Environmental Management
Quality Assurance Audit Checklist

Form Number: 18.1-1
Activity Number: XX-DOE-AU-XXX

1. Organization Evaluated:	2. ☐ Audit ☐ Surveillance	3. Prepared by: _____ (Printed Name) Signature: _____ Date: _____
5. Dates of Evaluation:		
6. Controlled Document: DOE/RW-0333P, Rev. 20, *Quality Assurance Requirements and Documents* [QARD]		7. Activity Evaluated:

8. Item No.	9. Characteristics to be Evaluated	10. Remarks	11. Results
	1.0 ORGANIZATION		
1-1	Verify that the organization has prepared or revised one or more controlled documents that describe their responsibilities and authorities, including management positions responsible for achieving and maintaining quality, internal and external organizational interfaces, organizational structures, and responsibilities for their scope of work. These documents shall be revised upon any reorganization that impacts responsibilities associated with the implementation of QARD-related activities. [QARD Section 1.2]		
1-2	Verify that the organization has the structure and responsibility asssignments for performing work and for achieving and maintaining quality. [QARD Section 1.2.1]		

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1-3	Verify that differences of opinion involving QA program requirements are being brought to the attention of the appropriate management and, if not resolved, elevated to higher levels of management. [QARD Section 1.2.2]		
1-4	Verify that the individuals or organizations responsible for establishing and executing the QA program that have delegated any or all of the work to others have still retained responsibility for the delegated work. [QARD Section 1.3.2]		
2-1	**2.0 QUALITY ASSURANCE PROGRAM** Verify that the QA program has developed documents that meet the requirements: • Policy statement signed by senior line management directing mandatory compliance with this QA program • a structured process of implementing documents that provide top-down implementation of upper-tier requirements • positive control over internal and external organizational interfaces • QARD revisions are reviewed by organizations that implement the QARD. Changes which impact their work scope are incorporated into their QA program documents • a matrix or other similar cross-reference, consistent with their scope of work, which provides the relationship between QARD to implementing documents. [QARD Sections 2.2.1A, B, C]		
2-2	Verify that the QA program has established a process for the identification of the QA program applicability and related activities. AND Verify that process includes those items and activities related to DOE HLW waste forms (i.e., waste form development through qualification, waste form production, and waste form acceptance).		

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	[QARD Section 2.2.2G for HLW] OR Verify that process includes those items and activities related to DOE SNF (i.e., SNF characterization, conditioning, treatment, and/or canisterization and acceptance). [QARD Section 2.2.2H for SNF]		
2-3	Verify that adequate processes have been established for planning work such that planning is completed prior to the start of work. In addition: • Planning shall ensure that work is accomplished under suitably controlled conditions • Planning shall provide for special controls, processes, test equipment, tools, and skills needed to attain the required quality/verification of quality and the need for verification of quality by inspection and test. [QARD Section 2.2.4]		
2-4	Verify that surveillances are scheduled and conducted for ongoing work activities at a frequency commensurate with the status and importance of work and documented in a report to appropriate management. Verify surveillances are performed by personnel knowledgeable about and not directly responsible for the work under surveillance. [QARD Section 2.2.5]		
2-5	Verify that management assessments are planned, documented, performed bienially, and distributed to management. Verify that management assessments evaluate: adequacy of resources and personnel; scope, status, and adequacy of the QARD program; effectiveness of the QARD program; and programmatic compliance to the QARD program. Verify that corrective actions address conditions adverse to quality identified in these activities.		

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	[QARD Section 2.2.6]		
2-6	Determine whether readiness reviews, peer reviews, and expert elicitation have been conducted and that they meet stated requirements. [QARD Sections 2.2.7 to 2.2.9]		
2-7	Verify that management of each organization regularly conduct self-assessments to assess the scope, status, adequacy, and compliance aspects of the QA program to ensure its effective implementation. [QARD Section 2.2.10]		
2-8	Verify that personnel are indoctrinated, trained , qualified, and certified prior to independently performing QA program work. Verify that personnel that require certification are given proficiency tests with acceptance criteria. [QARD Section 2.2.11A]		
2-9	Verify process for training, qualifying, and certifying personnel performing inspections or tests. Verify that validity of the certifications are verified prior to performing inspections. [QARD Sections 2.2.11B, E]		
2-10	Verify that personnel performing as auditors and technical specialists are trained and qualified, and lead auditors are trained, qualified, and certified per ANSI/ASME NQA-1-1983 with ANSI/ASME NQA-1A-1983 addenda. Verify that personnel who perform nondestructive examinations are trained, qualified and certified per ASNT SNT-TC-1A requirements with 3 or 5-year recertification interval. [QARD Sections 2.2.11C, D]		

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	3.0 DESIGN CONTROL		
3-1	Verify that applicable design inputs are being controlled by those responsible for the design and that: • Design inputs are identified and documented, and their selection reviewed and approved by those responsible for the design. • Design inputs are specified and approved on a timely basis to the level of detail necessary to permit the design work to be carried out in a correct manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes. • Data from scientific investigation activities used as design input are qualified per Supplement III prior to use in the design product. If not qualified prior to use in a design product, it is identified as such and tracked until qualified. Unqualified data directly relied on to address safety or waste-isolation issues are qualified. • Changes from approved design inputs and reasons for the changes are approved, documented, and controlled. • Design inputs based on assumptions that require confirmation are identified and controlled. [QARD Section 3.2.1]		
3-2	Verify that design process is controlled according to these requirements: • Design work is prescribed/documented on a timely basis to the level of detail necessary to permit the design process to be carried out in a correct manner and verification that the design meets requirements. • Design documents are adequate to support design, fabrication, construction, and operation. The documentation include not only the final design documents, such as drawings, specifications, and their revisions, but also documentation that identifies the important steps, including sources of design inputs supporting the final design. • Technical and QA standards are identified and documented and		

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	their selection reviewed and approved. Changes/deviations from specified QA and technical standards, and reason for changes or deviations, are identified, evaluated, approved, documented, and controlled. • Measures are established for selection and review for suitability of application of materials, parts, equipment, and processes that are ITWI or ITS functions of SSCs. • Information derived from experience, as set forth in reports or other documentation, are made available to cognizant design personnel. • The final design (approved design documents and approved changes thereto) is relatable to the design input by sufficient detail to permit design verification; identify assemblies and/or components that are part of the items being designed. • If prior to installation, a commercial grade item is modified or selected by special inspection and/or testing to meet requirements that are more restrictive than the supplier's published product description, then the item shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference. • Dimensional accuracy and completeness of design drawings and specifications are checked and documented. • Design drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria. • Design drawings and specifications are reviewed by independent personnel trained and qualified per QARD Section 2.2.11 in QA concepts and practices. [QARD Section 3.2.2]		
3-3	Verify that design analysis meet the following requirements: • Design analyses are performed, controlled, and documented. • Design analysis documents are legible and suitable for reproduction, filing, and retrieval. • Design analysis documents are detailed (purpose, method, assumptions, design input, references and units).		

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	• Calculations are identifiable (including SSC to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable and retrievable. • Design analyses are documented (definition of objective; definition of design inputs and sources; results of literature searches or other background data; identification of assumptions and indication of those that must be verified as the design proceeds; computer calculation including computer type, computer program [i.e., name], revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) that support application of the computer program to the specific physical problem; computer programs may be utilized for design analysis without individual verification of the program for each application, provided the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed and the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application; computer programs shall be controlled to ensure that changes are documented and approved by authorized personnel; and identification of the originator, reviewer, and approver. [QARD Section 3.2.3]		
3-4	Verify that design verification is performed using one or combination of the following: design review, alternate or simplified calculations, and qualification testing as described in Section 3.2.5 of the QARD. The extent of design verification required is a function of the importance to ITS/ITWI SSCs under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Verify that the process for verifying design includes the following: • Guidelines or criteria are established and described for determining the method of design verification. The particular		

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	design verification method used is identified and documented. • Procedural controls provide criteria for determining when design documents that reflect the commitments of the safety analysis report receive formal design verification by interdisciplinary or multi-organizational teams or by a single individual (a signature and date are acceptable documentation). • Results of design verification are documented, including the identification of the verifier. • Responsibilities of the verifier, areas and features to be verified, pertinent considerations to be verified, and the extent of documentation are identified in procedures. • Design verification is performed by competent individuals or groups other than the design originator[s], but may be from the same organization. In exceptional circumstances, refer to Section 3.2.4 of the QARD for additional requirements. • Design verification is performed in a timely manner prior to release for procurement, manufacture, construction, or release to another organization for use in other design work. In those cases where this timing cannot be met, such as when insufficient data exists, the unverified portion of the design shall be identified and controlled. Justification for this action is documented. • Where the design has been subjected to a previous verification process in accordance with the QARD, the verification process need not be duplicated for identical designs. • Use of previously proven designs and changes thereto is controlled. [QARD Sections 3.2.4 and 3.2.5]		
3-5	Verify that design changes, including field changes, are controlled in accordance with the following requirements: • Changes to final designs, field changes, and nonconforming items dispositioned as use-as-is or repair shall be justified and shall be subject to design control measures commensurate with those applied to the original design. • Changes are approved by the same affected groups or		

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	organizations which reviewed and approved the original design documents. • Where a significant design change is necessary because of an incorrect design, the design process and verification implementing documents are reviewed and modified as necessary. • Errors and deficiencies in approved design documents, including design methods (e.g., computer software supporting a safety or waste isolation function), that could adversely affect ITS SSCs or ITWI barriers are documented and action taken to ensure all errors and deficiencies are corrected. • Deviations from specified quality standards are identified and formally documented. Procedures are established to ensure control of these deviations. • Measures are provided to ensure personnel are notified of design changes/modifications that may affect the performance of their duties. [QARD Section 3.2.6]		
3-6	Verify that design interfaces are identified and controlled, in addition to the following requirements: • Design efforts are coordinated among participating design organizations and across technical disciplines. Interface controls include the assignment of responsibility and the establishment of implementing documents among participating design organizations and technical disciplines for the review, approval, release, distribution, and revision of documents involving design interfaces to ensure that SSCs are compatible geometrically, functionally, and with processes and environment. • Design information transmitted across interfaces are documented and controlled. • The status of the design information or document provided is identified in transmittals. • When it is necessary to initially transmit design information orally or by other informal means, the transmittal of design		

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	information is promptly confirmed and controlled with formal documentation initiated in accordance with the initiating organization's approved implementing document. [QARD Section 3.2.7]		
3-7	Verify that the basis, including any supporting analyses for the use of sampling plans for SSCs and barriers, and activities thereto, such as inspection and commercial dedication are documented. The following apply to the use of sampling plans: • Sampling plans used for high-safety-risk-significant activities use a criterion that provides at least a 95% confidence that there are only 5% defective items in a lot (95/5). • Reduced sampling plans may be used for low-safety-risk significant activities. • Lots sampled are essentially homogeneous. [QARD Section 3.2.8]		
4-1	**4.0 PROCUREMENT DOCUMENT CONTROL** Verify that procurement documents include the following provisions to ensure quality as applicable to the item (including spare parts and replacements) or service being procured: • Statement of the scope of work to be performed • Technical requirements (design bases; drawings, specifications, codes, standards, regulations, procedures, instructions with revision level or change status; tests, inspections, and acceptance requirements) • QA program requirements - To the extent necessary, suppliers are to have a QA program consistent with the applicable requirements, depending upon the type and use of the item or service being procured. A principal contractor QA program description is to comply with the QARD. A supplier QA program description is to comply with the purchaser QA program description document, depending on the scope, nature, type and use, or		

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	complexity of the item/service being procured. - Suppliers are to incorporate the appropriate QA requirements into any supplier procurement document issued to a sub-tier supplier. - When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the QARD or the purchaser's QA program. - Procurement of analytical services to support scientific investigation, procurement of data, or commercial calibration services, the procurement may be controlled in accordance with QARD Section 7.2.12B-D, respectively. • Right of access to supplier facilities and records, including access at each tier of procurement for the purpose of inspection, verification, audit, or surveillance by the purchaser or other designee authorized by the purchaser. • Provisions for hold points beyond which work cannot proceed without purchaser authorization. • Schedule for submittal of documents to purchaser for information, review and approval. When the purchaser requires the supplier to maintain specific QA records, the retention times and disposition shall be prescribed. • Reporting of nonconformances dispositioned as use-as-is or repair to the purchaser for approval of the disposition. • Identification of spare and replacement parts or assemblies, and instructions relative to the performance of special processes. • Controls to mitigate procurement and installation of counterfeit or fraudulent items. • Provisions for identifying that the procurement is subject to the provisions of 10 CFR 21. [QARD Section 4.2.1]		
4-2	Ensure that procurement document reviews are: • Performed and documented prior to issuance of the procurement document. • Correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement		

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	document has been prepared, reviewed, and approved. • Performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and scope of the procurement. • Performed by individuals or groups other than the one who generated the document that are trained and qualified in QA practices and concepts and concur with these documents with respect to the QA- related aspects. Ensure that procurement documents are approved. [QARD Section 4.2.2]		
4-3	Verify that changes to procurement documents are subject to the same degree of control as used in the preparation of the original documents. Verify that changes made as a result of proposal/bid evaluations or pre-contract negotiations are incorporated into the procurement documents. The evaluation of these changes and the resulting impact are completed prior to contract award. The evaluation considers: appropriate requirements as specified in this section; additional or modified design criteria; and analysis of exceptions or changes requested or specified by suppliers and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished. [QARD Section 4.2.3]		
	5.0 PROCEDURES, INSTRUCTIONS, AND DRAWINGS		
5-1	Verify that the QA Program requires that work is performed to controlled implementing documents. Verify that work is suspended if it cannot be accomplished as described in controlled implementing documents. [QARD Sections 5.2A, B]		

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5-2	Verify that implementing documents contain the following information as appropriate to the work to be performed: • Responsibilities and organizational interfaces of the organizations affected by the document. • Quantitative or qualitative acceptance criteria for determining that prescribed activities are accomplished and that prescribed results are satisfactorily attained. • Identification of the QA records generated by the implementing document. [QARD Section 5.2.2]		
6-1	**6.0 DOCUMENT CONTROL** Verify that controlled documents that specify quality or technical requirements, or prescribe QARD activities, including changes thereto, are prepared by the responsible and appropriate organization. Verify that these controlled documents are reviewed prior to approval and issuance for correctness, adequacy, accuracy, and compliance with established requirements. When specified by controlling procedures, verify that the review is performed by individuals other than the preparer who are trained and qualified in QA practices and concepts. [QARD Sections 6.2.1 to 6.2.3]		
6-2	Verify that the organization position for approving the document for release is identified. [QARD Section 6.2.4]		
6-3	Verify that distribution and use of documents are controlled: • A process is established to identify the current status of each document that is required to be controlled. This process is made		

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	accessible to document users. • Disposition of obsolete or superseded documents are controlled. • Effective dates are established for approved implementing documents. • The latest version (revision or change) of documents, either in hardcopy or electronic media, is made available for use prior to the start of the work at the location where the activity is performed. Documents are adhered to in the performance of work. [QARD Section 6.2.5]		
6-4	Verify changes to documents are reviewed prior to approval for release: • Changes are approved prior to approval for release. • Implementing documents define the method used to incorporate changes. If the defined method is other than reissue of the entire revised controlled document, the implementing document must define the maximum number of changes permitted prior to requiring reissue of the entire controlled document as a revision. • Implementing documents have a history of changes to QA program documents, including reason for the changes, documented and maintained. • Changes to documents, other than editorial corrections, are reviewed by the same organizations that performed the original review and approval. [QARD Section 6.2.6]		
6-5	Verify process for controlling expedited changes to implementing documents. Verify that editorial changes are distributed as a revision or change to the document, and is approved by the organizational position responsible for approving the document. [QARD Sections 6.2.7 and 6.2.8]		

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7-1	**7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES** Verify systematic approach for planning and documenting procurements which include the following requirements: • Identify procurement methods and organizational responsibilities (e.g., interfaces between design and procurement). • Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished. • Prior to the initiation of each individual activity identified in QARD Section 7.2.1D, identify and document the sequence of actions and milestones, indicating the completion of these activities and the preparation of applicable procedures. • Provide for the integration of the following activities: - Procurement document preparation, review, and change control according to the requirements of QARD Section 4.0. - Selection of procurement sources. - Proposal/bid evaluation and award. - Evaluation of OCRWM contractor/supplier performance. - Verifications, including any hold and witness point notifications. - Control of nonconformances. - Corrective action. - Acceptance of the item or service. - Identification of QA records. • Be accomplished as early as practicable, and no later than the start of those procurement activities that are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process. • Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance. • Include participation of representatives from the technical organizations and individuals that are trained and qualified in QA practices and concepts.		

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	[QARD Section 7.2.1]		
7-2	Verify that supplier's selection is based on an evaluation, performed by or for the purchaser before the contract is awarded, to determine the supplier's capability to provide items or services per procurement document requirements. Verify that the organizational responsibilities of the purchaser for source evaluation and selection to identify supplier's capability shall be identified. Verify measures for evaluating and selecting procurement sources include one or more of the following: • Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use, reflecting current capability. • Evaluation of the supplier's current QA records, supported by documented qualitative and quantitative information that can be objectively evaluated. • Evaluation of the supplier's technical and quality capability as determined by a direct evaluation of supplier's facilities and personnel, and implementation of the supplier's QA program. • The results of procurement source evaluation and selection. Verify that the results of procurement source evaluation and selection are documented. [QARD Section 7.2.2]		
7-3	Verify that the proposal/bid evaluation process includes the following: technical considerations, QA program requirements, supplier personnel, supplier production capability, supplier past performance, alternatives and exceptions. • Determination of the extent of conformance to procurement document requirements as performed by designated, technically-qualified individuals or organizations, including individuals that		

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	are trained and qualified in QA practices and concepts. • Include the following subjects as applicable to the type of procurement –technical considerations, QA program requirements, supplier personnel, supplier production capability, supplier past performance, alternatives, and exceptions. • Prior to contract award, the purchaser has resolved, or obtained commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation. • Any deficiencies that would affect quality are corrected before starting quality affecting work. • The supplier's QA program description document is accepted by the purchaser prior to the start of work. [QARD Section 7.2.3]		
7-4	Verify whether the purchaser of items and services establish measures to interface with the supplier to verify performance which include: • Establishing an understanding between the purchaser and supplier regarding the requirements and specifications identified in the procurement documents. • Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements. • Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements. • Identifying and processing necessary change information. • Establishing the method to be used to document information exchanges between purchaser and supplier. • Establishing the extent of source surveillance and inspection. [QARD Section 7.2.4A]		
7-5	Verify that annual performance evaluations are performed on each supplier to determine the need to schedule additional audits. These evaluations are documented and based on: review of supplier		

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	furnished documents and records; results of previous source verifications, audits, management assessments, and receiving inspections, including results of audits from other sources; and operating experience of identical or similar products furnished by the same supplier. Verify that the extent of verifications, including planning, is a function of the relative importance, complexity, and quantity of items or services being procured and supplier quality performance. Determine that verification activities are accomplished by qualified personnel assigned to check, inspect, audit, or witness supplier activities. Determine that verifications are conducted as early as practical and do not relieve suppliers of their responsibility for the verification of quality achievement. Determine that verifications include (i) the use of audits to evaluate supplier performance and (ii) evaluation of purchaser documentation to aid in the determination of the effectiveness of the supplier QA program. This documentation shall include documentation of source surveillance and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions. [QARD Section 7.2.4B]		
7-6	Verify that supplier-generated documents are controlled, processed, and accepted per established methods; and that measures are implemented to ensure that the submittal of these documents is accomplished per procurement document requirements. These measures provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria. [QARD Section 7.2.5]		

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7-7	Verify methods for accepting supplier-furnished items or services, either by evaluation of supplier certificate of conformance; performing one or a combination of source verification, receipt inspection, or post-installation test; technical verification of data produced; surveillance or audit of the activity (services only); or objective evidence review for conformance to procurement document requirements (services only). [QARD Section 7.2.6]		
7-8	Verify purchaser acceptance of items and services prior to installation or use, i.e. use of Certificate of Conformance (COC) per the following requirements: identify the purchased item or service to the specific procurement document; identify the specific procurement document requirements met by the purchased item or service, such as codes, standards and other specifications; identify any procurement document requirements that have not been met, together with an explanation and the means for resolving the nonconformances; certification process is described in the purchaser's or supplier's QA program description document; and measures shall be identified to verify the validity of certificates and the effectiveness of the certification process (i.e., by audit of the supplier or by an independent inspection or test of the item). [QARD Section 7.2.7]		
7-9	Verify the process used for planning and performing source verification activities with individuals trained and qualified in QA practices and concepts per written procedures to ensure conformance to procurement requirements. Source verification is implemented at predetermined points and performed at intervals consistent with the importance and complexity of the item. Documented evidence of acceptance of source verified items or services is furnished to the receiving destination of the item, to the purchaser, and to the supplier. [QARD Section 7.2.8]		

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7-10	Verify receipt inspection is performed in accordance with established inspection implementing documents and follows these requirements: • Consider the results of source verifications and audits and the demonstrated quality performance of the supplier. • Verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. • Planned and executed per the requirements of QARD Section 10.0. • Coordinated with a review of supplier documentation when procurement documents require such documentation be furnished prior to receiving inspection. [QARD Section 7.2.9]		
7-11	Verify that if post-installation testing method of acceptance is used as a method of acceptance, that it is mutually established by the QA program and the supplier and conducted per QARD Section 11.0. [QARD Section 7.2.10]		
7-12	Verify that purchaser and supplier establish and document the process for disposition of items that do not meet procurement document requirements. Verify control of supplier nonconformances, consisting of the following: • Technical or material requirements are violated. • A requirement in supplier documents, which have been approved by the purchaser, is violated. • The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework. • The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired. Verify that the purchaser verify implementation of the disposition and maintain records of supplier-submitted nonconformances.		

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	[QARD Section 7.2.11]		
7-13	Determine whether commercial grade (CG) items, commercial procurement of analytical services, data, and calibration services were initiated since the last audit. Verify process for procuring CG items as follows: • The item's critical characteristics are specified in approved design and procurement documents. • Verification of the item's critical characteristics is achieved by application of a dedication process to be performed by a specified dedicating entity. • Implementing processes are developed to be consistent with Electric Power Research Institute (EPRI) Guidelines. Verify process for procuring CG analytical services as follows: • Prior to issuing the procurement document, a documented quality control sample plan is developed. • Quality control analytical results are received and evaluated against acceptance criteria prior to use of data. • Data, quality control analytical results, the quality control sample plan, and evaluation documentation are submitted as QA records. Verify process for procuring commercial data as follows: • Planning for data acquisition and use is performed in accordance with QARD Supplement III.2.1. • The data produced by the procurement is identified, controlled, and qualified as described in QARD Supplement III.2.3 and III.2.4. Verify process for procuring commercial analytical services as follows: • Documented review of the supplier's accreditation may be used in lieu of external audits, inspections or tests following delivery, or in-process surveillances during the performance of the		

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	service. • The critical characteristics associated with the calibration are specified in approved design and/or procurement documents. • Verification of the critical characteristics is achieved by application of a dedication process to be performed by a specified dedicating entity. • Procurement documents require reporting as-found and as-left calibration data when calibrated items are found to be out of calibration. • The calibration certificate/report shall include identification of the laboratory equipment/standards used. [QARD Section 7.2.12]		
7-14	Verify the use of suppliers of ASME Section III Code Items. Note: When assessing whether a company has an acceptable QA program to enable it to become a supplier, credit may be taken for the fact that ASME has surveyed the ASME Code supplier and issued a Certificate of Authorization or Quality System Certification of the appropriate scope and for the desired location, without performing any additional evaluation of the supplier QA program. If audits of ASME Code suppliers are conducted, confirm that the suppliers are satisfactorily implementing: • Their accredited ASME Code QA program. • The technical and quality provisions specified in the purchase order. • The applicable provisions of the QARD or principal contractor QA program description document. • Applicable requirements contained in the regulations. [QARD Section 7.2.13]		

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	8.0 IDENTIFICATION AND CONTROL OF MATERIAL, PARTS, AND COMPONENTS		
8-1	Verify that identification is maintained on items or in documents traceable to the items. Verify that items are identified from time of initial fabrication, or receipt, up to and including installation or end use. Verify that identification relates an item to an applicable design or pertinent specifying document. Ensure that correct identification of an item is verified and documented prior to release for fabrication, assembly, shipping, or installation. [QARD Section 8.2.1]		
8-2	Verify that item identification methods include use of physical markings to the maximum extent possible or other means (physical separation, labels or tags, or procedural control) are employed if physical markings are impractical or insufficient. When physical markings are used, verify the following: • Uses materials and methods that provide a clear and legible ID. • Not detrimentally affect the function or service life of the item. • Be transferred to each part of an identified item when the item is subdivided. • Not be obliterated or hidden by surface treatments, coatings, or after installation unless other means of identification are substituted. [QARD Section 8.2.2]		
8-3	Verify that items are controlled per the following requirements: • If codes, standards, or specifications include specific identification or traceability requirements (e.g., identification or		

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	traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; specified inspection, test, or other records), the program is designed to provide such identification and traceability control. • If codes or standards do not include specific identification or traceability requirements, specifications specify identification and traceability methods appropriate to the item. • If items, including consumables, have a limited calendar (shelf) life, operating life, or operating cycles, their use is controlled to: - Uniquely identify them. - Establish records identifying the calendar (shelf) life, operating life, and/or operating cycles remaining. - Prevent the further use of such items, including consumables, which have reached the end of their calendar (shelf) life, operating life, or operating cycles. • If item storage is required, methods are established for the control of item identification that is commensurate with the planned duration and conditions of storage using the following methods: - Maintenance or replacement of markings and identification tags damaged during handling or aging. - Protection of identification on items subject to excessive deterioration resulting from environmental exposure or adverse storage conditions. - Update of existing program records. [QARD Section 8.2.3]		
9-1	**9.0 CONTROL OF SPECIAL PROCESSES** Verify that special processes conducted, such as welding, heat treating, chemical cleaning, and nondestructive examination. Verify special processes are controlled and meet the following criteria: • Results are highly dependent on the control of the process; or • Results are highly dependent on the skill of the operator; and • Quality of the results cannot be readily determined by inspection or test of the item.		

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	[QARD Section 9.2.1]		
9-2	Verify implementing documents for special process include or reference: • Organizational responsibilities, including those trained and qualified in QA practices and concepts, for the qualification of special process equipment and personnel. • Records to be maintained for each special process method. • Provisions for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment or personnel. • Qualification requirements for personnel, implementing documents, and equipment which comply with specified requirements. Certificates of qualification shall clearly delineate the specific processes that personnel are qualified to perform and the criteria used to qualify personnel in each process. • Conditions necessary for accomplishment of the special process include proper equipment, controlled parameters of the process, calibration requirements, and traceability between the item and the individual performing the special process. • Requirements of applicable codes and standards, including acceptance criteria for the special process. [QARD Section 9.2.2]		
9-3	Verify process for qualification and certification of nondestructive examination personnel as follows: • Personnel who perform nondestructive examinations shall be qualified and certified in accordance with QARD Section 2.2.11D. The qualification and certification include a performance demonstration as part of the practical examination. • Suppliers other than principal contractors may qualify their nondestructive examination personnel to other editions of SNT-TC-1A provided other editions are reconciled to the 1980 edition of SNT-TC-1A and found acceptable to the OQA. • Implementing documents are established for the control and		

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	administration of nondestructive examination personnel training, examination, and certification. Note that nondestructive examination include radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, acoustic emission, and leak testing. [QARD Section 9.2.3]		
10-1	**10.0 INSPECTION** Verify process for performing and documenting inspection planning, which include representatives of the interested technical organizations and individuals that are trained and qualified in QA practices and concepts. Inspection plans which include applicable codes, standards, specifications, and design documents, may be separate documents governed by procedural controls, or an integral part of approved implementing documents. Elements of an inspection plan include: • Characteristics to be inspected. • Description of inspection or process monitoring that will be used. • ID of the organization responsible for performing the inspection. • ID of mandatory hold points, when required. • Acceptance criteria. • Measuring and test equipment to be used to perform the inspection to ensure the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function. • If applicable, identification of a sampling plan per QARD Section 10.2.4. • Methods to record inspection results. [QARD Section 10.2.1]		
10-2	Verify process for selecting inspection personnel as follows: • Characteristics to be inspected. • Qualification of inspection personnel complies with QARD		

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	Section 10.0. • On-the-job training is performed under direct observation/supervision of a qualified person and verification of conformance by the qualified person until proper certification is achieved. • Data recorders, equipment operators, or other inspection or test team members who are supervised by a qualified inspector shall not be required to be a qualified inspector. • Inspections for acceptance are performed by individuals other than those who performed or directly supervised the work being inspected, and those individuals do not report directly to the supervisor immediately responsible for performance of the work. [QARD Section 10.2.2]		
10-3	Verify use of inspection hold points and documentation for waiving specified hold points. [QARD Section 10.2.3]		
10-4	When statistical sampling is used to verify the acceptability of a group of items, verify that the statistical sampling method is based on recognized standard practices and complies with the sampling plan requirements delineated in QARD Section 3.2.8. Verify inspection and monitoring of in-process or under construction items. If inspection of processed items is impossible or disadvantageous, verify that indirect control by monitoring of processing methods, equipment, and personnel is provided. Verify documentation of final inspection and acceptance of finished items (for completeness, markings, calibration, adjustments, protection from damage, or other characteristics). Final inspections include a review of the results and resolution of nonconformances		

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	identified by earlier inspections. Modifications, repairs, or replacements of items performed subsequent to final inspection require re-inspection or retest, as appropriate, to verify acceptability. Inspection documentation identify the following: • The item inspected. • Date of inspection. • The name or unique identifier of the inspector who documented, evaluated, and determined acceptability. • The name of the data recorder, as applicable. • The type of observation or method of inspection. • The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance. • Results or acceptability of characteristics inspected. • Measuring and test equipment used during the inspection, including the identification number and the most recent calibration date. • Reference to information on actions taken in connection with nonconformances. [QARD Sections 10.2.4 to 10.2.8]		
10-5	Verify qualification and certification of personnel performing inspections per QARD Section 2.2.11B and 2.2.11E. Verify process for maintaining inspector qualification and certification documentation. [QARD Section 10.2.9]		
11-1	**11.0 TEST CONTROL** Verify process for planning tests as follows: • Provide criteria for determining the accuracy requirements of test equipment and for determining when tests are required and defining how and when testing activities are performed. • Provisions for performing prototype, component, or feature		

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	qualification testing, including design verification testing, as early as possible before the installation would become irreversible. • Identification of the item to be tested and the test requirements and acceptance limits contained in applicable design and procurement documents. • Identification of test methods to be employed and instructions for performing the test. • Test prerequisites that address the following: calibrated instrumentation: appropriate and adequate test equipment and instrumentation, including accuracy requirements, trained personnel, condition of test equipment, and the completeness of the item to be tested; suitably controlled environmental conditions; and provisions for data acquisition and storage. • Mandatory inspection hold points for witnessing by the organization placing the hold point. • Methods to record data and results. • Provisions for ensuring that test prerequisites have been met. • Selection and identification of the measuring and test equipment (M&TE) to be used to perform the test to ensure that the M&TE is of the proper type, range, accuracy, and tolerance to accomplish the intended function. [QARD Section 11.2.1]		
11-2	Verify that tests are being performed per implementing documents as follows: • Provisions for determining when a test is required, describing how tests are performed by trained and qualified personnel. • Inclusion of or reference to test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate calibrated instrumentation is available and used, necessary monitoring is performed, and suitable environmental conditions are maintained. • Test requirements and acceptance criteria provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated.		

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	• Test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents. [QARD Section 11.2.2]		
11-3	Verify process for using other testing documents [ASTM specifications, supplier manuals, or other related documents containing acceptance criteria] instead of preparing special test implementing documents. Verify that other testing documents include adequate supplemental instructions, as required, to ensure the required quality of the testing work. [QARD Section 11.2.3]		
11-4	Verify that the test results are documented and their conformance with acceptance criteria is evaluated by a qualified individual within the responsible organization to ensure that test requirements have been satisfied. Verify test status of an item is identified per QARD Section 14.0. [QARD Section 11.2.4]		
11-5	Verify test documentation identify the following: • Item or work product tested • Date of test • Name of tester and data recorders • Type of observation • Identification of test criteria or reference documents used to determine acceptance • Results and acceptability of the test • Actions taken in connection with any deviations noted • Name of person evaluating and accepting the test results • Identification of M&TE used during the test including the ID number and the next calibration due date.		

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	[QARD Section 11.2.5]		
11-6	Verify personnel performing tests are qualified and certified per QARD Section 2.2.11 requirements. [QARD Section 11.2.6]		
12-1	**12.0 CONTROL OF MEASURING AND TEST EQUIPMENT** Verify that calibration controls are in place and being implemented that assure: • Measuring and Test Equipment (M&TE), including equipment that contains embedded software or programmable hardware is calibrated, adjusted, and maintained as a unit at prescribed intervals or, prior to use, against certified equipment, including reference and transfer standards having known valid relationship to nationally recognized standards. • Calibration standards have a greater accuracy than the required accuracy of standards being calibrated. If calibration standards with a greater accuracy than required of the standard being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements. The basis for the calibration acceptance is documented and authorized by responsible management. The level of management authorized to perform this function is identified. • Calibration standards used for the calibration of M&TE shall have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, shall have an accuracy that ensures the equipment being calibrated will be within required tolerance. The basis of acceptance shall be approved by responsible management. The level of management authorized to perform this function shall be identified. • Method and interval of calibration for each device is defined based on type of equipment, stability characteristics, required		

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	accuracy, precision, intended use, degree of use, and other conditions affecting measurement control. For M&TE used in one-time-only applications, the calibration shall be done both before and after use. • Calibration check is performed when accuracy of the M&TE is suspect; and when the M&TE has passed its calibration due date or interval and has been used since its last calibration and is removed from service (i.e., retired or surplus). • Calibrated M&TE is labeled, tagged, or otherwise suitably marked or documented to indicate due date of the next calibration. • Calibrated M&TE is uniquely identified to provide traceability to its calibration data. • Updates to software contained in M&TE that affect calibration require re-calibration of the equipment prior to use. [QARD Section 12.2.1]		
12-2	Verify documentation of the use of M&TE, including control of selected M&TE to ensure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. Verify that the documentation identify the processes monitored, the data collected, or items inspected or tested since the last calibration as appropriate to equipment use and its calibration schedule. [QARD Section 12.2.2]		
12-3	Verify controls for out-of-calibration M&TE as follows: • Tagged, segregated and not used, or otherwise controlled to prevent reissue until it has been recalibrated (see QARD Section 12.2.8B.1.) • Validity of results obtained using that equipment since its last valid calibration is evaluated and documented. If evaluation determines that processes monitored or items inspected or tested are suspect, it is documented per QARD Section 15.0. • If M&TE is consistently found to be out-of-calibration during		

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	the recalibration process, it is repaired or replaced. Verify process for lost or abandoned-in-place M&TE, including evaluation of the validity of results obtained using that equipment since its last valid calibration. Verify handling, storage, and use of M&TE to maintain accuracy. Verify control of selected M&TE to ensure that such items are the proper type for the intended use. [QARD Sections 12.2.3, 12.2.4, and 12.2.5] Note: Per QARD Section 12.2.6 Commercial Devices Calibration and control shall not be required for commercial devices when normal commercial device accuracy is adequate for the intended use of the commercial device.		
12-4	Verify that M&TE calibration documentation includes the following: • Identification of the M&TE calibrated; • Traceability to the calibration standard used for calibration; • Calibration data; • Identification of the individual performing the calibration; • Identification of the date of calibration and the re-calibration due date or interval, as appropriate; • Results of the calibration and statement of acceptability; • Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE, including evaluation results and repeated inspections or tests, as appropriate; and • Identification of implementing document (including revision level) used in performing calibration. [QARD Section 12.2.7] Note: Per QARD Section 12.2.6 Commercial Devices Calibration and control shall not be required for commercial devices when normal commercial device accuracy is adequate for the intended use of the commercial device.		

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	13.0 HANDLING, STORAGE AND SHIPPING		
13-1	Verify that handling, storage, cleaning, packaging, shipping, and preservation of items are conducted in accordance with established work and inspection implementing documents, shipping instructions or other specified documents. If required for critical, sensitive, perishable, or high-value articles, specific implementing documents for handling, storage, cleaning, packaging, shipping, and preservation are prepared and used. [QARD Section 13.2.1]		
13-2	Identify and determine use and control of special equipment (e.g., containers, shock absorbers, and accelerometers) and special protective environments (i.e., inert gas atmosphere and specific moisture content levels and temperature levels). Verify that use of special handling tools and equipment is controlled, as necessary to ensure safe and adequate handling; inspected and tested at specified time intervals and in accordance with implementing documents to verify that the tools and equipment are adequately maintained; and operators of special handling and lifting equipment are experienced or trained to use the equipment. [QARD Section 13.2.2]		
13-3	Verify that measures are established for marking and labeling for the packaging, shipping, handling, and storage of items as necessary to adequately identify, maintain, and preserve the item. Verify that markings and labels indicate the presence of special environments or the need for special controls if necessary. [QARD Section 13.2.3]		
	14.0 INSPECTION, TEST, AND OPERATING STATUS		
14-1	Verify methods for identifying items that have satisfactorily passed required inspections and tests; and preclude the inadvertent		

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	installation, use, or operation of items that have not passed required inspections and tests. [QARD Section 14.2.1]		
14-2	Verify that the status of required inspection and tests of items is indicated when necessary to preclude inadvertent bypassing of such inspections and tests. Verify that the status of inspections and tests is identified either on the items or in documents traceable to the items. Verify that the status is maintained through the use of legible and easily recognizable status indicators (e.g., tags, markings, labels, and stamps) or other means (e.g., travelers, inspection, or test records). Verify that the authority for applying and removing status indicators is specified. To prevent the inadvertent use or operation of an item that is out of service (e.g., a nonconforming, inoperative, or malfunctioning item), verify that status indicators such as tags or markings are placed at all locations where operation of the item can be initiated (e.g., control panels, switches, breakers, valves, or systems). [QARD Section 14.2.2]		
	15.0 NONCONFORMING MATERIAL, PARTS, OR COMPONENTS		
15-1	Verify that nonconforming items are documented, reported, and evaluated as follows: • Nonconformances are documented and reported to the appropriate levels of management responsible for the conditions. In addition, organizations affected by the nonconformance are notified in writing. • Nonconformances are tracked and trended in accordance with the requirements of QARD Section 16.0.		

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	• Nonconformance documentation clearly identifies and describes the characteristics that do not conform to specified criteria. • Nonconforming characteristics are reviewed, and recommended dispositions of nonconforming items are proposed and approved. • The review include determining the need for corrective action according to the requirements of Section 16.0 and the need for reporting in accordance with 10 CFR 21 and 10 CFR 63.73. • Recommended dispositions are evaluated and approved by individuals who are independent of the work that produced the disposition. • Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area being evaluated, have an adequate understanding of the requirements, and access to pertinent background information. • The responsibility and authority for reviewing, evaluating, and approving the disposition, and closing nonconformances are specified. • Further processing, delivery, installation, or use of a nonconforming item is controlled pending the evaluation and approval of the disposition. • Nonconformances are corrected or dispositioned before initiation of the preoperational test program on the item. [QARD Section 15.2.1]		
15-2	Verify that nonconforming items are identified by marking, tagging, or other methods that do not adversely affect their end use. Verify that the identification is legible and easily recognizable. If the identification of a nonconforming item is not practical, verify then that the container, package, or segregated storage area, as appropriate, is identified. [QARD Section 15.2.2]		

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15-3	Verify that nonconforming items are segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible due to physical conditions, other precautions are employed to preclude inadvertent use. Verify that the nonconforming items are dispositioned as follows: • Disposition of use-as-is, limited use (this disposition is limited to Supplement II nonconforming samples), reject, repair, or rework for nonconforming items is identified and documented. • Technical justification for the acceptability of a nonconforming item that has been dispositioned as repair, limited use or use-as-is is documented. • Items that do not meet original design requirements that are dispositioned as use-as-is or repair are subject to design control measures commensurate with those applied to the original design. - If changes to the specifying document are required to reflect the as-built condition, then the disposition requires action to change the specifying document to reflect the accepted nonconformance. - Any document or QA record change required by the disposition of the nonconformance is identified in the nonconformance documentation, and when each document or record is changed, the justification for the change identifies the nonconformance documentation. • The disposition of an item to be reworked or repaired contains a requirement to reexamine (e.g., by inspection, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items are reexamined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria. • Replacement items are inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives. [QARD Sections 15.2.3 and 15.2.4]		

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16-1	**16.0 CORRECTIVE ACTION** Verify process for identifying, classifying, documenting, reporting, trending, and conducting follow-up of conditions adverse to quality and significant conditions adverse to quality as follows: Conditions Adverse to Quality (CAQs) • A CAQ is identified and documented when a failure, malfunction, deficiency, defective item, or nonconformance is identified. • Conditions adverse to quality are classified to distinguish between CAQs and significant CAQs in regard to their significance, and corrective actions shall be taken accordingly. • Conditions adverse to quality are evaluated for reportability in accordance with 10 CFR 21 and 10 CFR 63.73. • Responsible management completes remedial action as soon as practical. Significant Conditions Adverse to Quality (SCAQs) • Criteria for determining a SCAQ are established and documented. • SCAQs shall be documented and reported to management responsible for the condition and their upper management in a prompt manner. • SCAQs are evaluated for a stop work condition by the QA organization to determine whether stopping work is warranted. • Responsible management performs investigative action to determine the extent and impact of the condition, and document the results. • Responsible management determines, documents, and completes remedial action. • Responsible management determines the root cause of the problem and takes corrective action to prevent recurrence as soon as practical. • Processes are established to verify the implementation of corrective actions associated with significant conditions adverse to quality.		

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	[QARD Sections 16.2.1 and 16.2.2]		
16-2	Verify that conditions adverse to quality are documented, tracked, and reported to appropriate levels of management. Verify that the responsible management determines extent of the adverse condition and completes remedial action as soon as practical. [QARD Section 16.2.3]		
16-3	Verify that significant conditions adverse to quality are evaluated for a "STOP WORK CONDITION" by the QA organization to determine if stopping work is warranted. Verify that the QA management has taken appropriate actions to lift and close the stop work. Verify that the responsible management performs investigative action to determine the extent and impact of the condition, and documents the results. Verify that the responsible management determines, documents, and completes remedial actions, including the root cause of the problem and taken corrective action to prevent recurrence as soon as practical. [QARD Section 16.2.4]		
16-4	Verify that processes have been established to verify the implementation of corrective actions associated with CAQs and SCAQs. [QARD Section 16.2.5]		
16-5	Verify that criteria are estalbished for determining adverse quality trends. Verify that reports of nonconformances and CAQs are evaluated to		

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	identify adverse quality trends. Verify that trend evaluation is performed in a manner and at a frequency that provides for prompt identification of adverse quality trends and assists in identifying root cause. Verify that trend evaluations are promptly distributed to management for review and appropriate corrective action. [QARD Section 16.2.6]		
17-1	**17.0 QUALITY ASSURANCE RECORDS** Verify that implementing documents identify QA records and the organization submitting them to records management system. [QARD Sections 17.2.1 and 17.2.2]		
17-2	Verify that QA records are legible, accurate, complete, and identifiable to the item or activity to which they apply. Verify that QA records are protected from damage or loss until the records are submitted to the records management system. Verify that records are considered valid when stamped, initialed, or signed and dated by authorized personnel or authenticated. The authentication may take the form of a statement by the reporting individual or organization. If the nature of the record (e.g., magnetic or optical media) precludes stamping, initialing, or signing, then other means of identifying the record as complete by authorized personnel are permitted. Handwritten signatures are not required if the document is clearly identified as a statement of the reporting individual or organization. QA records may be originals or copies.		

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	[QARD Section 17.2.2B-F]		
17-3	Verify that a receipt control system for QA records is established to include: • An individual or organization is assigned the responsibility for receiving QA records for permanent or temporary storage. • A method is established for verifying that the QA records received are in agreement with the transmittal document. • QA records are protected from damage, deterioration, or loss when received. • Legibility and completeness of QA records are verified. • The receipt control system permits a current and accurate assessment of the status of QA records during processing. • QA records are indexed, including location of the QA records within the records management system, identification of the item or related activity to which the QA records pertain, and the record retention times. [QARD Section 17.2.4]		
17-4	Verify process for correcting information to QA records, including documents that will become QA records as follows: • Include the initials or signature of the person authorized to make the correction and the date the correction was made. • Corrections to QA records are reviewed and approved by the originating organization. If the organization responsible for generating the record is no longer available, a new responsible organization is identified and documented. [QARD Section 17.2.5]		
17-5	Verify that there are predetermined storage facilities for storing and preserving QA records which meet the requirements of applicable standards, codes, and regulatory agencies per an approved implementing document that: • Describes the storage facility and filing system		

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	• Provides a method for verifying that QA records are in agreement with the transmittal document and that the records are legible • Controls governing QA record access, retrieval, and removal • Provides methods for filing supplemental information and for disposition of superseded QA records. [QARD Section 17.2.6A]		
17-6	Verify that storage methods preclude deterioration of QA records, as follows: • The storage area is constructed and maintained to minimize risk of damage or destruction from disasters (such as wind, floods, or fires); environmental conditions such as high and low temperatures and humidity; and infestations of insects, molds, or rodents. • QA records are filed in binders or in folders/envelopes for storage in steel file cabinets or on shelving in containers appropriate for the QA record medium being stored. • The storage arrangement provides adequate protection of special processed records (i.e., radiographs, photographs, negatives, microform, and electronic and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of QA record being stored. The guidance provided in NRC Regulatory Issue Summary 2000-18, *Guidance on Managing Quality Assurance Records in Electronic Media*, shall be complied with in the development of procedures governing the management of electronic media records. • The storage area is protected from unauthorized entry, larceny, and vandalism. [QARD Section 17.2.6B]		
17-7	Verify that QA records are retrievable, and that access to storage facilities is controlled with a list designating personnel with permitted access to QA records.		

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	[QARD Section 17.2.7]		
17-8	Verify that QA records are defined (lifetime or nonpermanent), retention times specified and, for nonpermanent records, the conditions for disposal are met. Verify that supplier QA records are addressed accordingly. Criteria for lifetime QA records: • Those that would be of significant value in demonstrating capability for safe operation. • Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item. • Those that would be of significant value in determining the cause of an accident or malfunction of an item. • Those which provide required baseline data for in-service inspection. Criteria for nonpermanent QA records, which are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not meet the criteria for lifetime QA records: • Nonpermanent QA records shall be retained until the issuance of a license to receive and possess SNF/HLW. At a minimum, nonpermanent QA records shall be retained for 10 years or the life of the item if less than 10 years. • For programmatic nonpermanent QA records, the retention period shall be considered to begin on completion of the activity. • For product nonpermanent QA records, the retention period shall be considered to commence upon completion of delivery. [QARD Section 17.2.8]		
17-9	Determine whether dual storage facilities in lieu of implementing QARD Section 17.2.10 are used for the storage of QA records per the following applicable requirements:		

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	• Dual storage facilities for the storage of QA records provide facilities for copies of each record at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. • Dual storage facilities are not required to meet the design and construction requirements specific for a long-term single storage facility, but shall meet the other requirements of this QARD section. [QARD Section 17.2.11]		
17-10	For temporary storage facilities of QA records during processing, review, or use until turnover to the OCRWM for disposition per the following requirements, verify that: • QA records are temporarily stored in a container or facility with a 1-hour fire rating, or dual storage is provided as follows: • Single storage, containers or facilities bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection or be certified by a person competent in the technical field of fire protection or that dual storage is provided and that the maximum time limit for storage is specified. • The period of time allowed for records to be in temporary storage will be specified in appropriate procedures. [QARD Sections 17.2.12 and 17.2.14]		
17-11	Verify that there are implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records. [QARD Section 17.2.13]		
18-1	**18.0 AUDITS** Verify that there are schedules for internal and external audits to provide coverage, consistency, and coordination with ongoing work. In scheduling internal audits ---		

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	• Coordinate with the responsible line manager and scheduled in a manner to provide coverage, consistency, and coordination with ongoing work. • Schedule at a frequency commensurate with the status and importance of the work. • Schedule to begin as early in the life of the work as practical and continue at intervals consistent with the schedule for accomplishing the work. • Supplement regularly scheduled internal audits with additional audits of specific subjects, when necessary. • Perform internal audits of applicable QARD elements to verify QA program compliance and effectiveness at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter. • Conduct performance-based internal audits on selected work to determine QA program effectiveness. In scheduling external audits (audits of suppliers) --- • Coordinate with the responsible line manager and scheduled in a manner to provide coverage, consistency, and coordination with ongoing work. • Begin as early in the life of the work as practical. • Continue at intervals consistent with the schedule for accomplishing the work. • At a frequency commensurate with the status and importance of the work. Verify that audits are performed at intervals not to exceed 12 months or at least once during the life of the work. Identify any performance-based audits conducted to date. External audits for compliance and effectiveness are performed triennially or at least once during the life of the work, whichever is shorter. Verify that schedules are revised periodically to ensure that coverage is maintained current. [QARD Sections 18.2.1 to 18.2.4]		

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18-2	Verify the process for planning audits. Verify that an audit plan is developed and includes the following: audit scope, requirements for performing the audit, audit personnel, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used. Verify independence and authority of selected and assigned auditors. Verify that an audit team is identified before beginning each audit that includes representatives from the QA organization, and when appropriate, applicable technical specialists. A lead auditor is appointed to supervise the team, organize and direct the audit, and coordinate the preparation and issuance of the audit report. Selected lead auditors and auditors are qualified in accordance with the requirements of this section. Technical specialists, when used, shall be indoctrinated and trained in accordance with Subsection 2.2.11C. Verify that in the case of internal audits, personnel having direct responsibility for performing the work being audited shall not be involved in the selection of the audit team. The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited. [QARD Sections 18.2.5 to 18.2.7]		
18-3	Verify performance of audits in accordance with written procedures or checklists; that elements selected for the audit are evaluated against specified requirements; that audit results are documented by auditing personnel and reported to and reviewed by management having responsibility for the area audited. [QARD Section 18.2.8]		

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18-4	Verify conditions adverse to quality are documented and corrected in accordance with QARD Section 16.0. [QARD Section 18.2.8F]		
18-5	Verify that the audit report is prepared and signed by the audit team leader, and issued to management of the audited organization. Verify audit report contains: a description of the audit scope, identification of the auditors; identification of personnel contacted during the audit; summary of the audit results including a statement on the effectiveness of the QA program elements evaluated; and a description of each reported condition adverse to quality, including those conditions identified as audit findings in sufficient detail to enable corrective action to be taken by the audited organization according to the requirements of Section 16.0. [QARD Section 18.2.9]		
18-6	Verify that the adequacy of corrective actions for conditions adverse to quality are evaluated and accepted by the auditing organization prior to closure. Verify that follow-up action is taken by the auditing organization to verify that corrective action for the audit finding is accomplished in a timely manner. [QARD Sections 18.2.11 and 18.2.12]		
18-7	Verify that personnel performing audits, including auditors, technical specialists, and lead auditors are qualified and certified per QARD Section 2.2.11C. [QARD Section 18.2.13]		
SI-1	**SUPPLEMENT I, SOFTWARE** Verify that software acquisition, development, modification, and maintenance are planned and traceable utilizing a software life cycle methodology: requirements, design, implementation, testing, installation and checkout, operations and maintenance, and		

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	retirement. Verify that software life cycles contain control points that, when reached, ensure specified software is documented, reviewed, and baselined. [QARD Supplement I.2.1A, I.2.3]		
SI-2	Verify that verification and validation activities are planned, documented, and performed for software, software changes, or system configurations that are determined to impact the software. Verify that validation test plans, test cases, and test results are documented, reviewed, and approved prior to use of the software. Determine that software verification is performed at the end of the requirements, design, implementation, and testing life cycle phases to ensure that the products of a given life cycle phase are traceable and fulfill the requirements of the previous phase and/or previous phases. Verify that software verification evaluates the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software, and is traceable to the software design requirements: Tests and test results from reviews and verifications shall be included in the acceptance test documentation; and tests conducted as reviews or verifications do not substitute for performing comprehensive, end-of-development acceptance tests. Verify that software verification and validation activities are performed by individuals not associated with development of the software. [QARD Supplement I.2.1B]		
SI-3	Verify that software has a plan addressing software QA for each new software project at the start of the software life cycle, which		

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	identifies: • A description of the overall nature and purpose of the software. • The software products to which it applies. • The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities. • Required documentation. • Standards, conventions, techniques, or methodologies that shall guide the software activity. • Required software reviews. • Methods for error reporting and corrective action. [QARD Supplement I.2.2]		
SI-4	Verify that the software configuration management (SCM) process is established to include configuration identification, change control, and status accounting, as each baseline element is approved. [Note that support software (i.e., systems software and software tools) is not qualified or baselined. However, such software is placed under configuration management control (including change control) by SCM (see QARD Section I.1.D)]. Verify that configuration items to be controlled include, at a minimum, and as appropriate: documentation (e.g., plans requirements, designs, user manuals, test reports, user information); computer program(s) (e.g., source, object, backup files, media); and support software. Verify that configuration identification includes: definition of the baseline elements of each software baseline; a unique identifier of each software item, including version or revision, to be placed under SCM; assignment of unique identifiers that relate baseline documents to their associated software items. Verify that cross-references between baseline documents and associated software are maintained. [QARD Supplement I.2.4A-E]		

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SI-5	Verify that configuration change control includes: • A release and control process for baseline elements. • Changes to baseline elements are formally controlled and documented. This documentation contains a description of the change, the rationale for the change, and the identification of affected baseline elements. • A formal evaluation of the baseline element or change to the baseline element and approval by the organization responsible for approving the baseline element. • The transmission of information concerning approved changes to all organizations affected by the changes. • Software verifications performed for the changes, as necessary, to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained. • Software validation performed as necessary for the change. Verify that configuration status accounting includes: • A listing of the approved baseline elements and unique identifiers. • Status of proposed, in-process, or approved changes to baseline elements. • A history of changes to the software items, including descriptions of the changes made between versions of software items. [QARD Supplement I.2.4F-G]		
SI-6	Verify that a software problem reporting and resolution system, integrated with the SCM process, is implemented for software errors and failures to ensure problems are promptly reported to impacted organizations and to ensure formal processing of problem resolutions. If a problem that constitutes a condition adverse to quality is identified in software, verify that the condition adverse to quality is documented and controlled per QARD Section 16.0.		

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	[QARD Supplement I.2.5]		
SI-7	For procured software, verify that the procurement documents specify the applicable requirements of QARD Sections 4.0 and 7.0. For procured software services, verify that the organization providing the services has plan(s) for software QA per QARD Supplement I.2.2A that meets the requirements of QARD Section I.2.7. [QARD Supplement I.2.6]		
SI-8	Verify acquired software or software previously developed not using this Supplement, and are controlled and qualified per QARD Section I.2.4. For software that has not been previously approved under a program consistent with this Supplement for use in its intended application (e.g., freeware, shareware, procured COTS, or otherwise acquired software), other than software described in Paragraphs I.1C and I.1D, verify that this software is qualified in accordance with the requirements of this Supplement. Verify that this software is identified and controlled per QARD Section I.2.4 prior to qualification. [QARD Supplement I.2.1A.2, I.2.7]		
SI-9	Verify that the use of released software is controlled and documented; and is independently reviewed and approved to ensure that the software selected is suitable to the problem being solved. If the intended use of the software item will require the use of inputs outside the ranges verified during validation testing, verify that the appropriate baseline elements are re-verified and re-validated for the expected range of inputs prior to continuing use. Verify that documentation for the receipt of software obtained from		

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	SCM in accordance with QARD Section I.2.4 is provided and maintained for software in operation or use. Verify that controls are established to permit authorized access and prevent unauthorized access to operating environment. [QARD Supplement I.2.8]		
SII-1	**SUPPLEMENT II, SAMPLE CONTROL** Verify methods for identifying and controlling samples in a manner consistent with their intended use and for traceability are established and maintained. Verify that controls identify responsibilities, including interfaces between organizations, for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use; and that controls include specifics on orientation relative to the location that was sampled, as appropriate Verify the sample identification methods which include the use of physical markings are documented, maintained from their initial collection through final use, and verified before the sample is released for use or analysis. If physical markings are either impractical or insufficient, verify that other appropriate means are employed (e.g., physical separation, labels or tags attached to containers, or other procedural control). If samples have limited use or storage life, verify that methods are established that preclude using the sample beyond its intended use or storage life. Verify that measures are established for the marking and labeling for packaging, shipping, handling, and storage of samples, as necessary, to adequately identify, maintain, and preserve the sample.		

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	Verify that markings and labels indicate the presence of special environments or the need for special controls, if necessary. [QARD Supplements II.2.1 to II.2.4, and II.2.7]		
SII-2	Verify that handling, storage, cleaning, packaging, shipping, and preservation of samples are described in implementing documents and measures are identified and used, including special equipment (i.e., containers), special protective environments (i.e., inert gas and moisture and temperature limits), and special handling tools and equipment. Verify that implementing documents specify the representative samples to be archived if the need to archive samples is identified. [QARD Supplements II.2.5 and II.2.6]		
SII-3	Verify processing of nonconforming samples per QARD Section 15.0. [QARD Supplement II.2.8]		
SIII-1	**SUPPLEMENT III, SCIENTIFIC INVESTIGATION** Verify that scientific investigations are planned per QARD Section 2.0, coordinated with organizations, and that there are provisions for determining accuracy, precision, and representativeness of results. [QARD Supplement III.2.1]		
SIII-2	Verify that scientific investigations are performed using implementing documents and/or scientific notebooks, which contain the following: • Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics. • Identification of method(s) and computer software used.		

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	• Identification of any samples or M&TE used. • Description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries. • Description of changes made to methods used, as appropriate. Verify control and use of scientific notebooks, including its periodic review by an independent qualified individual. Verify that software utilized in the performance of scientific investigations are controlled as follows: • Computer software used to develop or execute models is controlled in accordance with Section III.2.6 C. • Data acquisition and control applications, integral to the operation, maintenance, or calibration of a scientific investigation testing apparatus and verified or validated in conjunction with the M&TE or hardware as a unit, is controlled by QARD Section 12.2.1A. [QARD Supplement III.2.2]		
SIII-3	Verify that data is traceable to its qualification status for the lifetime of the data. [QARD Supplement III.2.3]		
SIII-4	Verify that unqualified data is qualified using one or a combination of the following methods: • Data were generated under a program similar to the QARD • Use of corroborating data–rationale needs to be explained and justified • Confirmatory testing • Peer review • Technical assessment Verify that data from scientific investigation activities that are used		

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	as direct input to site characterization, and scientific analysis or performance modeling that address safety and waste isolation issues are qualified from origin, except as allowed in Paragraph III.2.4B.2. Verify that external source data that are not identified as established fact and are used as direct input to scientific analysis or performance modeling are qualified for its intended use. [QARD Supplement III.2.4]		
SIII-5	Verify that model development and approaches to validation are planned, controlled, and documented. Verify that planning identifies the validation methods and the validation criteria used. If model validation activities are completed after documentation of the model (i.e., using new confirmation test data gathered in the field or laboratory), verify that these activities are described in the work-planning document. [QARD Supplement III.2.6A]		
SIII-6	Verify that model documentation includes: • Model objective (intended use) and definition. • Description of conceptual model and scientific basis, as well as alternatives for the selected conceptual model, including rationale for not selecting alternatives. • Results of literature searches and applicable background information. • Inputs and their sources. • Identification of and rationale for assumptions are made to develop or apply the model, including model idealizations, as well as those assumptions that support the input to the model and impact model results. • Mathematical and numerical methods and software used, including governing equations, formulas, and algorithms, and their scientific and mathematical bases. • Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.		

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	• Initial/boundary conditions. • Limitations (i.e., data available for model development, valid ranges of model application, spatial and temporal scaling). • Uncertainties (e.g., conceptual model, mathematical model, process model, abstraction model, system model, parameters) and how they affect the model. • Identification of the originator, reviewer, and approver. [QARD Supplement III.2.6B]		
SIII-7	Verify that any software used to develop or execute the model is qualified per QARD Supplement I requirements. [QARD Supplement III.2.6C]		
SIII-8	Verify that the criteria for model validation are clearly established to: • Determine the adequacy of the scientific basis for the model is consistent with the model application and justified in the model documentation. • Demonstrate that the model is sufficiently accurate for its intended use. • Define the importance of the model for assessing repository system performance. • Describe the relative level of confidence for the model. • Define the supporting information needed to substantiate validation. Verify methods used to validate from conceptual model to mathematical model to process model to abstraction model to system model: • Describe the relative level of confidence for the model. • Define the supporting information needed to substantiate validation. • Corroboration of model results. • Peer review (Subsection 2.2.8) or independent technical review		

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	(Subsection 6.2.3). • Performance confirmation studies using validation test model predictions prior to comparison with field or laboratory data. • Comparison of model results with other results obtained from the implementation of an alternative validated model. [QARD Supplement III.2.6E]		
SIV-1	**SUPPLEMENT IV, FIELD SURVEYING** Verify that a permanent system of horizontal and vertical controls is established and maintained. [QARD Supplement IV.2.1A]		
SIV-2	Verify the system is used in accordance with implementing documents to obtain the accurate location and relocation of designated features, including locations of sample or data collection. [QARD Supplement IV.2.1B]		
SIV-3	Verify that pertinent survey documents are identified, maintained, and verified for completeness as the work progresses. [QARD Supplement IV.2.2]		
SV-1	**SUPPLEMENT V, CONTROL OF THE ELECTRONIC MANAGEMENT OF INFORMATION** Verify process controls are established to ensure that information is suitably protected from damage and destruction during its prescribed lifetime and are readily retrievable. [QARD Supplement V.2.1A]		
SV-2	Verify process controls are established to ensure a description is prepared of how information will be stored with respect to media, conditions, location, retention time, security, and access.		

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	[QARD Supplement V.2.1B]		
SV-3	Verify process controls are established to ensure that storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written). [QARD Supplement V.2.1C]		
SV-4	Verify process controls are established to ensure that the completeness and accuracy of the information input and any subsequent changes to the information are maintained. [QARD Supplement V.2.1D]		
SV-5	Verify process controls are established to ensure that the security and integrity of the information is maintained. [QARD Supplement V.2.1E]		
SV-6	Verify process controls are established to ensure that transfers of information are error free or (where applicable) within a defined permissible error rate, to ensure that no information is lost in transfer and the input is recoverable from the output. Examples of information transfers include copying raw information from a notebook to a computerized form, copying from computer tape to disk, and writing to a compact disk. [QARD Supplement V.2.1F]		
App A-1	**APPENDIX A, WASTE CUSTODIAN INTERFACE** Verify federal waste custodian interface with OCRWM on information and/or data to suppor activities subject to the QARD (e.g., scientific document development, design, etc.) [QARD Appendix A.1.2A]		

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App A-2	Verify flowdown of appropriate provisions of the EM/RW MOA from the federal waste custodians to its contractors. [QARD Appendix A.1.2D]		
App A-3	Verify DOE Field Office, HLW Program, involvement on the OCRWM interface with the Office of Environmental Management as defined in the EM/RW MOA. [QARD Appendix A.2.2]		
App C-1	**APPENDIX C, STORAGE AND TRANSPORTATION** Verifiy that handling, loading, verification, and maintenance of casks/canisters to be accomplished by utilities, vendors, or others will be subject to the provisions of their NRC-approved 10 CFR 50, Appendix B; 10 CFR 71 Subpart H; or 10 CFR 72, Subpart G QA programs, or the QARD if the former programs are not available. [QARD Appendix C.2]		