

U. S. Department of Energy



Consolidated Audit Program

Checklist 1

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

Revision 3.8
January 2012

Audit ID:

Date:

Approved by:  DOECAP Manager, January 2012

Audit ID: _____

Laboratory: _____

Auditor: _____

Areas of Review During Audit

___ Organization and Management

___ Test Methods & SOPs

___ Outside Support

___ Quality Systems

___ Sample Handling

___ Acceptance Receipt

___ Services & Supplies

___ Personnel

___ Records

___ Complaints

___ Equipment

___ Report Format & Content

___ LIMS (if needed)

___ Measurement Traceability & Calibration

___ AIHA (if needed)

A = Acceptable

U = Unsatisfactory

NA = Not Applicable

F = Finding

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:

- 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 QSAS 2.8
- Refer to Page 43 for the record of revision.

Approved by:  DOECAP Manager, January 2012

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
1.0	Organization and Management		
1.1	<p>The QA Plan includes an organization chart showing that QA personnel:</p> <ul style="list-style-type: none"> • operate independently from line management; • are not directly involved with cost, schedule or production functional areas; and, • report directly to the highest level of laboratory management. <p><i>QSAS, Sections 4.1.5 j, 3, 4.1.5 b, 4.1.5 j 1;</i> <i>AIHA Laboratory QA Policies, Section 2A.4.1</i></p>		
1.2	<p>General QA responsibilities include:</p> <ul style="list-style-type: none"> • non-conformance reports; • oversight of corrective actions; • oversight of Performance Evaluation (PE) analysis; • independent report to management; • internal audits; • review of Statements of Work (SOWs) and SOPs; • procurement QA; and • awareness of identified laboratory issues. <p><i>QSAS, Section 4.1.5 j;</i> <i>AIHA Laboratory QA Policies, Section 2A.4.1, 2A.4.14, and 2A.4.15</i></p>		

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1.3	<p>A QA Officer has been designated in writing and has been empowered to:</p> <ul style="list-style-type: none"> • stop unsatisfactory work; • prevent reporting results from an out-of-control measurement system; • initiate and monitor the corrective action process; and • revise, control and distribute the QA Plan. <p><i>QSAS, Sections 4.1.5.j, 8 DOE-1, 4.2.5, and 4.10.1</i></p>		
1.4	<p>The laboratory organization possesses well-defined and documented roles and responsibilities for each quality- related or key position (this includes the Health and Safety Officer, the Radiation Safety Officer and the backup Radiation Safety Officer).</p> <p><i>QSAS, Section 4.2.4; AIHA Laboratory QA Policies, Section 2A.5.2</i></p>		
1.5	<p>The laboratory QC Manager or his/her designee periodically reviews control charts at a specified frequency for out-of-control conditions and initiates appropriate corrective action procedures.</p> <p>Control charts are defined as a graphical representation of data taken from a repetitive measurement or process. Control charts may be developed for various characteristics, (e.g., mean, standard deviation, range, etc.) of the data.</p> <p>Data analysis software may also be used for the statistical evaluation of data for trends and biases.</p> <p><i>QSAS, Section 4.1 DOE-1; AIHA Laboratory QA Policies, Section 2A.5.9.1.5</i></p>		

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2.0	Quality System – Establishment, Audits, Essential Quality Controls, and Data Verification		
2.1	The laboratory has developed a laboratory QA Plan consistent with DOE QSAS that is issued and maintained as a controlled document. <i>QSAS, Introduction and Section 4.2.3</i>		
2.2	The QA Plan is accessible to all laboratory personnel and they are aware of its location. <i>QSAS, Section 4.2.1; AIHA Laboratory QA Policies, Section 2A.4.2</i>		
2.3	The QA Plan defines the laboratory’s policies and its commitment to: <ul style="list-style-type: none"> • ethical standards; • provide accurate, defensible data; • client confidentiality; • good laboratory practices; and, • client service. <i>QSAS, Sections 4.2.2 and 4.7; AIHA Laboratory QA Policies, Section 2A.4.2</i>		
2.4	The QA Plan includes a listing of certifications and accreditations and a list of all test methods under which the laboratory performs its accredited testing. If this list is not part of the QA plan, the QA plan should include a reference to its location. <i>QSAS, Section 4.2 DOE-2</i>		

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2.5	<p>For those managing, performing, and assessing work, the QA Plan describes the:</p> <ul style="list-style-type: none"> • organizational structure, • functional responsibilities, • levels of authority, and • interfaces. <p><i>QSAS, Section 4.1.5 f; AIHA Laboratory QA Policies, Section 2A.4.2.1</i></p>		
2.6	<p>The laboratory has established a minimum frequency for review of controlled documents and procedures, e.g., SOPs.</p> <p><i>QSAS, Section 4.2 DOE-1; AIHA Laboratory QA Policies, Section 2A.4.3</i></p>		
2.7	<p>The laboratory has established an internal audit program that includes:</p> <ul style="list-style-type: none"> • independent assessments by technically qualified personnel; • maintenance of an audit schedule; • audit procedures; • standard formats for reporting findings to laboratory management; and, • methods for implementing and verifying corrective actions. <p><i>QSAS, Sections 4.13.1 and 4.13.4; AIHA Laboratory QA Policies, Section 2A.4.14</i></p>		

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2.8	<p>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.</p> <p><i>QSAS, Section 4.13 DOE-1;</i></p>		
2.9	<p>Assessment results are documented, reported to and reviewed by the level of management with authority to affect any necessary corrective actions.</p> <p><i>QSAS, Section 4.14.2;</i></p>		
2.10	<p>There has been documented review by management to assess the effectiveness of the quality improvement system.</p> <p><i>QSAS, Section 4.14.1; AIHA Laboratory QA Policies, Section 2A.4.15</i></p>		
2.11	<p>The laboratory has established a system to identify problems, non-conformances, out-of-control events and issues that are not part of scheduled assessments.</p> <p><i>QSAS, Section 4.10.1; AIHA Laboratory QA Policies, Sections 2A.4.9 and 2A.4.10</i></p>		
2.12	<p>All audits, review findings and any corrective actions that arise from them are adequately documented.</p> <p><i>QSAS, Sections 4.12.1.1 and 4.12.2.5.2 f); AIHA Laboratory QA Policies, Section 2A.4.14 and 2A.4.15</i></p>		

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2.13	<p>The laboratory can 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)</p> <p><i>QSAS, Section 5.9DOE-1; AIHA Laboratory QA Policies, Section 6B</i></p>		
2.14	<p>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.</p> <p>(This requirement does not replace the laboratory's participation in program specific PE programs or for PE required for TNI NELAC accreditation)</p> <p><i>QSAS, Section 5.9 DOE-1</i></p>		
2.15	<p>Laboratories that provide volatile organic and wet chemistry analyses to DOE will be required to maintain proficiency in nationally recognized PE programs for all matrices that the laboratory provides data to DOE.</p> <p>(These analytes are not available from MAPEP)</p> <p><i>QSAS, Section 5.9 DOE-1</i></p>		

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2.16	<p>The laboratory corrective action process encompasses its PE program and is documented by:</p> <ul style="list-style-type: none"> • 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. <p><i>QSAS, Section 5.9, DOE-1; AIHA Laboratory QA Policies, Section 6B</i></p>		
2.17	<p>A corrective action process has been implemented that determines:</p> <ul style="list-style-type: none"> • events leading to the adverse condition; • technical activities associated with the problem; • generic implications of the problem; • extent to which similar problems have occurred; • assignment of personnel to corrective action; • a defined schedule for completion; • documentation of corrective action plan; • effectiveness of corrective actions; • actions taken to preclude recurrence; and • client notification. <p><i>QSAS, Sections 4.10.6; 4.13.2 DOE-2, AIHA Laboratory QA Policies, Section 2A.4.11</i></p>		

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2.18	<p>Approved DOECAP corrective action plans are implemented according to the timeframe stated in the CAP.</p> <p>(Willful disregard for the implementation of approved corrective actions plans may result in a Priority I finding and may result in the loss of work until the corrective action is implemented)</p> <p>QSAS Section 4.10 DOE-1</p>		
2.19	<p>The laboratory has a system in place to record incidents involving the spillage of reagents and client samples.</p> <p><i>QSAS, Section 5.2 DOE-2</i></p>		
2.20	<p>The laboratory has a system that tracks corrective actions to completion.</p> <p><i>QSAS, Section 4.10DOE-1; AIHA Laboratory QA Policies, Section 2A.4.11</i></p>		
2.21	<p>The laboratory maintains:</p> <ul style="list-style-type: none"> • a list of typical Method Detection Limits (MDLs) and Minimum Detectable Activity (MDA) achieved for water, soil and other matrices commonly analyzed (MDAs are required for radiochemistry laboratories only); • procedures for determining limits of detection and frequency of verification; and, • documentation for each MDL study. <p><i>QSAS, Section 5.9DOE-3 and Appendix D.1.2</i></p>		

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3.0	Personnel		
3.1	The laboratory maintains records of indoctrination and training in the form of: <ul style="list-style-type: none"> • attendance sheets; • training logs; • personnel training records; and, • a description of the training and indoctrination <i>QSAS, Sections 5.2.6 c, 1, and 2;</i> <i>AIHA Laboratory QA Policies, Section 2A.5.2</i>		
3.2	Documentation is maintained indicating training in: <ul style="list-style-type: none"> • technical skills; • laboratory analytical methods; • QC procedures; • safety policies; • waste management practices; • and if applicable, radioactive materials control, and radiation worker training. <i>QSAS, Sections 5.2.5 and 5.8 DOE-1</i> <i>AIHA Laboratory QA Policies, Section 2A.5.2</i>		

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3.3	<p>The following personnel criteria have been satisfied:</p> <ul style="list-style-type: none"> • management has established personnel qualifications for each position; • management has established training requirements for each project person; and, • personnel qualifications are reviewed and documented periodically. <p><i>QSAS, Sections 5.2.2, 5.2.6 a, and c; AIHA Laboratory QA Policies, Section 2A.5.2</i></p>		

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4.0	Equipment		
4.1	<p>The laboratory maintains a current list of available major equipment type, date of purchase, repair history, and operational status.</p> <p><i>QSAS, Section 5.5 DOE-9 AIHA Laboratory QA Policies, Section 2A.5.5</i></p>		
4.2	<p>A system is in place to address instrument operational problems. This system includes the following elements:</p> <ul style="list-style-type: none"> • fault finding/trouble shooting; • procedures to repair malfunctioning equipment; and, • actions to be taken to prevent recurrence. <p><i>QSAS, Sections 5.5.5 g and 5.5.7</i></p>		
4.3	<p>A schedule of preventive maintenance activities for all instruments that contribute to the quality of the analytical data has been developed and the performance of preventive maintenance is documented.</p> <p><i>QSAS, Sections 5.5.3 and 5.5.6; AIHA Laboratory QA Policies, Section 2A.5.5</i></p>		
4.4	<p>The laboratory maintains a program to ensure that balances are calibrated before initial use and annually thereafter; and that balances are labeled to that effect by an independent (third party) professional technician.</p> <p><i>QSAS, Section 5.5DOE-4</i></p>		

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4.5	<p>Class 1 (formerly referred to as Class S) certified check weights shall be calibrated every five years using recognized National Metrology Institute, such as NIST, traceable references, when available.</p> <p>Alternatively, Class 1 check weights may be reverified using controlled check weight standards that are used exclusively for this purpose (the weights must be traceable to National Metrology Institute traceable references)</p> <p><i>QSAS, Section 5.5 DOE-4</i></p>		
4.6	<p>Initial and verification checks shall be documented.</p> <p><i>QSAS, Section 5.5 DOE-4</i></p>		
4.7	<p>The laboratory has an SOP in place to clearly identify equipment that has been taken out of service.</p> <p><i>QSAS, Section 5.5.7</i></p>		

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5.0	Measurement Traceability and Calibration		
5.1	All measuring operations and testing equipment having an effect on the accuracy or validity of tests are calibrated and/or verified before being put into service and on a continuing basis. <i>QSAS, Section 5.6.1; AIHA Laboratory QA Policies, Section 2A.5.6</i>		
5.2	Measurements made by the laboratories are traceable to recognized standards of measurement where available. <i>QSAS, Section 5.6.2.1; AIHA Laboratory QA Policies, Section 2A.5.6</i>		
5.3	The laboratory maintains a record of all calibration certificates that indicate traceability to national standards of measurement and associated uncertainty of measurement and/or statements of compliance with an identified metrological specification. <i>QSAS, Sections 5.6.3.2 and 5.6.4 a; AIHA Laboratory QA Policies, Section 2A.5.6</i>		
5.4	There is a program of calibration and verification for reference standards. <i>QSAS, Section 5.6.3.1; AIHA Laboratory QA Policies, Section 2A.5.6</i>		

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5.5	<p>An SOP is in place for reagent and deionized water production that includes (at a minimum):</p> <ul style="list-style-type: none"> • preventive maintenance of water purification equipment; • control criteria, and ; • corrective action process for out-of-specification-water. <p><i>QSAS, Section 5.5 DOE-4</i></p>		
5.6	<p>Procedures are defined for ensuring that balances, refrigerators, ovens, thermometers and other laboratory equipment are accurate and that their performance is monitored and documented.</p> <p>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.</p> <p>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.</p> <p><i>QSAS, Section 5.5 DOE-4; AIHA Laboratory QA Policies, Section 2A.5.5</i></p>		
5.7	<p>Catastrophic failures of refrigerators and freezer units are addressed in laboratory SOPs.</p> <p><i>QSAS, Section 5.5 DOE-2</i></p>		

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5.8	<p>Temperature monitoring data loggers are acceptable provided they have the capability of providing notification of an out of control event to responsible individual(s) during routine and non-routine work periods.</p> <p>Corrective actions shall be performed in the event of an out of control event or catastrophic failure of a refrigerator or freezer.</p> <p><i>QSAS, Section 5.5 DOE-4</i></p>		
5.9	<p>The SOPs or the test method SOPs reference the details or the initial calibration procedures, including calculations, integrations, and acceptance criteria associated statistics.</p> <p><i>QSAS, Section 5.4.1.2; AIHA Laboratory QA Policies, Section 2A.5.4</i></p>		
5.10	<p>Sufficient raw data records are retained to permit reconstruction of the initial and continuing calibrations using, as appropriate, but not limited to:</p> <ul style="list-style-type: none"> • calibration date, • test method, • instrument, • analysis date, • each analyte name, • concentration, • response, and • calibration curve or response factor. <p><i>QSAS, Section 4.12.2.1; AIHA Laboratory QA Policies, Section 2A.4.13</i></p>		

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6.0	Test Methods and Standard Operating Procedures (SOPs)		
6.1	Laboratory activities affecting quality are defined in documented instructions or SOPs that are: <ul style="list-style-type: none"> • distributed in a controlled manner; • periodically reviewed and updated; • available to all laboratory personnel; and, • retained in the laboratory's archives. <i>QSAS, Sections 4.3.2.2 b and 5.4.1.1 c;</i> <i>AIHA Laboratory QA Policies, Section 2A.4.3</i>		

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6.2	<p>SOPs are in place for (but not limited to) the following areas:</p> <ul style="list-style-type: none"> • sample management; • reagent/standard preparation; • general laboratory techniques; • test methods; • equipment calibration and maintenance; • QC; • corrective action; • manual calculations and integrations; • data reduction and validation; • reporting; • records management; • information management; • health and safety; • radioactive material management; • waste disposal; and • each accredited analysis or test method. <p><i>QSAS, Section 5.4.1.1; EPA SW-846, Chapter 1, Section 4.3; AIHA Laboratory QA Policies, Section 2A.4.2.1</i></p>		

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6.3	<p>The laboratory has an SOP delineating the records control system that includes:</p> <ul style="list-style-type: none"> • specifications of items, data, and processes of which records are to be controlled; • requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements; • requirements and responsibilities for record transmittal, distribution, change, retention, protection, preservation, traceability, archival, retrieval, and disposal; • verification that records received are legible and are in agreement with the transmittal document requirements for access to and control of the files; • procedures for the control and client confidentiality accountability of records removed from the storage location; • procedures for filing of supplemental information and disposing of superseded records; • storage of records in a manner approved by the organizations responsible for the records; • replacement, restoration, or substitution of lost or damaged records; and, • procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct the data. <p><i>QSAS, Sections 4.12.1 and 4.12.2; AIHA Laboratory QA Policies, Section 2A.4.13</i></p>		

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6.4	<p>The laboratory has SOPs in place to validate non-standardized methods, laboratory designed/developed methods, standardized methods used outside their intended range and amplifications of standardized methods to confirm that the methods are fit for the intended use. The SOPs may include:</p> <ul style="list-style-type: none"> • scope; • description of the type of item to be tested or calibrated; • parameters or quantities to be determined; • apparatus, equipment, reference standards and reference materials required; • environmental conditions required and any stabilization period needed; • criteria and/or requirements for approval/rejection; • data to be recorded and method of analysis and presentation; and, • uncertainty or procedure for estimating uncertainty. • description of the procedure, including affixing identification marks, handling, transporting, storing and preparing of items, checks to be made before the work is started, checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use, method of recording the observations and results, any safety measures to be observed; <p><i>QSAS, Section 5.4.4; & 5.4.5</i> <i>AIHA Laboratory QA Policies, Section 2A.5.4</i></p>		

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6.5	The laboratory has a data review procedure in place that includes both the analyst and an independent data reviewer. <i>QSAS Section 4.2 DOE-3 AIHA Laboratory QA Policies, Section 2A.5.4.5</i>		
6.6	The laboratory has a procedure in place to track the expiration date of standards and to remove expired standards from use. <i>QSAS, Section 5.6.4 a</i>		
6.7	Controlled procedures are accessible to the individual performing the analyses, data reviewers, and the QA staff. <i>QSAS, Section 5.4.1.1 c; AIHA Laboratory QA Policies, Section 2A.5.4</i>		
6.8	A demonstration of capability must be made prior to using any test method and at any time there is a change in instrument type, personnel, or test method. <i>QSAS, Section 5.4.2.2; AIHA Laboratory QA Policies, Section 2A.5.4</i>		
6.9	When sub-sampling (obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory uses documented SOPs and appropriate techniques to obtain representative sub-samples. <i>QSAS, Section 5.7.1</i>		

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6.10	The laboratory has established SOPs to ensure that all QC measures are reviewed and evaluated before data is reported <i>QSAS, Section 5.9.2 a; AIHA Laboratory QA Policies, Section 2A.5.9</i>		

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7.0	Sample Handling, Sample Acceptance Policy, and Sample Receipt		
7.1	The laboratory has 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 <i>QSAS, Section 5.8.2;</i> <i>AIHA Laboratory QA Policies, Section 2A.5.8</i>		
7.2	The laboratory has SOPs in place to address the following: <ul style="list-style-type: none"> • 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. <i>QSAS, Sections 5.8.3.1 a - c; and 5.8.3.2</i>		
7.3	Prior to performing radiological surveys, the radiological survey instrumentation is checked for operational performance using a radiological source, a battery check, is performed, and the nominal background is measured. All performance checks are documented and available for review. <i>QSAS, Section 5.8 DOE-7</i>		

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7.4	<p>Shipping containers from DOE sites are opened under a ventilation hood.</p> <p>The laboratory has 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) QSAS, Section 5.8 DOE-7</p>		
7.5	<p>Radiological surveys of sample shipping containers are surveyed as soon as possible from the time of receipt by the laboratory.</p> <p>Materials submitted for industrial hygiene or asbestos analyses are opened in an established manner to prevent worker exposure.</p> <p>Sample receiving practices are developed and implemented for the receipt of beryllium, beryllium oxide, and asbestos materials.</p> <p>QSAS, Section 5.8 DOE-7</p>		
7.6	<p>All shipping containers from known radiological areas are surveyed for radiological contamination on all external surfaces.</p> <p>QSAS, Section 5.8 DOE-7</p>		
7.7	<p>Sample custodians document anomalies encountered in the sample receiving process.</p> <p>QSAS, Section 5.8.3.1 c; AIHA Laboratory QA Policies, Section 2A.5.8</p>		

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7.8	<p>A sample receiving logbook or equivalent system is 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.</p> <p><i>QSAS, Sections 5.8.3.1 d; AIHA Laboratory QA Policies, Section 2A.5.8.2</i></p>		
7.9	<p>When the laboratory receives samples, an internal Chain of Custody (COC) procedure is in place.</p> <p><i>QSAS, Section 5.8 DOE-4; AIHA Laboratory QA Policies, Section 2A.5.8.1</i></p>		
7.10	<p>Internal custody is maintained until final disposition or return of the sample to the client.</p> <p><i>QSAS, Section 5.8 DOE-4; AIHA Laboratory QA Policies, Section 2A.5.8</i></p>		
7.11	<p>The laboratory has established procedures to ensure that radioactivity levels are consistent with the accompanying documentation and that laboratory regulatory levels are not exceeded.</p> <p><i>QSAS, Section 6.2.3</i></p>		
7.12	<p>A radiological control program that addresses analytical radiological control is implemented by the laboratory.</p> <p>The radiological control program shall explicitly define how low level and high level samples will be identified, segregated, and processed in order to prevent sample cross contamination.</p> <p><i>QSAS, Appendix D.4.8</i></p>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
8.0	Records		
8.1	Documents are retained for five years or per contract specifications. <i>AIHA Laboratory QA Policies requires at least three years retention of records.</i> <i>QSAS, Section 4.12.2.4 b;</i> <i>AIHA Laboratory QA Policies, Section 2A.4.13.2</i>		
8.2	A system is in place to ensure that quality records are legible, accurate, and complete, e.g., independent review of records, logbooks, etc. <i>QSAS, Section 4.12.1.2;</i> <i>AIHA Laboratory QA Policies, Section 2A.4.13</i>		

Approved by:  DOECAP Manager, January 2012

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

Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
8.3	<p>All observations and results recorded by the laboratory are documented on pre-printed forms, electronic media, or entered into permanent laboratory logbooks.</p> <p>Laboratory records are maintained and allow historical reconstruction of all laboratory activities that produce analytical data.</p> <p><i>QSAS, Section 4.12.1.5</i></p>		
8.4	<p>Corrections to documents that will become quality records are made by drawing a single line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory).</p> <p><i>QSAS, Section 4.12.1.5.d; QSAS 4.12 DOE-2 AIHA Laboratory QA Policies, Section 2A.4.13</i></p>		

Approved by:  DOECAP Manager, January 2012

Audit ID: _____

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
8.5	<p>Hardcopy laboratory notebooks (logbooks) comply with the following:</p> <ul style="list-style-type: none"> • permanent bound laboratory logbooks are required and loose leaf binders are not permitted; • are controlled through a documented system; • have sequentially numbered pages; and • have unique serial numbers clearly displayed on each notebook; • logbooks shall be reviewed on a regular frequency; and • documentation of the reviews shall be maintained. <p>A review frequency is established for all laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, verification, validation, and record archival.</p> <p>Electronic logbooks are permitted and must be protected against change and are to be controlled, protected as primary records.</p> <p><i>QSAS, Section 4.12 DOE-6</i></p>		
8.6	<p>All logbook pages must be closed when the activities documented are completed or carried over to another logbook page. The person responsible for performing the closure shall be the one who performed the last activity documented. Closure shall occur at the end of the last activity performed or as soon as practicable thereafter.</p> <p><i>QSAS, Section 4.12, DOE-6</i></p>		

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

Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
8.7	<p>Records of data and other technical information are maintained in environmentally secure controlled access storage, which shall protect the records from unauthorized access or damage. Alternatively, the laboratory stores duplicate records at a different location.</p> <p><i>QSAS, Sections 4.12.1.4 and 4.12.2.4; AIHA Laboratory QA Policies, Section 2A.4.13</i></p>		
8.8	<p>Physical or administrative controls exist to ensure that:</p> <ul style="list-style-type: none"> • COC is not broken during times that laboratory staff are present or not present; • access to all samples and subsamples is controlled and documented. <p><i>QSAS, Sections 4.12 and 4.12 DOE-1</i></p>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
8.9	<p>Strip charts, tabular printouts, computer data files, analytical notebooks, and run logs include:</p> <ul style="list-style-type: none"> • laboratory sample identification code; • date and time of analysis; • instrumentation identification and instrument operating conditions/parameters (or reference to such data); • analysis type; • all calculations (including manual calculations); • analyst's or operator's initials/signature; • sample preparation information (clean ups, volumes, weights, etc.); • sample analysis; • standard and reagent origin; receipt, preparation or use; • calibration criteria; • QC assessments; and, • method performance criteria. <p><i>QSAS, Section 4.12.2.5.3</i></p>		
8.10	<p>The following administrative records are maintained.</p> <ul style="list-style-type: none"> • personnel qualifications, experience and training records; • initial and continuing demonstration of proficiency for each analyst; and, • a log of names, initials and signatures for all individuals who are responsible for signing or initiating any laboratory record. <p><i>QSAS, Section 4.12.2.5.4 AIHA Laboratory QA Policies, Section 2A.5.2</i></p>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
8.11	<p>The laboratory's legal COC records establish an intact, continuous record of the physical possession, storage and disposal of sample containers, collected sample(s), sample aliquots, and sample extracts or digestates.</p> <p><i>QSAS, Section 4.12, DOE-1</i></p>		
8.12	<p>Tracking records for legal COC include all information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting.</p> <p><i>QSAS, Section 4.12 DOE-1</i></p>		
8.13	<p>Transfer of samples, sub-samples, digestates or extracts to another party is subject to all of the requirements for legal COC.</p> <p><i>QSAS, Section 4.12 DOE-1</i></p>		
8.14	<p>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.</p> <p><i>QSAS, Section 4.12 DOE-1</i></p>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
9.0	Laboratory Report Format and Content		
9.1	Written SOPs are in place for the notification of affected organizations regarding nonconforming items. <i>QSAS, Section 4.9.1 d AIHA Laboratory QA Policies, Section 2A.4.9 and 2A.5.8</i>		
9.2	The laboratory has SOPs for reviewing and documenting changes made to data after report preparation that ensures traceability of updates. <i>QSAS, Section 4.3.3.4 AIHA Laboratory QA Policies, Section 2A.5.10</i>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
10.0	Subcontracting Analytical Samples		
10.1	The laboratory has records to indicate that it advised the client in writing of its intention to sub-contract any portion of the testing to another party. <i>QSAS, Section 4.5.2;</i> <i>AIHA Laboratory QA Policies, Section 2A.4.5</i>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
11.0	Outside Support Services and Supplies		
11.1	<p>Contracted items and services that have the potential to affect the quality of analytical tests are controlled to ensure conformance with contractual requirements. Such control includes one or more of the following:</p> <ul style="list-style-type: none"> • source evaluation and selection (pre-performance/pre-award survey); • source verification; • audit; and/or, • examination of items or services before use. <p><i>QSAS, Section 4.6;</i> <i>AIHA Laboratory QA Policies, Section 2A.4.6</i></p>		
11.2	<p>The use of sub-tier or sub-client for performance of work for DOE shall not be permitted without permission for the contract holder's procurement representative or designee.</p> <p><i>(Note: Some clients may not allow any subcontracting to third party (sub-tier) laboratories. If this is the case, then this will be specifically noted in site-specific contracts via Contracts, Task Orders, Laboratory Delivery Orders, etc.)</i></p> <p><i>QSAS 4-5 DOE-1</i></p>		
11.3	<p>Where there are indications that subcontractors knowingly supplied items or services of substandard quality, this information is forwarded to appropriate management for action.</p> <p><i>QSAS, Section 4.6 DOE-2</i></p>		

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

Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
12.0	Complaints		
12.1	The laboratory has documented policies and SOPs for the resolution of complaints received from clients or other parties about the laboratory's activities. <i>QSAS, Section 4.8; AIHA, Laboratory QA Policies, Section 2A.4.8</i>		

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Audit ID: _____ Laboratory: _____ Auditor: _____

Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
13.0	Laboratory Information Management System (LIMS): If LIMS Audit Checklist Not Performed		
13.1	System backups occur on a regular and published schedule and can be performed by more than one person within an organization. <i>QSAS 5.4 DOE-4; AIHA Laboratory QA Policies, Section 2A.4.13</i>		
13.2	Periodic testing of the LIMS system backups is performed and documented to demonstrate that the backups contain all required data. QSAS, Section 5.4 DOE-4		
13.3	Computer programs (software) used for instrument performance output, data reduction, and/or for data interpretation are validated before use and verified on a regular basis. Documentation is readily available for review. <i>QSAS, Section 5.4 DOE-4; AIHA Laboratory QA Policies, Section 2A.5.4.4</i>		
13.4	Documentation for changes made to data in the LIMS includes: <ul style="list-style-type: none"> • the original recorded required documentation; • clear evidence that a change was made; • the reason for the change; • the date of the change; • the person who made the change; and, • the person who authorized the change. <i>QSAS, Section 4.12 DOE-2 and 4.12 DOE-3</i>		

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Audit ID: _____ Laboratory: _____ Auditor: _____

Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
13.5	Software Change Control documentation identifies: <ul style="list-style-type: none"> • persons requesting and authorizing software changes; • requirements to be met by the change; • measures for testing and QA; • approving changes;; • implementing changes <i>QSAS, Section 5.4.7.2 a</i>		
13.6	Operating system privileges and file access safeguards are implemented to restrict the use of the LIMS data to users with unauthorized access. <i>QSAS, 5.4 DOE-4</i>		
13.7	The LIMS is protected from the introduction of computer viruses. <i>QSAS, Section 5.4. DOE-4</i>		
13.8	Individual user names and passwords have been implemented. <i>QSAS, Section 5.4., DOE-4</i>		
13.9	Users are trained in computer awareness security initially upon employment and thereafter, on an annual basis. Documentation of the training will be maintained and available for review. <i>QSAS, Section 5.4 DOE-4</i>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
13.9	<p>SOPs exist for:</p> <ul style="list-style-type: none"> • verifying electronic and hard copy data; • handling client requested deliverables and modifications; • making changes to LIMS raw data that affect data quality; • software change control methods, which include instructions for requesting, testing, approving, documenting, and implementing changes; and • emergency, backup, disaster recovery, and contingency plans for the LIMS. <p><i>QSAS, Sections 4.2 DOE-3; 4.12.3; 5.4 DOE-4; 4.12.4; and 5.4.7.2 b</i></p>		
13.10	<p>Fire extinguishers designed to avoid damage to computer equipment must be available and mounted in visible, accessible areas.</p> <p><i>QSAS, Section 5.4 DOE-4</i></p>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
14.0	American Industrial Hygiene Association (AIHA): Additional Industrial Hygiene QA Criteria		
14.1	The laboratory is currently accredited by AIHA. Policy Statement – no reference		
14.2	The QA plan is reviewed and approved by management at least annually. <i>AIHA Laboratory QA Policies, Section 2A.4.2.2</i>		
14.3	If the laboratory analyzes for lead, it possesses Environmental Lead Laboratory Accreditation Program (ELLAP) accreditation and it demonstrates successful participation in the AIHA Environmental Lead Proficiency Testing (ELPAT). <i>AIHA Laboratory QA Policies, Section 2C</i>		
14.4	If the laboratory analyzes for bulk asbestos, it demonstrates successful participation in the National Voluntary Laboratory Accreditation Program (NVLAP) Bulk Asbestos Accreditation Program or the AIHA Bulk Asbestos Program. <i>AIHA Laboratory QA Policies, Section 2B</i>		
14.5	The Technical Manager possesses a BS or BA in an applicable physical or biological science and has a minimum of three (3) years non-academic analytical chemistry experience, two (2) of which must be in IH analysis. <i>AIHA Laboratory QA Policies, Section 2A.5.2.1.1 and 2B.3.1</i>		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
14.6	The Quality Manager possesses a BS or BA in an applicable basic or applied science and has at least 1 year of nonacademic analytical or quality control experience, and has documented training in statistics or laboratory quality assurance/quality control. <i>AIHA Laboratory QA Policies, Section 2A.5.2.1.2</i>		
14.7	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. <i>AIHA Laboratory QA Policies, Section 2B.3.2.2</i>		
14.8	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. <i>AIHA Laboratory QA Policies, Section 2B.3.2.3</i>		
14.9	At least quarterly, the Quality Manager provides reports to laboratory management regarding QA matters. These reports include information on internal audits, proficiency program performance, nonconformities, and corrective/preventive actions taken. <i>AIHA Laboratory QA Policies, Section 2A.4.15.3</i>		

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Laboratory: _____

Auditor: _____

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

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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