument calibration, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits. *ISO/IEC 17025 Clause 4.9.1*		
9.3	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures a r e the corrective action procedures for internal audits promptly followed? *ISO/IEC17025 Clause 4.9.2*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
9.4	Does the laboratory notify all affected customers of potential data quality issues resulting from nonconforming work? *QSM Rev. 5.0, Module 2, Section 4.9.3*		
9.5	Is notification performed according to a written procedure? Q*SM Rev. 5.0, Module 2, Section 4.9.3*		
9.6	Are records of corrections taken to resolve the nonconformance submitted to the customer(s) in a timely and responsive manner? *QSM Rev. 5.0, Module 2, Section 4.9.3*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
10.0	**Improvement**		
10.1	Does the laboratory continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review? *ISO/IEC 17025 Clause 4.10*		
10.2	**General** Has the laboratory established policy and a procedure and designation of appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified? ***NOTE:*** A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, and feedback from customers and from staff observations. *TNI EL-VI-M2-2009, Section 4.11.1 and ISO/IEC 17025, Clause 4.11.1*		
10.3	**Cause Analysis** Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem? ***NOTE:*** Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration. *TNI EL-VIM2-2009, Section 4.11.2 and ISO/IEC 17025, Clause 4.11.2*		
10.4	**Selection and Implementation of Corrective Actions** Where corrective action is needed, does the laboratory identify potential corrective actions? *TNI EL-VIM2-2009, Section 4.11.3 and ISO/IEC 17025, Clause 4.11.3*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
10.5	Does the laboratory select and implement the action(s) most likely to eliminate the problem and to prevent recurrence? *TNI EL-VI-M2-2009, Section 4.11.3 and ISO/IEC 17025, Clause 4.11.3*		
10.6	Does the laboratory document and implement any required changes resulting from corrective action investigations? *TNI EL-VIM2-2009, Section 4.11.3 and ISO/IEC 17025, Clause 4.11.3*		
10.7	Does the laboratory monitor the results to ensure that the corrective actions taken have been effective? *ISO/IEC 17025:2005 Clause 4.11.4*		
10.8	**Additional Audits** Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with ISO/IEC/IEC 17025, does the laboratory ensure that the appropriate areas of activity are audited in accordance with internal audits as soon as possible? ***NOTE:*** Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified. *ISO/IEC 17025:2005 Clause 4.11.5*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
10.9	Does the laboratory have documented procedure(s) to address corrective actions, implementation of corrective actions, and internal audits for corrective actions? Do these procedure(s) also include: a) which individual(s) or positions are responsible for assessing each QC data type; and b) which individual(s) or positions are responsible for initiating and/or recommending corrective actions? *TNI EL-VIM2-2009, Section 4.11.6*		
10.10	Is cause analysis applied to failures that indicate a systematic error? *TNI EL-VIM2-2009, Section 4.11.7*		
10.11	Does the laboratory have and use a record system for tracking corrective actions to completion and for analyzing trends to prevent the recurrence of the nonconformance? *QSM Rev. 5.0, Module 2, Section 4.11.8, AIHA-LAP 2A.4.11.1*		
10.12	Are approved corrective actions developed to address findings during DOECAP audits/assessments implemented? *QSM Rev. 5.0, Module 2, Section 4.11.8*		
10.13	Are any changes to approved corrective action plans approved by the DOECAP Operations Team, as appropriate? *QSM Rev. 5.0, Module 2, Section 4.11.8*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
10.14	The following is guidance to *ISO/IEC Clause 4.6.1:* Willful avoidance of approved corrective action implementation may result in the issuance of a DOECAP Priority I finding. As a result, work may be discontinued until implementation is verified by the DOECAP Operations Team.	NA	Clarification only response not required.

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
11.0	**Preventive Action**		
11.1	Are needed improvements and potential sources of nonconformities, either technical or concerning the management system, identified? *ISO/IEC 17025 Clause 4.12.1*		
11.2	When improvement opportunities are identified or if preventive action is required, are action plans developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement? *ISO/IEC 17025 Clause 4.12.1*		
11.3	Do procedures for preventive action include the initiation of actions and the application of controls to ensure that they are effective? *ISO/IEC 17025 Clause 4.12.2*		
11.4	Are records of preventive actions maintained for review? *QSM Rev. 5.0, Module 2, Section 4.12.1*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
12.0	**Control of Records**		
	General		
12.1	Does the laboratory establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records? *ISO/IEC 17025 Clause 4.13.1.1*		
12.2	Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions? *ISO/IEC 17025 Clause 4.13.1.1*		
12.3	Are all records legible, 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? ***NOTE:*** Records may be in any media, such as hard copy or electronic media. *ISO/IEC 17025 Clause 4.13.1.2*		
12.4	Are retention times of records established? *ISO/IEC 17025 Clause 4.13.1.2*		
	Clarification ONLY Dual storage of records at separate locations is considered an acceptable option for the purpose of protecting records against fire, theft, or loss. *QSM Rev. 5.0, Module 2, Section 4.13.1.2*		
12.5	Are all records held secure and in confidence? *ISO/IEC 17025 Clause 4.13.1.3*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
12.6	Does the laboratory have procedures to protect and back-up records stored electronically and to prevent unau thorized access to or amendment of these records? *ISO/IEC 17025 Clause 4.13.1.4*		
12.7	Does the laboratory retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period? ***NOTE 1**:* In certain fields it may be impossible or impractical to retain records of all original observations. ***NOTE 2:*** Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback. *ISO/IEC 17025 Clause 4.13.2.1*		
12.8	Do the records for each test or calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original? *ISO/IEC 17025 Clause 4.13.2.1*		
12.9	Do the records include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results? *ISO/IEC 17025 Clause 4.13.2.1*		
12.10	Are observations, data and calculations recorded at the time they are made and identifiable to the specific task? *ISO/IEC 17025 Clause 4.13.2.2*		

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12.11	When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and the correct value entered alongside? *ISO/IEC 17025 Clause 4.13.2.3*		
12.12	Are all such alterations to records signed or initialed by the person making the correction? *ISO/IEC 17025 Clause 4.13.2.3*		
12.13	In the case of records stored electronically, are equivalent measures taken to avoid loss or change of original data? *ISO/IEC 17025 Clause 4.13.2.3*		
12.14	Has the laboratory established a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation? *TNI EL-VIM2-2009, Section 4.13.3 a)*		
12.15	Does this system produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts? *TNI EL-VIM2-2009, Section 4.13.3 a)*		
12.16	Does the laboratory retain all records for a minimum of five (5) years from generation of the last entry in the records? *TNI EL-VIM2-2009, Section 4.13.3 b)*		
12.17	Are records available for the auditing bodies? *TNI EL-VIM2-2009, Section 4.13.3c)*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
12.18	Are records that are stored only on electronic media supported by the hardware and software for their retrieval? *TNI EL-VIM2-2009, Section 4.13.3d)*		
12.19	Is the access to archived information documented with an access log? *TNI EL-VIM2-2009, Section 4.13.3 e)*		
12.20	Is all information necessary for the historical reconstruction of data maintained by the laboratory? i) all raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records); ii) a written description or reference to the specific method used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value; iii) laboratory sample ID code; iv) date of analysis; v) time of analysis is required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations); vi) instrumentation identification and instrument operating conditions/parameters (or reference to such data); vii) all manual calculations; viii) analyst's or operator's initials/signature or electronic identification;		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
12.20 con't	ix) test results; x) standard and reagent origin, receipt, preparation, and use; xi) calibration criteria, frequency and acceptance criteria; xii) data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions; xiii) quality control protocols and assessment; xiv) electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; xv) method performance criteria including expected quality control requirements; xvi) proficiency test results; xvii) records of demonstration of capability for each analyst, and xviii) a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record? *TNI EL-VIM2-2009, Section 4.13.3 f)*		
12.21	Are all generated data, except those generated by automated data collection systems, recorded legibly in permanent ink? *TNI EL-V1M2-2009 Section 4.13.3 g) i) ii), AIHA-LAP 2A.4.13.5*		
12.22	Are the following requirements implemented: i) Are individuals who are making corrections to records dating and initialing the corrections? ii) Are corrections due to reasons other than transcription errors specified? iii) Do records for changes made to data (either hardcopy or electronic) include the identification of the person who made the change and the date of the change? *TNI EL-V1M2-2009 Section 4.13.3 g) i) ii), QSM Rev. 5.0 Section 4.13.3 iii), AIHA-LAP 2A.4.13.4*	A	

Audit ID:	Laboratory:	Auditor:

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
12.23	If permanent, bound laboratory notebooks (logbooks) are not used are measures in place to prevent the removal or addition of pages? *QSM Rev. 5.0, Module 2,Section 4.13.4*		
12.24	Electronic logbooks are acceptable. For permanent, bound logbooks the following applies: a) Laboratory notebook pages pre-numbered, all entries signed or initialed and dated by the person responsible for performing the activity at the time the activity is performed, and all entries recorded in chronological order? b) All notebook pages closed when the activities recorded are completed or carried over to another page? c) The person responsible for performing the closure is the person who performed the last activity recorded? d) Closure occurred at the end of the last activity recorded on a page, as soon as practicable thereafter? e) Documentation of the closure includes analyst initials and date? f) Each laboratory notebook has a unique serial number clearly displayed? *QSM Rev. 5.0, Module 2, Section 4.13.4*		
12.25	Does the laboratory have procedures for the independent review of technical and quality records to ensure they are legible, accurate, and complete? *QSM Rev. 5.0, Module 2, Section 4.13.5*		
12.26	Has the laboratory established a review frequency for all records such as laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, verification, validation, and archival? *QSM Rev. 5.0. Module 2, Section 4.13.6*		
12.27	Are records of the reviews maintained and made available for review? *QSM Rev. 5.0, Module 2, Section 4.13.6*		

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12.28	If not self-explanatory (e.g., a typo or transposed number), does corrections to technical and quality records also include a justification for the change? *QSM 5.0, Module 2, Section 4.13.7*		.
12.29	Does the record control system SOP address the requirements for access to and control of the files, including accountability for any records removed from storage? *QSM 5.0. Module 2, Section 4.13.8*		
12.30	Are all SOPs archived for historical reference, per regulatory or customer requirements? *QSM 5.0, Module 2, Section 4.13.9*		
12.31	Does the laboratory have a procedure for permanent laboratory closure and disposal of any remaining records associated with DOE analytical data? *QSM 5.0, Module 2, Section 4.13.9*		
12.32	Does the laboratory have a system in place to record incidents involving spillage of customer samples or significant spillage of chemicals? *QSM 5.0, Module 2, Section 4.13.10*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
13.0	**Internal Audits (ISO/IEC 17025:2005(E), Clause 4.14**		
13.1	Does the laboratory periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and ISO/IEC/IEC 17025? ***NOTE:*** The cycle for internal auditing should normally be completed in one year. *ISO/IEC 17025:2005 Clause 4.14.1, AIHA-LAP 2A.4.14.1*		
13.2	Does the internal audit program address all elements of the management system, including the testing and/or calibration activities? *ISO/IEC 17025:2005 Clause 4.14.1*		
13.3	Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management? *ISO/IEC 17025:2005 Clause 4.14.1*		
13.4	Do trained and qualified personnel, who are, wherever resources permit, independent of the activity to be audited, carry out internal audits? *ISO/IEC 17025:2005 Clause 4.14.1*		
13.5	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, does the laboratory make timely corrective actions, and notify customers in writing if investigations show that the laboratory results may have been affected? *ISO/IEC 17025:2005 Clause 4.14.2*		
13.6	For the area of activity audited, are the audit findings and corrective actions that arise from them recorded? *ISO/IEC 17025:2005 Clause 4.14.3*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
13.7	If the laboratory is part of an organization performing activities other than testing and/or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory defined in order to identify potential conflicts of interest? *ISO/IEC 17025:2005 Clause 4.1.4*		
13.8	Do follow-up audit activities verify and record the implementation and effectiveness of corrective actions? *ISO/IEC17025: 2005 Clause 4.14.4*		
13.9	Additional Items a) Does the laboratory have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results? b) Does the laboratory management ensure that these actions are discharged within the agreed time frame? c) Is the internal audit schedule completed annually? *TNI EL-V1M2-2009 Section 4.14.5*		
13.10	Does the audit schedule ensure that all areas of the laboratory are reviewed over the course of one year? *QSM Rev. 5.0, Module 2, Section 4.14.6*		
13.11	Are audit personnel trained and qualified in the specific management system element or technical area under review? *QSM Rev 5.0, Module 2, Section 4.14.7*		
13.12	Has the laboratory determined the training and qualification requirements for audit personnel, including quality managers, and established procedures to ensure that audit personnel are trained and qualified (i.e., have the necessary education or experience required for their assigned positions)? *QSM Rev 5.0, Module 2, Section 4.14.7*		

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13.13	Are these requirements and procedures documented or recorded? *QSM Rev 5.0, Module 2, Section 4.14.7*		
13.14	Has management ensured that sufficient resources are available so all internal audits are conducted by personnel independent of the activity to be audited? *QSM Rev. 5.0, Module 2, Section 4.14.8*		
13.15	Do personnel conducting independent assessments have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management? *QSM Rev. 5.0, Module 2, Section 4.14.8*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
14.0	**Management Reviews (ISO/IEC 17025/2005(E), Clause 4.15**		
14.1	In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements? Does the review include: • the suitability of policies and procedures; • reports from managerial and supervisory personnel; • the outcome of recent internal audits; • corrective and preventive actions; • assessments by external bodies; • the results of interlaboratory comparisons or proficiency tests; • changes in the volume and type of the work; • customer feedback; • complaints; • recommendations for improvement; • other relevant factors, such as quality control activities, resources and staff training. ***NOTE 1:*** A typical period for conducting a management review is once every 12 months. ***NOTE 2:*** Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year. ***NOTE 3:*** A management review includes consideration of related subjects at regular management meetings. *ISO/IEC17025: 2005(E), Clause 4.15.1*		

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	Management reviews and internal audits are separate activities. The management review is not performed in lieu of an internal audit. It is an independent, executive review of the laboratory's management system. *QSM Rev. 5.0, Module 2, Section 4.15.1*	NA	**Clarification Only – Response Not Required**
14.2	Does management review also include laboratory radiation health and safety, radioactive hazardous waste, and radioactive materials management functions, where applicable (i.e., when radioactive samples are analyzed)? *QSM Rev. 5.0, Module 2, Section 4.15.1*		
15.0	**Data Integrity Investigations (TNI STANDARD, VOLUME 1, 2009 Section 4.16)**		
15.1	Are all investigations resulting from data integrity issues conducted in a confidential manner until they are completed? *TNI 2009 El-V1M2-2009, Section 4.16*		
15.2	Are these investigations documented, as well as any notifications made to clients receiving any affected data? *TNI 2009 El-V1M2-2009, Section 4.16*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
16.0	**Technical Requirements**		
	General (ISO/IEC 17025:2005(E), Clause 5.1		
	Personnel		
16.1	Does laboratory management ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates? ***NOTE 1:*** In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or specified by the customer. *ISO/IEC 17025:2005(E), Clause 5.2.1*		
16.2	When using staff that is undergoing training, is appropriate supervision provided? *ISO/IEC 17025:2005(E), Clause 5.2.1*		
16.3	Are personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required? *ISO/IEC 17025:2005(E), Clause 5.2.1*		
16.4	Does the management of the laboratory formulate the goals with respect to the education, training and skills of the laboratory personnel? *ISO/IEC 17025:2005(E), Clause 5.2.2*		
16.5	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel? *ISO/IEC 17025:2005(E), Clause 5.2.2*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
16.6	Are the training programs relevant to the present and anticipated tasks of the laboratory? *ISO/IEC 17025:2005(E), Clause 5.2.2*		
16.7	Is the effectiveness of the training actions taken evaluated? *ISO/IEC 17025:2005(E), Clause 5.2.2*		
16.8	Does the laboratory use personnel who are employed by, or under contract to, the laboratory? CLARIFICATION: The laboratory ensures that all personnel, including part-time, temporary, contracted, and administrative personnel, are trained in the basic laboratory QA and health and safety programs. *QSM Rev. 5.0, Section 5.2.3 and ISO/IEC 17025:2005(E), Clause 5.2.3*		
16.9	Where contracted and additional technical and key support personnel are used, does the laboratory ensures that such personnel are supervised and competent and that they work in accordance with the laboratory's management system? *QSM Rev. 5.0, Section 5.2.3 and ISO/IEC 17025:2005(E), Clause 5.2.3*		
16.10	Does the laboratory maintain current job descriptions for managerial, technical, and key support personnel involved in tests and/or calibrations? *ISO/IEC 17025:2005(E), Clause 5.2.4*		
16.11	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period? *TNI EL-V1M4-2009 Section 1.6.2*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes

16.12	Is documentation maintained for each initial DOC in a manner that the following information is readily available for each affected employee:
	
	analyst(s) involved in preparation and/or analysis;
	
	a) matrix;
	b) analyte(s), class of analyte(s), or measured parameter(s);
	c) identification of method(s) performed;
	d) identification of laboratory-specific SOP used for analysis, including revision number;
	e) date(s) of analysis; and
	f) summary of analyses, including using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations of the sample (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory shall assess performance against established and documented criteria?
	
	TNI EL-V1M4-2009, Section 1.6.2.1 and 1.6.2.2 c)		

16.13	If the method or regulation does not specify an initial DOC, is the following procedure implemented? a) The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) sufficient to prepare four (4) aliquots at the concentration specified, or if unspecified, to a concentration of one (1) to four (4) times the limit of quantitation. b) At least four (4) aliquots shall be prepared and analyzed according to the method(s) either concurrently or over a period of days. *TNI-EL-V1M4, Section 1.6.2.2 a) and b); TNI-EL-V1M6, Section 1.6.2.2 a) and b)*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
16.14	Does the laboratory document that other approaches to initial DOC are adequately applied? *TNI-EL-V1M4, Section 1.6.2.2; TNI-EL-V1M6, Section 1.6.2.2*		
16.15	Does the laboratory have a documented procedure describing ongoing DOC? *TNI-EL-V1M4, Section 1.6.3.1; TNI-EL-V1M6, Section 1.6.3.1*		
16.16	Do the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or the TNI standard? *TNI-EL-V1M4, Section 1.6.3.1; TNI-EL-V1M4, Section 1.6.3.1*		
16.17	Does the laboratory have a documented procedure describing ongoing DOC? *TNI-EL-V1M4, Section 1.6.3.2; TNI-EL-V1M6, Section 1.6.3.2*		
16.18	Does the on-going demonstration include one of the following: a) Acceptable performance of a blind sample (single blind to the analyst); b) another initial DOC; c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCSs for each method for each analyst each year; d) a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary; e) if a) through d) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) may be performed. *TNI EL-V1M4, Section 1.6.3.2; TNI EL-V1M6, Section 1.6.3.2*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
16.19	Are the following job elements included as minimum requirements: • the responsibilities with respect to performing tests and/or calibrations; • the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results; • the responsibilities for reporting opinions and interpretations; • the responsibilities with respect to method modification and development and validation of new methods; • expertise and experience required; • qualifications and training programs; • and managerial duties? *ISO/IEC 17025:2005(E), Clause 5.2.4 Note*		
16.20	Has management authorized 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? *ISO/IEC 17025:2005(E), Clause 5.2.5*		
16.21	Does the laboratory maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel? *ISO/IEC 17025:2005(E), Clause 5.2.5*		
16.22	Are the records of this information readily available and does it include the date on which authorization and/or competence is confirmed? *ISO/IEC/IEC 17025:2005(E), Clause 5.2.5*		
16.23	Have requirements been developed for the qualification of the laboratory technical manager? *TNI EL-VIM2-2009, Section 5.2.6*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
16.24	Is data integrity training provided as a formal part of new employee orientation and also provided on an annual basis for all current employees? *TNI EL-V1M2-2009, Section 5.2.7*		
16.25	Does the initial data integrity training and the annual refresher training include a signature attendance sheet or other form of documentation that demonstrates all staff has participated and understand their obligations related to data integrity? *TNI EL-V1M2-2009, Section 5.2.7*		
16.26	At a minimum, are the following topics and activities included in data integrity training: a) organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping; b) training, including discussion regarding all data integrity procedures; c) data integrity training documentation; d) in-depth data monitoring and data integrity procedure documentation; and e) specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards? *TNI EL-V1M2-2009, Section 5.2.7*		
16.27	Does top management acknowledge its support for data integrity by implementing the specific requirements of the laboratory's data integrity program? *QSM, Rev. 5.0, Module 2, Section 5.2.7 and TNI EL-VIM2-2009, Section 5.2.7*		

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Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
16.28	Does the data integrity training include the following practices : a) Fabrication, falsification, or misrepresentation of data; b) Improper clock setting (time traveling) or improper date/time recording; c) Unwarranted manipulation of samples, software, or analytical conditions; d) Misrepresenting or misreporting QC samples; e) Improper calibrations; f) Concealing a known analytical or sample problem; g) Concealing a known improper or unethical behavior or action; h) Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official? *QSM, Rev. 5.0, Module 2, Section 5.2.7 and TNI EL-VIM2-2009, Section 5.2.7*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
17.0	**Accommodation and Environmental Conditions (ISO/IEC 17025/2005(E), Clause 5.3)**		
17.1	Are the following implemented to address accommodations and environmental conditions? a) When cross-contamination is a possibility, are samples suspected of containing high concentrations of analytes isolated from other samples? b) Are storage blanks stored with all volatile organic samples, regardless of suspected concentration levels? c) Are storage blanks used to determine if cross-contamination may have occurred? d) Does the laboratory have written procedures and criteria for evaluating storage blanks, appropriate to the types of samples being stored? e) Are the storage blanks stored in the same manner as the customer samples? f) Are storage blanks analyzed at a minimum of every 14 days and is the data from the analysis of the storage blanks available for review? g) If contamination is discovered, does the laboratory have a correction or action plan in place to identify the root cause and eliminate the source; determine which samples may have been impacted and address implementation measures to prevent recurrence? *QSM Rev. 5.0, Section 5.3.3 and ISO/IEC 17025/2005(E), Clause 5.3.3*		
17.2	Does the laboratory have a safety inspection program in place that includes routine inspections of laboratory areas for safety-related concerns? *QSM Rev. 5.0,Module 2, Section 5.3.5*		
17.3	Does the laboratory have established SOPs to ensure the following: a) that reported data are free from transcription and calculation errors; b) that all quality control measures are reviewed and evaluated before data are reported; c) that manual calculations are addressed; and d) that manual integrations are addressed? *QSM Rev. 5.0 Module 2, Section 5.4.7.1; ISO/IEC Clause 5.4.7.1*		

Audit ID:	Laboratory:	Auditor:

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
17.4	When manual integrations are performed, do raw data records include a complete audit trail for those manipulations (i.e., the chromatograms obtained before and after the manual integration must be retained to permit reconstruction of the results)? *QSM Rev. 5.0, Module 2, Section 5.4.7.1*		
17.5	Does the person performing the manual integration sign and date each manually integrated chromatogram and record the rationale for performing manual integration (electronic signature is acceptable)? *QSM Rev. 5.0, Module 2, Section 5.4.7.1*		
17.6	Are records for manual integrations maintained electronically as long as all requirements, including signature requirements, are met and the results can be historically reconstructed? *QSM Rev. 5.0, Module 2, Section 5.4.7.1*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
18.0	**Sample Handling, Sample Acceptance Policy, and Sample Receipt**		
18.1	Does the laboratory have a documented system for uniquely identifying the items (samples) to be tested, to ensure that there can be no confusion regarding the identity of such items at any time? *TNI EL-V1M2-2009, Section 5.8.5; AIHA-LAP 2A.5.8.3*		
18.2	Does the laboratory have SOPs in place to address the following: • checking sample preservation (pH); • proper containers; • preserving samples when required; • notifying clients of shipping or sample anomalies; • checking holding times and notification of laboratory personnel of short holding times; • use of fume hoods for opening samples and shipping containers; and, • radiation screening of samples, laboratory notification and labeling requirements for radioactive samples. *QSM Rev. 5.0, Module 2, Sections5.8.4 a) and 5.8.7.1 and TNI EL-VIM2-2009, Section 5.8.7.1*		
18.3	Prior to performing radiological surveys, is the radiological survey instrumentation checked for operational performance using a radiological source, a battery check, is performed, and the nominal background is measured? *QSM Rev. 5.0, Module 2, Section 5.8.4 c)*		
18.4	Are raw data records maintained to document radiological survey equipment performance? *TNI EL-V1M2, Section 5.5.13.1 c)*		
18.5	Are shipping containers from DOE sites opened under a ventilation hood? *QSM Rev. 5.0, Module 2, Section 5.8.4 b) and c)*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
18.6	Does the laboratory have a procedure and records to verify contamination control on a semiannual basis such as a smoke test or flow meter measurements? (Document the process for hood contamination control) *QSM Rev. 5.0, Module 2, Section 5.8.4 b) and c)*		
18.7	Are radiological surveys of sample shipping containers surveyed as soon as possible from the time of receipt by the laboratory? *QSM Rev. 5.0, Module 2, Section 5.8.4 b) and c)*		
18.8	Are materials submitted for industrial hygiene or asbestos analyses opened in an established manner to prevent worker exposure? *QSM Rev. 5.0, Module,2 Section 5.8.4 b)*		
18.9	Are sample receiving practices developed and implemented for the receipt of beryllium, beryllium oxide, and asbestos materials? *QSM Rev. 5.0, Module 2, Section 5.8.4 b)*		
18.10	Are all shipping containers from known radiological areas surveyed for radiological contamination on all external surfaces? *QSM Rev. 5.0, Module 2, Section 5.8.4 c)*		
18.11	Do the sample custodians document anomalies encountered in the sample receiving process? *ISO/IEC 17025, Clause 5.8.3*		
18.12	Is a sample receiving logbook or equivalent system used to record the chronology of sample entry into the laboratory including, but not limited to, time, date, customer, sample identification numbers, signature or initials of person making the entry? *TNI EL-VIM2-2009, Section 5.8.7.3; AIHA-LAP 2A.5.8.2, a, b, c*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
18.13	When the laboratory receives samples, is an internal Chain of Custody (COC) procedure in place? *QSM Rev. 5.0, Module 2, Section 5.8.8 and TNI EL-VIM2-2009, Section 5.8.8 AIHA-LAP 2A.5.8.1*		
18.14	Is internal custody maintained until final disposition or return of the sample to the client? *QSM Rev. 5.0, Module 2, Section 5.8.8*		
18.15	Do physical or administrative controls exist to ensure that: • COC is not broken during times that laboratory staff are present or not present; • access to all samples and subsamples is controlled and documented? *QSM Rev. 5.0, Module 2, Section 5.8.9*		
18.16	Is the transfer of samples, sub-samples, digestates or extracts to another party subject to all of the requirements for legal COC? *QSM Rev. 5.0, Module 2, Section 5.8.9 e)*		
18.17	Do records indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility or sample returned to client), and the name of the individual who performed the task? *QSM Rev. 5.0, Module 2, Section 5.8.9*		
18.18	Does the laboratory implement a radiological control program that addresses analytical radiological control? *TNI EL-V6-2009, Section 1.7.2.7 c)*		
18.19	Does the radiological control program explicitly define how low level and high level samples will be identified, segregated, and processed in order to prevent sample cross contamination? *TNI EL-V6-2009, Section 1.7.2.7 c)*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
19.0	**Laboratory Information Management System (LIMS): If LIMS Audit Is Not Performed**		
19.1	Do system backups occur on a regular and published schedule and can more than one person within the organization perform the system backups? *QSM Rev. 5.0, Module 2, Section 5.4.7.2, k) vi)* - See Checklist 5, LOI 4.7		
19.2	Are tests of the system backups performed and recorded to demonstrate that the backup systems contain all required data? *QSM Rev. 5.0, Module 2, Section 5.4.7.2, k) vii)* - See Checklist 5, LOI 4.8		
19.3	Is the instrument transmitting LIMS raw data uniquely identified when the data is recorded? *EPA 2185 GALP, Section 8.4.3* - See Checklist 5, LOI 2.8		
19.4	Are the time(s) and date(s) also documented? *EPA 2185 GALP, Section 8.4.3* - See Checklist 5, LOI 2.9		
19.5	Are the procedures and practices for making changes to LIMS raw data documented and does the documentation provide evidence of the change and preserve the original recorded documentation? Does the document include the following: • date changed; • the reason for the change; • the person who made the change; and if different; • the person who authorized the change? *QSM Rev. 5.0, Module 2, Section 4.2.8.4, v, EPA 2185 GALP, Section 8.4.5* - See Checklist 5, LOI 2.10		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
19.6	Does the facility Software Change Control documentation identify: • persons requesting and authorizing software changes; • requirements to be met by the change; • measures for testing and QA; • approving changes; • implementing changes; and • establishment of priority of change requests? *QSM Rev. 5.0, Module 2, Section 5.4.7.2, i) iii)* - See Checklist 5, LOI 3.7		
19.7	Are the operating system privileges and file access safeguards implemented to restrict the use of LIMS data to users with authorized access? *QSM Rev. 5.0, Module 2, Section 5.4.7.2, d, k) ii)* - See Checklist 5, LOI 4.3		
19.8	Do application-specific safeguards protect the LIMS? *QSM Rev. 5.0, Module 2, Section 5.4.7.2, k) v)* - See Checklist 5, LOI 4.5		
19.9	Are individual user names and passwords required for all LIMS users? *QSM Rev. 5.0, Module 2, Section 5.4.7.2, d)* - See Checklist 5, LOI 1.8		
19.10	Upon employment, do employees have initial training in computer security awareness, and have ongoing refresher training on an annual basis? Is the documentation of this training maintained and available for review? *QSM Rev. 5.0, Module 2, Section 5.4.7.2, e, k) iii)* - See Checklist 5, LOI 4.1		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
19.11	Do SOPs exist for: • making changes to electronic data; • how electronic data are processed, maintained, and reported by the LIMS; • 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.; • the retention of electronic data, documentation, and records pertaining to the LIMS; • emergency, backup, disaster recovery, and contingency plans for the LIMS? *QSM Rev. 5.0, Module 2, Section 5.4.7.2; i – ii; ISO/IEC 17025, Clause 5.4.7.2, a - c* - See Checklist 5, LOIs 2.4, 2.5, 2.3, 2.6, and 4.6		
19.12	Are fire extinguishers designed to avoid damage to computer equipment available and mounted in visible, accessible areas? *EPA 2185 GALP, Section 8.6, Security, 3. Physical and Environmental Safeguards* - See Checklist 5, LOI 4.10		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
20.0	**American Industrial Hygiene Association Laboratory Accreditation Program (AIHA): Additional Industrial Hygiene QA Criteria**		
20.1	Is the laboratory currently accredited by AIHA for the appropriate fields of testing/methods? *Policy Statement – no reference*		
20.2	If the laboratory analyzes for lead, does it have an Environmental Lead Laboratory Accreditation Program (ELLAP) and does it demonstrate successful participation in the AIHA Environmental Lead Proficiency Testing (ELPAT)? *AIHA-LAP 2C*		
20.3	If the laboratory analyzes for bulk asbestos, can it demonstrate successful participation in the National Voluntary Laboratory Accreditation Program (NVLAP) Bulk Asbestos Accreditation Program or the AIHA Bulk Asbestos Program? *AIHA-LAP 2B*		
20.4	Does the Technical Manager possesses a BS or BA in an applicable physical or biological science and have a minimum of three (3) years relevant non-academic analytical chemistry experience, two (2) of which must be in IH analysis? *AIHA-LAP 2A.5.2.1.1 and 2B.3.1* Does the Technical Manager authorize and document that all analyses for which the laboratory is accredited are completed by personnel with appropriate education and/or technical background? Does the Technical Manager function as, or designate, the approved signatory? *AIHA-LAP 2A.5.2.1.1, 2A.5.10.2*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
20.5	Does the Quality Manager possess a BS or BA in an applicable basic or applied science and have at least 1 year of nonacademic analytical or quality control experience appropriate to the types of analyses performed by the laboratory; or in lieu of a bachelor's degree, four years of nonacademic or quality control experience; and have documented training in statistics or laboratory quality assurance/quality control? *AIHA-LAP 2A.5.2.1.2*		
20.6	Do all analysts and technicians demonstrate, and have documented, the ability to produce reliable results at a minimum of every 6 months through accurate analysis of certified reference materials, proficiency testing samples, or in-house quality control samples? *AIHA-LAP 2A.5.2.1.3, 2B.3.2.2*		
20.7	Do all analysts and technicians have a minimum of 20 business days of hands-on experience conducting analyses in an industrial hygiene laboratory before initiation of **independent** work on customer samples? *AIHA-LAP 2B.3.2.3*		
20.8	At least quarterly, does the Quality Manager provide reports to laboratory management regarding QA matters? Do these reports include information on internal audits, proficiency program performance, nonconformities, and corrective/preventive actions taken? *AIHA-LAP 2A.4.15.3*		
20.9	Are Management reviews conducted at least annually and review results shared, as appropriate, with laboratory personnel? *AIHA-LAP 2A.4.15.1 and 2A.4.15.2*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
20.10	Have analysts completed an external or internal training program for all applicable analyses or analytical techniques prior to performing unsupervised analyses on samples submitted by customers and are the dates of authorization to perform specific tasks recorded? *AIHA-LAP 2A.5.2.4; 2B.3.2.1*		
20.11	Is analyst training documented in laboratory records and does it include a description of the content and duration of the program? *AIHA-LAP 2A.5.2.5*		
20.12	Does the laboratory have a written procedure describing the process used to estimate measurement uncertainty, including at a minimum? a) Definition of the measured b) Identification of the contributors to uncertainty c) Details of the approaches used for estimating measurement uncertainty, such as Type A and/or Type B. When using the Type A approach, does the laboratory utilize one or more of the following options: 1) Uncertainty specified within a standard method 2) Laboratory Control Samples and Matrix Spikes 3) Duplicate Data 4) Proficiency testing (PT) Sample Data d) Identification of the contributors of variability for qualitative test methods e) All calculations used to estimate measurement uncertainty and bias f) The reporting procedure. *AIHA-LAP Appendix G 5.4*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
20.13	Are external calibration services, whenever possible, obtained from providers accredited to ISO/IEC/IEC 17025 by an ILAC signatory, a CIPM recognized National Metrology Institute (NMI) or a State Weights and Measures Facility that is part of the NIST Laboratory Metrology Program? Do calibration certificates indicate traceability to the SI or reference standard and include the measurement result with the associated uncertainty of measurement? *AIHA-LAP 2A.5.5.5 Appendix H, 5.2*		
20.14	Do reference materials have a certificate of analysis that documents traceability to a primary standard or certified reference material and associated uncertainty, when possible? When applicable, does the certificate document the specific NIST SRM or NMI certified reference material used for traceability? *AIHA-LAP Appendix H, 5.4*		
20.15	Are calibrations performed in-house documented in a manner that demonstrates traceability via an unbroken chain of calibrations regarding the reference standard/material used, allowing for an overall uncertainty to be estimated for in-house calibration? *AIHA-LAP Appendix H, 5.5*		
20.16	Are control charts or quality control databases used to record quality control data and compare them with acceptance limits? Are procedures in place to monitor trends and the validity of test results? *AIHA-LAP 2A.5.9.1.5*		
20.17	Does the test report also include 1) the reporting limit and 2) modifications to the test method, if applicable? *AIHA-LAP 2A.5.10.1, a, b*		

Item Number	Line of Inquiry	Status	Summary of Observations Objectives Evidence Previewed Audit Notes
20.18	Does the final report state the measured quantitative result of the analysis of any blank samples submitted to the laboratory? Does the report also include a statement that discloses whether or not the sample results have been corrected for contamination based on the field blank or other analytical blank? *AIHA-LAP 2A.5.10.5*		

Audit ID:	Laboratory:	Auditor:

Notes:

Notes: a) The exact nature of some test methods may preclude rigorous, statistically valid estimation of analytical uncertainty. In these cases the laboratory attempts to identify all components of analytical uncertainty and make a reasonable estimation, and ensures that the form of data reporting does not give a wrong impression of the uncertainty. A reasonable estimation will be based on knowledge of method performance and previous experience. When estimating the analytical uncertainty, all uncertainty components which are of importance in the given situation will be taken into account.

b) In those cases where a well-recognized test method specifies limits to the values of the major source of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the requirements on analytical uncertainty by following the test method and reporting instructions.

c) The laboratory is only responsible for estimating the portion of measurement uncertainty that is under its control. As stated in Section 5.10.3.1.c, test reports include a statement of the estimated analytical uncertainty only when required by the customer. If a project requires analytical uncertainty to be reported, the laboratory reports the estimated uncertainty based on project specific procedures or, if not available, any other scientifically valid procedures.

The estimated analytical uncertainty can be expressed as a range (±) around the reported analytical results at a specified confidence level. A laboratory may report the in-house, statistically-derived LCS control limits based on historical LCS recovery data as an estimate of the minimum laboratory contribution to analytical uncertainty at a 99% confidence level. For testing laboratories, the laboratory ensures that the equipment used can provide the analytical portion of measurement uncertainty needed by the customer.

QSM Rev. 5.0 Section 5.4.6 and TNI STANDARD, VOLUME 1, 2009 5.4.6

Record of Revision for Checklist 1
Quality Assurance Management Systems and General Laboratory Practices

Revision Number	Effective Date	Reason for Revision	Line of Inquiry
3.5	11/2009	Added roles and responsibilities for the backup RSO.	1.4
3.5	11/2009	Willful avoidance of implementation of DOECAP corrective action plans may result in a P1 finding or discontinuation of work.	2.18
3.5	11/2009	Add requirement for radiochemistry laboratories to maintain a list of typical MDAs.	2.21
3.5	11/2009	Verification of Class 1 check weights must be performed with weights that are traceable to the National Metrology Institute (such as NIST).	4.5
3.5	11/2009	Deleted the requirement for daily refrigerator and freezer monitoring in the event that samples are not being stored from a DOE site.	5.6
3.5	11/2009	Added performance checks for radiological survey instrumentations.	7.3
3.5	11/2009	Shipping containers from DOE sites must be opened under a ventilation hood.	7.4
3.5	11/2009	Radiological surveys of sample shipping containers shall be performed as quickly as possible from the time of receipt by the laboratory.	7.5
3.5	11/2009	All shipping containers from known radiological areas must be surveyed on all external surfaces.	7.6
3.5	11/2009	Changed reference for internal chain of custody from QSAS Section 5.8 DOE-4 to DOE-5	7.10
3.5	11/2009	Changed reference for LOI 8.5 8 to QSAS Section 4.12 DOE-6	8.5
3.5	11/2009	Required review frequency for all laboratory notebooks to include: instrument logbooks, standards logbooks, and records for data reduction, verification, validation, and record archival.	8.5
3.5	11/2009	Changed reference for LOI 8.5 8 to QSAS Section 4.12 DOE-6	8.6
3.5	11/2009	Periodic testing of LIMS system backups.	13.2
3.5	11/2009	Annual refresher training for all employees on an annual basis.	13.9
3.7	11/2011	Added requirement for ventilation hoods for receiving DOE samples and the requirements for a procedure and records for contamination control.	7.4
3.7	11/2011	Added requirements for the receipt of IH samples including asbestos, Be, and BeO	7.5
3.7	11/2011	Added the following to the Note section of the checklist: Fully document any deviation from the LOI or the requirements of QSAS 2.7	Page 1
3.8	1/2012	Added the following to the Note section of the checklist: Fully document any deviation from the LOI or the requirements of QSAS 2.7	Page 1
4.0	12/2013	Incorporated requirements of DoD/DOE Quality Systems Rev. 5.0, TNI EL-V1-2009, ISO/IEC 17025:2005, and AIHA Laboratory Accreditation Policy	All
4.1	1/27/2014	General to correct and consolidate LOIs.	All
4.2	2/4/2014	General to correct LOIs after further review	All
4.3	2/26/2014	General to correct LOIs after final review and use in laboratory audits.	All

Revision Number	Effective Date	Reason for Revision	Line of Inquiry
4.4	3/2014	Deletion of quarterly accuracy checks for mechanical pipettes	7.11