U. S. Department of Energy

Consolidated Audit Program

Treatment, Storage and Disposal Facilities

Checklist 1

Quality Assurance Management Systems

Revision 1.2
November 30, 2007

Audit ID:	**Date:**

Audit ID: _____ TSDF: _____ Auditor: _____

Prepared by: Todd Hardt Approved by: Jorge Ferrer, DOECAP Manager

Areas of Review During Audit

____QA Program
____Document Control
____Test Control
____QA Records
____Assessments
____Inspection
____Personal Training and Qualifications
____Control of Purchased Items/Services
____Control of Measuring& Test Equipment
____Identification and Control of Items
____Control of Processes
____Inspection, Test, and Operating Status
____Instructions, Procedures, & Drawings
____Procurement Document Control
____Control of nonconforming Items
____Corrective Action

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Access to all referenced regulations are available at the following URL:

- https://doecap.oro.doe.gov
- http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1

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.

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Item Number	Lines of Inquiry	Status	Response/Comment
1.0	**Quality Assurance Program**		
1.1	***Program Management***		
1.1.1	Responsibilities for establishment and implementation of the quality assurance program are defined. *NQA-1 Requirement 1*		
1.1.2	The facility has a documented quality assurance program that is planned, implemented, and maintained. A documented Quality Assurance Plan is consistent with license conditions. *NQA-1 Requirement 2*		
1.1.3	The documented quality assurance program describes the organizational structure, functional responsibilities, and levels of authority. *NQA-1 Requirement 2*		
1.1.4	The scope of the documented quality assurance program meets the applicable Quality Assurance criteria as licensed by the Nuclear Regulatory Commission (NRC) or a State under Agreement with the NRC. *Radioactive Materials License*		
1.1.5	The organization establishes and implements processes to detect and correct quality problems. *Integrated Safety Management and NQA-1 Requirement 2*		

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1.1.6	The controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity and assurance that prerequisites for the given activity have been satisfied. *NQA-1 Requirement 2*		
1.1.7	Management regularly assesses the adequacy and effective implementation of the quality assurance program *NQA-1 Requirement 2*		
1.2	***Personnel Training and Qualification***		
1.2.1	The facility has a formal program that defines job qualifications and required training based on job function. Training requirements include/meet environmental, health & safety and operational requirements. *NQA-1 Requirement 2, RCRA, OSHA*		
1.2.2	Indoctrination and training are commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person. *NQA-1 Requirement 2*		
1.2.3	The person responsible for shipping of hazardous materials, radioactive materials and/or hazardous waste must be trained and qualified. *49 CFR 172, Subpart H*		

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1.2.4	The organization maintains a program that assures personnel performing or managing activities affecting quality receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. *NQA-1 Requirement 2*		
1.2.5	The responsible organization designates those activities that require qualification of personnel and the minimum requirements for such personnel. *NQA-1 Requirement 2*		
1.2.6	Training records are complete and maintained in a formal record keeping system. Training records for all personnel reviewed were current and compliant with regulatory requirements. R*CRA, OSHA, DOT and NQA-1*		
1.3	***Design Control***		
1.3.1	The facility design were completed and approved as required by the applicable permits.		
1.4	***Procurement***		
1.4.1	Applicable design bases and other requirements necessary to assure adequate quality are included or referenced in documents for procurement of items and services. *NQA-1 Requirement 4*		

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1.4.2	To the extent necessary, procurement documents require suppliers to have a quality assurance program consistent with the applicable requirements *NQA-1 Requirement 4*		
1.4.3	Technical requirements are specified in the procurement documents. These requirements are specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service. *NQA-1 Requirement 4*		
1.4.4	Procurement document reviews are performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents. *NQA-1 Requirement 4*		
1.5	***Instructions, Procedures, and Drawings***		
1.5.1	Activities affecting quality and services are prescribed by and performed in accordance with documented instructions, procedures or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. *NQA-1 Requirement 5*		

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1.5.2	The activities are described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions are determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience). *NQA-1 Requirement 5*		
1.6	***Document Control***		
1.6.1	The preparation, issue and change of documents that specify quality requirements, or prescribe activities affecting quality such as instructions, procedures, and drawings are controlled to assure correct documents are being employed. *NQA-1 Requirement 6*		
1.6.2	Documents specifying quality requirements and changes thereto are reviewed for adequacy and approved for release by authorized personnel. *NQA-1 Requirement 6*		

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1.6.3	The following controls are applied to documents and changes thereto: 1. The identification of controlled documents; 2. the specified distribution of controlled documents for use at the appropriate location; 3. the identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents; 4. the review of controlled documents for completeness; 5. approval prior to distribution; and a method to ensure the correct documents are being used. *NQA-1 Requirement 6*		
1.7	***Control of Purchased Items and Services***		
1.7.1	Controls of purchased items and services provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion. *NQA-1 Requirement 7*		
1.8	***Identification and Control 0f Items***		
1.8.1	Controls are established to assure that only correct and acceptable items are used or installed and identification is maintained on the item or in documents traceable to the item, or in a manner which assures that identification is established and maintained. *NQA-1 Requirement 8*		

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1.8.2	Items having limited calendar or operating life or cycles are identified and controlled to preclude use of items whose shelf life or operating life has expired. *ASME NQA-1 Requirement 8*		
1.9	***Control of Special Processes***		
1.9.1	Processes are controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means and include or reference procedure, personnel, and equipment qualification requirements. *NQA-1 Requirement 9*		
1.9.2	Conditions necessary for accomplishment of the process include proper equipment, controlled parameters of the process, specified environment and calibration requirements. *NQA-1 Requirement 9*		
1.9.3	Records are maintained as appropriate for the currently qualified personnel, processes and equipment of each special process. *NQA-1 Requirement 9*		

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1.10	***Inspection***		
1.10.1	Inspections required verifying conformance of an item or activity to specified requirements or continued acceptability of items in service are planned and executed. *(Note: RCRA inspections are covered in the Waste Operations checklist)* *NQA-1 Requirement 10*		
1.11	***Test Control***		
1.11.1	Characteristics to be tested and test methods to be employed are specified. *NQA-1 Requirement 11*		
1.11.2	Test results are documented and their conformance with test requirements and acceptance criteria evaluated. *NQA-1 Requirement 11*		
1.11.3	Test records are established and maintained to indicate the ability of the item to satisfactorily perform its intended function or to meet its documented requirements. *NQA-1 Requirement 11*		

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1.12	***Control of Measuring and Test Equipment***		
1.12.1	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits. *NQA-1 Requirement 12*		
1.12.2	Selection of measuring and test equipment is based on the type, range, accuracy and tolerance needed to accomplish the required measurements for determining conformance to specified requirements. *NQA-1 Requirement 12*		
1.12.3	Measuring and test equipment is calibrated at prescribed time periods or usage and whenever the accuracy of the equipment is suspect. Calibration is made against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration is documented. *NQA-1 Requirement 12*		
1.12.4	Equipment is suitably marked or otherwise identified to indicate calibration status. *NQA-1 Requirement 12*		
1.12.5	Records are established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform their intended function. *NQA-1 Requirement 12*		

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1.13	***Inspection, Test and Operating Status***		
1.13.1	The status of inspection and test activities is identified either on the item or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. *NQA-1 Requirement 14*		
1.13.2	Status is maintained through indicators, such as physical location and tags, markings, operating documents, quality records or other suitable means. *NQA-1 Requirement 14*		
1.14	***Control of Nonconforming Items***		
1.14.1	Items that do not conform to specified requirements are controlled to prevent inadvertent installation or use. *NQA-1 Requirement 15*		
1.14.2	Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. *NQA-1 Requirement 15*		

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1.14.3	Nonconforming items are identified by legible marking, tagging, or other methods not detrimental to the item. Identification is made either on the item, the container or the package containing the item. *NQA-1 Requirement 15*		
1.14.4	Nonconforming items are evaluated and recommended dispositions are proposed. Further processing, delivery, installation, or use of a nonconforming item is controlled pending the evaluation and an approved disposition by authorized personnel. *NQA-1 Requirement 15*		
1.14.5	The responsibility and authority for the evaluation and disposition of nonconforming items is defined and responsibility for the control of further processing, delivery or use of nonconforming items is designated in writing. *NQA-1 Requirement 15*		
1.15	***Corrective Action***		
1.15.1	Conditions adverse to quality are identified promptly and corrected as soon as practical. *NQA-1 Requirement 16*		
1.15.2	The cause of the condition is determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality are documented and reported to appropriate levels of management. *NQA-1 Requirement 16*		

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1.15.3	Completion of corrective actions is verified. *NQA-1 Requirement 16*		
1.16	***Quality Assurance Records***		
1.16.1	Quality assurance records furnish documentary evidence that items or activities meet specified quality requirements. Quality Assurance records are identified, generated, authenticated, maintained, and their final disposition specified. *NQA-1 Requirement 17*		
1.16.2	Requirements and responsibilities for records management activities are documented. *NQA-1 Requirement 17*		
1.16.3	Record retention periods are documented. *NQA-1 Requirement 17*		
1.16.4	Databases are routinely backed up and data files protected from loss. Site QA Plan		
1.16.5	Manual data entry steps are checked for transcription and calculation errors. *Site QA Plan*		

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1.17	***Assessments***		
1.17.1	Assessments are performed to verify that performance criteria are met and to determine the effectiveness of the program. *NQA-1 Requirement 18*		
1.17.2	Assessments are performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. *NQA-1 Requirement 18*		
1.17.3	Assessment results are documented and reported to and reviewed by responsible management. Follow-up action is taken where indicated. *NQA-1 Requirement 18*		
1.17.4	Independent assessment personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. *NQA-1 Requirement 18*		
1.17.5	Follow-up action is taken to verify that corrective action is accomplished as scheduled. *NQA-1 Requirement 18*		

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