Quality Assurance Program

Revision 12

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[X] Non-Proprietary
[ ] Proprietary
[ ] Restricted Information

[ ] New
[ ] Title Change
[X] Revision

Effective Date: 11/21/2024

Table of Contents

RECORD OF REVISIONS

Revision	Revision Title Description and Reason for Change	NRC Approval Required
9	• Added Record of Revisions Table • Changed Group Director from reporting to the COO to the Group President. • Added the ability to extend audit due dates • Added DOE Order 414.1D to Attachment 1	No
10	• Updated Organizational Chart to add COO, WM • Revised Section 1.2 with regards to President and CEO, and COOs. • Revised 3.8 to align with NQA-1. • Section 18 Revised information on audit frequency.	Yes
11	• Updated throughout to include the new ES Business Division of Nuclear Services. • Updated to include latest NRC Guidance on NEI Technical Report 14-05A, Guidelines for the Use of Accreditation in Lieu of Commercial Grade Dedication Surveys for Procurement of Laboratory and Test Services, Revision 1, based on NRC Safety Evaluation Report. • Updated the Organizational Chart to reflect current company alignment. • Minor Editorial changes/clarifications that do not impact commitments. • Updated Attachment 8.2 to better align with ISO 9001:2015	No
12	• Added third column to the Records of Revision Table to document if NRC approval is required. • Updated the Organizational Chart to reflect current company alignment.	No

PURPOSE

This document describes the Quality Assurance Program (hereinafter referred to as the QAP) that has been developed to ensure products and services provided by Energy*Solutions* meet applicable regulatory, industry, and contract requirements. Energy*Solutions* is committed to the delivery of superior products and service to all our customers.

The QAP describes the Company's overall approach for the control of quality for products and services being provided by the Company. This approach is based on ASME NQA-1-2008 with the NQA-1a-2009 Addenda, Part I, *Requirements for Quality Assurance Programs for Nuclear Facilities*. A review was performed on Part II, *Quality Assurance Requirements for Nuclear Facility Applications*, to determine applicability to Energy*Solutions'* activities. The review determined that only Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*, and Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, apply. The requirements from Subpart 2.7 and Subpart 2.14 have been incorporated into the QAP. [Note that additional Part II requirements may apply to some specific services being provided by Energy*Solutions.* These additional requirements will be addressed in the applicable QA Project Plans/Programs associated with those services.]

The QAP satisfies the requirements of 10 CFR 20, Appendix G; 10 CFR 50, Appendix B; 10 CFR61.12(j); 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; 10 CFR 830, Subpart A; and DOE O 414.1D. A crosswalk matrix is included as Attachment 1 and provides a visible presentation of how these regulations and standards have been addressed in the QAP. Attachment 2 provides a presentation of how the QAP addresses the Quality Management System defined in ISO 9001-2015.

SCOPE

This QAP applies to Energy*Solutions* and any wholly or partially-owned subsidiary, affiliate, or partnership engaged in activities affecting quality as defined by the regulatory codes and standards applicable to the scope of work of Energy*Solutions*. The QAP is supported by detailed implementing quality procedures. The QAP is implemented in a graded and customized approach which is based on the importance to safety and safety significance of structures, systems, and components and on a specific evaluation of regulations, risks, complexity, and history of previous implementation. The application of a graded approach for implementation of the QAP only allows grading of rigor in implementing these requirements and does not relieve Energy*Solutions* of its responsibility to maintain compliance with associated regulatory codes and standards.

Where Energy*Solutions* participates in a joint venture company, international company operations, major federal project activities, or other unique business applications, facility/project specific QA programs may be used. These specific QA programs may include additional and/or more restrictive requirements. For these specific QA programs, the requirements of the QAP are used as a guide in complying with applicable governing requirements. A documented comparison is made by the appropriate Quality Management and Business Group Leaders to confirm the basic principles are being applied.

1. ORGANIZATION

1.1 Organizational Structure

Primary Energy*Solutions* offices and facilities are located in Salt Lake City, Utah; Clive, Utah; Oak Ridge, Tennessee; Bear Creek, Tennessee; Erwin, Tennessee; Memphis, Tennessee; Clinton, Tennessee; Barnwell, South Carolina; Aiken, South Carolina, Kingston, Tennessee (Gallaher Rd Facility), Alanta Georgia and Charlotte, NC. Energy*Solutions* satellite project and field offices are established as necessary to be responsive to project demands and have reporting relationships to the Energy*Solutions* organization located at the primary locations. The structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality are clearly established in writing. Energy*Solutions* is organized by five business service groups: (1) Waste Management (WM) Group; (2) Decommissioning and Dismantling (D&D) Group; (3) Nuclear Services Group; (4) Federal Services and (5) International Group, descriptions are as follows:

1.1.1 Waste Management (WM) Group

This Group provides nuclear products, technology, engineering, nuclear field/fuel pool services, and licensing at the Barnwell, South Carolina; and Oak Ridge, Bear Creek, Clinton, Erwin, and Memphis, Tennessee facilities. Maintenance, engineering and operations support of 10CFR Part 71 transportation cask fleet is handled at the Barnwell South Carolina facility. Disposal services are provided at the Clive Utah and Barnwell South Carolina facilities.

1.1.2 Decommissioning and Dismantling (D&D) Group

This Group provides a full range of services for decommissioning of nuclear power plants across the decommissioning life cycle at the Charlotte, North Carolina office. Services range from pre-shutdown licensing and strategic planning activities to turnkey management and license stewardship throughout decontamination and dismantlement, including Final Status Survey (FSS) and License Termination Plan (LTP) activities.

1.1.3 Nuclear Services (NS) Group

This Group provides a full range of services supporting the nuclear industry and potential customers who may want to enter this market; located in Atlanta, Georgia, Charlotte, North Carolina, and at Kingston, Tennessee (Gallaher Rd Facility). These services may include fabrication, construction, maintenance, modifications, and performance/application of special processes (e.g, welding, coating application, etc.).

1.1.4 Federal Services (FS) Group

This Group provides a full range of services supporting the United States Federal infrastructure. These services may include services across the decommissioning life cycle, fabrication, construction, maintenance, modifications, and performance/application of special processes (e.g, welding, coating application, etc.)

1.1.5 International Group

This Group provides a full range of services supporting the European & other international markets. These services may include the recycling/disposal of radioactive components.

1.2 Responsibilities and Authority

Energy*Solutions* is divided into five Operational Groups, Waste Management (WM), Decommissioning and Dismantlement (D&D), Nuclear Services (NS), Federal Service (FS) and International. These Operational Groups report to the Chief Operating Officer and operate under this Quality Assurance Program. The organization chart in Figure 1 reflects the reporting relationship of the QA organization to the highest levels of Energy*Solutions* management. This chart is typical and will not be revised in the QAP unless the QA organizational relationship changes. Excluding the titles listed below, titles used are functional titles. Actual titles may vary, and alignment between actual titles and the Quality Assurances Program functional titles is maintained in approved company documents.

1.2.1 President and Chief Executive Officer (CEO)

The CEO has overall responsibility for all activities including roles and responsibilities within Energy*Solutions.* Additionally, the CEO approves the Quality Policy and Quality Assurance Program.

1.2.2 Chief Operating Officer (COO)

The COO has overall responsibility for the coordination of all operations has the overall responsibility for establishing the quality policy for the company.

1.2.3 Senior Vice President Regulatory Affairs

The Senior Vice President Regulatory Affairs has overall responsibility for compliance oversight for Energy*Solutions,* including Quality Assurance.

1.2.4 Group Director, Quality Assurance

The Group Directors, Quality Assurance have unencumbered access to the CEO, COO, and Company Presidents for all matters of quality. The Group

Directors are responsible for establishing and maintaining the QAP and quality assurance procedures, verifying effective QAP implementation, and providing support to projects and operations. The Group Directors have no unrelated duties and responsibilities that would preclude the attention to these assigned quality responsibilities.

The Group Directors have been granted authority, access to work areas, and organizational freedom to:

- Identify quality problems;
- Initiate, recommend, and provide solutions to quality problems through organizational channels;
- Verify implementation of solutions;
- Assure that further processing, delivery, installation, or use is controlled until proper corrective actions have occurred. The Group Directors have authority to stop work when deemed appropriate; and
- Maintain independence from cost and scheduling considerations.

The Group Directors ensure that persons or organizations not directly responsible for performing the work verify quality achievement. The Group Directors are responsible for assessing the adequacy of implementation of the QAP through periodic assessments and by participating in audit and assessment activities. The Group Directors ensure that activities affecting quality are performed in accordance with approved procedures that provide sufficient detail to meet customer and regulatory requirements.

The position description for a Group Director includes prerequisite experience and/or required training. Qualifications for a Group Director, QA include:

- A Bachelor's degree in a technical field or equivalent experience;
- At least 10 years' experience in quality assurance, engineering, or manufacturing;
- A working knowledge of applicable quality-related codes, standards, and regulatory requirements; and
- The ability to prescribe, apply, and assess compliance with the applicable requirements.

1.2.5 Quality Assurance Management

In their respective areas, Quality Assurance Management ensures that activities affecting quality are performed in accordance with approved procedures that provide sufficient detail to meet customer and regulatory

requirements. Quality Assurance Management has unencumbered access to the Group Directors, QA, for all matters of quality, and have the authority to stop work if required.

1.2.6 Facilities and Project Management

Facility and Project Management has overall responsibility for the development and implementation of quality requirements and controls for their operations, projects, and activities.

The implementation of quality requirements begins with order entry and is performed by receiving, reviewing, and processing customer orders by the responsible project/facility team. The order entry process is limited to orders or procurements for items or activities affecting quality. This project team is comprised of, at a minimum, representatives from project/facility management, contracts, and Quality Assurance. These reviews are comprised of verification that customer requirements are adequately defined, documented, and understood and that the company has the capacity to meet the contract requirements. Changes to contracts are reviewed in the same manner as the original order.

Organizational structure is documented for projects defining levels of authority and lines of communication. Personnel responsibilities are defined to provide understanding of project goals and accountability for operations. Quality, safety, technical criteria, and levels of rigor are described in implementing procedures specific to project and fixed-based facility operations. All levels of management are responsible for establishing appropriate methods in written procedures to ensure quality objectives can be achieved as well as meeting customer and regulatory requirements. When more than one organization is involved in the execution of activities, the responsibility and authority of each organization is clearly established and documented.

1.3 Delegation of Work

Senior management may delegate, in writing, any or all of the work performed under this QAP to others but retains responsibility for the delegated work.

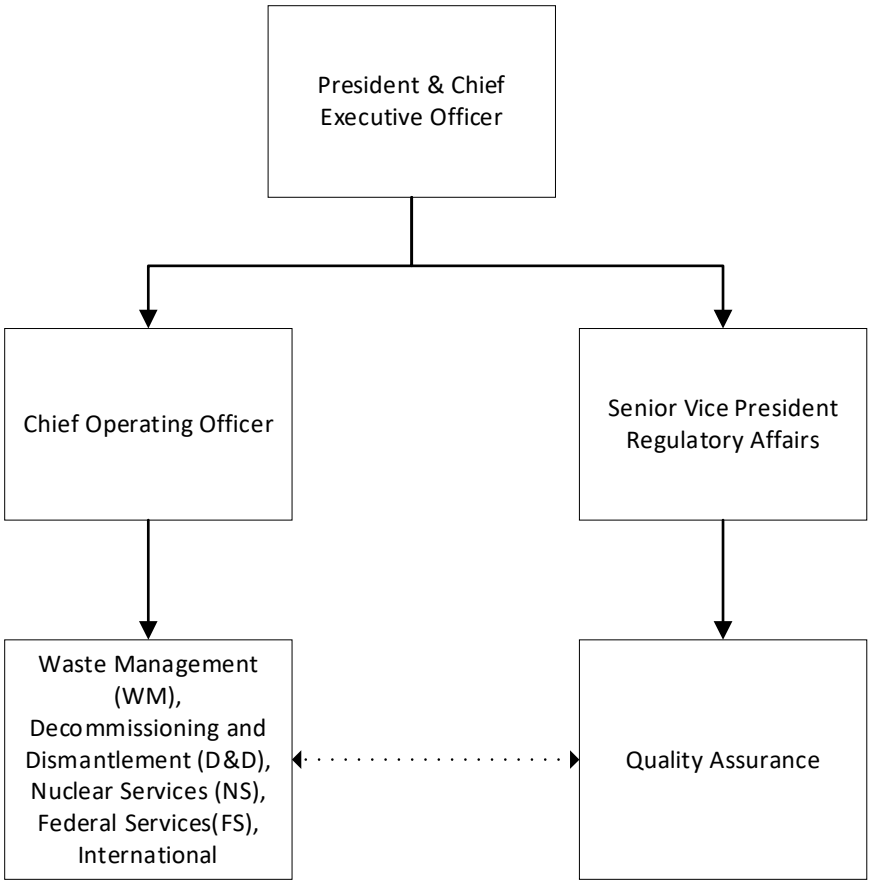

Figure 1: QA Organization

2. QUALITY ASSURANCE PROGRAM

The Energy*Solutions* QAP consists of planned and systematic actions intended to assure that activities affecting quality are performed under suitably controlled conditions to an extent consistent with their importance and expected outcomes. The Program is based on a model of ensuring that quality-affecting work is *planned* to ensure prerequisites have been satisfied, *performed* in accordance with established procedures, *monitored* for satisfactory performance, and *improved* based on the results of problem detection processes and feedback. Management is responsible for establishing the QAP requirements at the earliest time consistent with the schedule for accomplishing activities affecting quality, fostering an attitude of support, and encouraging personnel to complete their work in a quality manner. All employees are responsible for identifying non-compliant work or areas for improvement. Management is responsible for identifying (both internal and external) customer needs and expectations.

2.1 QAP Application

The QAP is the top-level document that describes the practices for a planned and disciplined approach to achieve quality. The QAP is reviewed and approved by the Chief Executive Officer and represents Energy*Solutions*' overall approach to quality.

Facility/project specific QA programs, such as Quality Assurance Project Plans (QAPP) or Quality Assurance Operational Plans (QAOP) are written for the control of special project or operational activities describing criteria unique to the scope of work. The QAPP or QAOP is developed and maintained by the Project or Facility Manager and is based on appropriate national or international QA consensus standards consistent with regulatory or contractual requirements. When a project contract requires working to a facility/project specific QA program, project management ensures that the facility/project specific QA program provides controls that are equivalent with the requirements of the QAP.

Implementing procedures describe how Energy*Solutions* implements the requirements of the QAP. These procedures document methods for planning, reviewing, implementing, controlling, and verifying activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.

The QAP applies to all activities that are important-to-safety or are safety-related and requires compliance with any or all of the documents listed below:

- 10CFR20, Appendix G
- 10CFR50, Appendix B
- 10CFR61.12(j)
- 10CFR71, Subpart H
- 10CFR72, Subpart G
- DOE O 414.1D and 10CFR830, Subpart A
- ANSI/ASME NQA-1

The applicability of the QAP takes into consideration the regulatory requirements for important-to-safety and safety-related items and activities, as well as the complexity and impact on safety, the need for special controls, demonstration of compliance through inspection and test, and the degree of standardization of the item. The requirements of the QAP are implemented using a graded approach, allowing control over items and activities to be commensurate with their importance and level of risk and are not reductions in quality requirements. Measures are established for identifying the structures, systems, and components

to be covered by the QAP. The QAP requirements are implemented through procedures during all stages of an activity.

When a project's contract requires working to an existing client quality assurance program, project management ensures that the client program, as a minimum, provides controls that are consistent with the requirements of the QAP by performing an equivalency review.

2.2 Quality Achievement, Management, and Verification

The achievement of quality is the responsibility of all employees. The QAP is planned, implemented, and maintained in accordance with established processes. The QAP provides for ensuring that personnel who perform or manage activities affecting quality are indoctrinated, trained, and qualified, as necessary, to ensure suitable proficiency is achieved and maintained. The QAP requires management to regularly assess the adequacy and effective implementation of the QAP and to employ a tiered approach to verifying quality for established processes, including self-checks by the individuals performing the work, supervisory oversight and reviews, independent inspection, and surveillance.

The management team provides systematic planning to establish the scope of work, analyze hazards, and confirm the appropriateness of controls to be applied. Work performed is then monitored to confirm performance within the established controls and to provide feedback to achieve continuous improvement as an integral process of assuring effectiveness of the quality system.

A Quality Assurance management team regularly performs effectiveness reviews of activities that affect quality, and regulatory requirements.

On an annual basis, Quality Assurance provides the President and CEO an assessment on the effectiveness of the QAP. This assessment is based on performance indicators, reviews of audits, independent assessments, inspections, surveillances, and trending analysis.

Issues concerning quality are resolved by the Group Director, QA or as necessary by the CEO.

2.3 Personnel Qualification and Certification

2.3.1 Training and Indoctrination

Managers assess their organizations' training needs and assure that all personnel performing activities affecting quality are indoctrinated, trained, and qualified according to their level of responsibility and assigned functions. This includes indoctrination to and familiarization with the QAP and any special skills training required for the performance of job activities. Qualification is completed prior to performing work. The extent of such training is commensurate with the scope, nature, and

complexity of the activity, as well as the education, experience, and abilities of the individual. Training scopes, objectives, and methods of implementation are included in approved procedures.

2.3.2 Inspection and Test Personnel

Inspection and test personnel have experience commensurate with the scope of work and the complexity of the activity. Inspection and test personnel are selected and trained in accordance with approved procedures. The job performance of inspection and test personnel is reevaluated at periodic intervals not to exceed three years. Certification or qualifications that are revoked for deficient job performance will result in the evaluation of items inspected or tested by the individual.

Personnel performing nondestructive examinations are qualified in accordance with the American Society of Nondestructive Testing recommended practice.

Certification documentation is maintained in accordance with approved procedures.

Any person who has not performed inspection or testing activities in the qualified area for a period of one year is reevaluated.

2.3.3 Lead Auditors and Inspectors

Quality Assurance Lead Auditors are qualified and certified by Energy*Solutions*. Lead Auditors are certified in accordance with established procedures, and records are maintained. Training methods, minimum experience requirements, and certification practices are in accordance with NQA-1-2008, Nonmandatory Appendix 2A-3. Proficiency evaluations are performed annually and documented for Lead Auditors and appropriate certification renewal or re-qualification actions are taken.

Personnel performing inspection activities are qualified and certified in accordance with established procedures that comply with NQA-1-2008, Nonmandatory Appendix 2A-1.

Lead Auditor and Inspector certification documentation is maintained in accordance with approved procedures.

The qualification and requirements for use of auditors and technical specialists used to support the audit process are specified in approved procedures.

3. DESIGN CONTROL

Design Control procedures ensure that the design meets applicable regulatory requirements, and that design activities are carried out in a planned and controlled manner. Procedures describe responsibilities for design interface, control, verification, and change. Approved procedures govern translation of applicable customer and regulatory requirements and design bases into design, procurement, and procedural documents, as well as controlling the design documents and design document distribution. Computer programs used to calculate or develop quality related data, used in important-to-safety and safety-related items and activities, are developed, procured, qualified, and maintained in accordance with NQA-1a-2009, Part II, Subpart 2.7.

3.1 Design Input

Management and engineering organizations are responsible for identifying and documenting design input. Design inputs include:

- Design basis;
- Performance requirements;
- Regulatory requirements;
- Customer specifications;
- Industry codes and standards; and
- Technical requirements.

Design inputs are identified and documented and their selection reviewed and approved in a timely manner by the responsible design organization. Documented design inputs provide the necessary level of detail to ensure that the design activity can be performed correctly and provide a consistent basis for making decisions, accomplishing design verification, and evaluating changes.

3.2 Design Process

Energy*Solutions* describes and controls the design process through approved procedures to permit the design process to be implemented in a correct manner and to permit verification that the design meets requirements. Appropriate design documents are developed to support the design, construction/manufacture, and operation. Quality standards are identified, documented, and approved by cognizant personnel. In addition, measures are established for selection and review for suitability of application of materials, parts, equipment, and processes.

Design activities result in design output documents that meet the design input requirements in sufficient detail to permit design verification. The final design specifies required inspections and tests and includes or references appropriate acceptance criteria. Design documents contain the identification of assemblies and/or components that are part of the item being designed. When such assemblies and components are commercial grade items, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics are controlled as described in Section 7.12.3.

If a commercial grade item is modified prior to its installation or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part is represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.3 Design Analysis

Design analysis is controlled by procedures describing the responsibilities of the individuals and organizations involved. Approved procedures govern translation of applicable customer and regulatory requirements and design bases, as well as control the use of computer programs and reporting.

Computer program acceptability is verified prior to use or the results are verified with the design analysis for each application. The computer program is verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. The encoded mathematical model must be shown to produce a valid solution to the physical problem associated with the particular application.

Design analysis reports provide details of (where applicable):

- The objective of the analysis;
- Design inputs and their sources;
- Literature research and background data;
- Assumptions and designation of those that must be verified as design proceeds;
- Calculation methodology and calculations;
- Summary of results and compliance with requirements;
- Identification of computer calculations, including computer hardware and software; and
- Review and approval as specified in engineering procedures.

3.4 Design Verification

Design verification is performed to ensure that appropriate requirements and customer needs are translated to the design documents. Design verification is performed in accordance with approved procedures that define responsibilities, methods, and documentation requirements. Design verification is performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor provided:

- The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or
- The supervisor is the only individual competent to perform the verification.

Cursory supervisory reviews do not satisfy the intent of this requirement. No individual is ever the verifier for his/her own work or input.

Design verification is usually performed and discrepancy resolution is completed prior to the release of the design output document for production use or process implementation. An exception would be cases where insufficient data exists to finalize the design at a point in the project where material procurement or preliminary facility construction must begin. In such cases, unverified portions of the design are identified and controlled. Final design verification is completed prior to reliance on the item or process to perform its function. Engineering managers document completion of design verification.

Where the design has been subjected to a verification process in accordance with this QAP, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previous designs, with respect to meeting pertinent design inputs, is verified for each application. The original design and associated verification documentation are referenced in records of subsequent application of the design.

The design verification method is based on regulatory and contractual requirements, level or complexity of the design, state of the art considerations, i.e., materials, fabrication processes, etc., and operating conditions. Design verification methods include, but are not limited to, formal design reviews, alternate calculation, and qualification testing. The level of design verification applied complies with identified requirements.

3.5 Design Review

Managers are responsible for ensuring design reviews are performed at appropriate phases of the design process. Design review performance requirements, methods, and responsibilities are included in approved procedures.

The design is evaluated for the adequacy of the incorporated design inputs and the design methods used. Responsibilities for action items are assigned, completed, and action item results are incorporated into the final design.

Individuals or multi-disciplined design review teams perform independent reviews on important-to-safety and safety-related items. These reviews are performed by competent personnel and address the following:

- Design input selection;
- Design output compared to design input and verification requirements from interfacing organizations;
- Appropriate design methods and computer programs used;
- Design inputs correctly incorporated into the design;
- Suitable materials, parts, processes, and inspection and testing criteria been specified;
- Adequately described, reasonable, and identified assumptions;
- Where necessary, are the assumptions identified for subsequent re-verifications when the detailed design activities are completed; and
- Assignment of quality levels.

3.6 Alternate Calculation

The requirements for verification by alternate calculations are described in procedures that include the review of appropriateness of assumptions, input data, and computer program or other calculation methods used.

3.7 Qualification Tests

Qualification testing (synonymous with design validation) provides the assurance that products conform to defined user needs and/or requirements. Qualification tests of important-to-safety and safety-related items validate and demonstrate the adequacy of performance under conditions that simulate the most severe design conditions in accordance with written test procedures and test specifications. Operating modes and environmental conditions are considered in determining the most adverse conditions. Test specifications are reviewed and approved by the responsible engineering organization. The engineering group responsible for the design approves results of the qualification tests. For tests performed on models or mockups, scaling laws are established and verified. Test results obtained for model or mockup test work are subject to error analysis, where applicable, prior to use in final design work. Where the test is intended to verify only specific design features, the other features of the design are verified by other means. Information regarding verification that is incomplete, including incomplete qualification tests, is available prior to installation of equipment.

3.8 Design Changes

Changes to design input, final design, field changes, and temporary and permanent modifications are justified and subject to design control measures commensurate with those applied to the original design. These measures include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. The evaluation includes facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. Changes are approved by the same group organization responsible for review and approval of the original design documents.

When the organization originally responsible for review and approval of the original design documents is no longer responsible, the owner or their designee has the responsibility or designates a new responsible organization. The design organization approving the change must demonstrate competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into documents, where such incorporation is appropriate. When a significant design change is required because of an incorrect design, the design process and verification procedure are reviewed and modified as necessary.

3.9 Configuration Management of Operating Facilities

Configuration management requirements are documented in procedures as soon as practical prior to operating the facility and are maintained for the life of the facility. The procedures identify the responsible organizations whose functions affect operation, design, maintenance, construction, licensing, and procurement. The configuration management program:

- Includes measures to ensure changes that may affect the approved configuration are recognized and processed;
- Identifies, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources;
- Identifies the activities of organizations that can affect the approved configuration;
- Identifies the design bases and the approved configuration for the approved modes of operation;
- Identifies the controls implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design bases;
- Controls the implementation sequence of approved configuration changes to assure the configuration conforms to the design bases;
- Identifies the approvals required to change the design bases, including the design authority;
- Requires the configuration of the facility to be documented in drawings, specifications, procedures, and other documents, as appropriate, to reflect the status of the facility. The process used to control the current revision and issuance of these documents is specified in approved procedures and takes into account the use of the document and the need for revision in support of operations.

3.10 Interface Control

Formal design interfaces are established when multiple organizations (internal or external) participate in the design process. Procedures are written that establish and document responsibility and authority for transmittal, review, approval, release, distribution, and revision of design inputs and design output documents. Transmittals indicate the status of design information or of documentation submitted, including any incomplete items that require further actions. When it is necessary to initially transmit design information orally or by other means, the transmittal is confirmed promptly by a controlled document.

3.11 Software Design Control

The design of computer software used to calculate or develop important-to-safety and safety-related data are developed, maintained and revised in accordance with written, approved procedures. The procedures require the identification of the software engineering method and the method of controlling life-cycle documentation, review, approval, operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program. Additional requirements to be identified, as applicable, during the design process are: computational sequence necessary to meet the software requirements, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and applicable relationships between data structures and process structures.

Software design verification is performed to ensure that appropriate requirements and customer needs are translated to the design documents. Software design verification is performed in accordance with approved procedures that define responsibilities, methods, and documentation requirements. Software design verification is performed by competent individual(s) or group(s) other than those who developed and documented the original design but may be from the same organization. The verification may be performed by the originator's supervisor provided the supervisor:

- Did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or
- Is the only individual competent to perform the verification.

Cursory supervisory reviews do not satisfy the intent of this requirement. No individual is ever the verifier for his/her own work or input.

Design verification methods include, but are not limited to, formal design reviews, alternate calculation, and tests performed during computer program development. The extent of verification and the methods chosen are a function of the complexity of the software, the degree of standardization, the similarity with previously proved software, and the importance to safety.

3.12 Software Configuration Management

Software configuration management controls are specified in approved procedures. Software configuration management includes but is not limited to configuration identification, change control, and status control. Configuration items are maintained under configuration management until the software is retired.

Software configuration management controls include establishing a software baseline. A baseline is established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline are added to the baseline. The baseline defines the most recently approved software configuration. The labeling system for configuration items:

- Uniquely identifies each configuration item;
- Identifies changes to configuration items by revision;
- Provides the ability to uniquely identify each configuration of the revised software available for use.

Changes to software are formally documented. The documentation includes:

- A description of the change;
- The rationale for the change;
- The identification of affected software baselines.

The procedures specify the organizations that are authorized to evaluate and approve changes to the software including the baseline. Changes are documented and traceable to the software design requirements. Appropriate acceptance testing is performed for the change.

The status of the software's configuration is documented and maintained current. The process includes the status of changes that are proposed and approved but not implemented. The controls include notification of the changes to affected organizations.

3.13 **Documents and Records**

Design documents and records include not only final design documents, such as drawings and specifications and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

4. PROCUREMENT DOCUMENT CONTROL

Controls for procured items and services are established in approved programs and procedures. These programs and procedures require the technical, quality, regulatory, and administrative requirements applicable to the procurement to be specified in procurement documents. To the extent necessary, procurement documents require suppliers to adequately implement a quality program consistent with the type and use of the item or service being purchased.

Management is responsible for supplying personnel to perform the procurement process and ensuring that project-specific requirements for procurement documents are documented.

4.1 Content of the Procurement Document

Procurement documents include the following, as applicable: the scope of work; technical and regulatory requirements; quality criteria for items and services; guidelines for review by quality assurance; quality requirements for suppliers and sub-tier suppliers; documentation requirements; quality record maintenance and retention; right of access for audit or inspection; requirements for reporting and approving supplier generated nonconformances; and requirements for identification of spare and replacement parts and related data required for ordering these parts.

4.2 Procurement Document Review

Technical, and quality personnel, as required, who have an understanding of the requirements and intent of the procurement, review the procurement documents prior to award.

Technical or quality assurance program changes made as a result of bid evaluations or negotiations are incorporated into the procurement documents prior to their issuance to the supplier.

Procurement document review is performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.3 Procurement Document Changes

Technical and quality assurance program changes to procurement documents receive the same levels of review and approval as the original.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Management is responsible for ensuring that activities affecting quality are described in instructions, procedures, or drawings that are prepared and approved prior to commencing activities. All Energy*Solutions* employees are responsible to perform their activities in accordance with the requirements of these documents. These documents include or reference appropriate quantitative and qualitative acceptance criteria to verify that the activity has been satisfactorily accomplished.

The activity is described to a level of detail commensurate with the complexity of the activity and the need to ensure consistent and acceptable results. The need for, and the level of detail in, written procedures or instructions are determined by management based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

Management is responsible for maintaining these documents current to reflect actual work practice. Instructions, procedures, and drawings are prepared, reviewed, issued, and controlled in accordance with approved procedures.

6. DOCUMENT CONTROL

Documents that prescribe or affect quality are controlled to ensure that the proper revisions are used and that superseded or obsolete documents are not inadvertently used. Controlled documents include documentation for activities affecting quality such as procedures and drawings.

The document control system ensures that all documents are properly identified, distributed, and retained as specified in approved procedures. Documents are reviewed for adequacy and approved for release by authorized personnel prior to issuance. Documents are issued to and used at the location where the activity is performed. Document changes other than typographical errors and editorial corrections, or minor changes, are reviewed and approved in the same manner as the original document.

6.1 Document Preparation, Review, Approval, and Issuance

Management is responsible for identifying documents to be controlled and for their distribution. Controls are established in approved procedures that define responsibility, authority, issue, use, and revision of controlled documents. Managers ensure that documents are reviewed for adequacy, completeness, and correctness prior to issue.

6.2 Document Changes

Major changes are reviewed and approved using the same process as the original document. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Minor changes such as inconsequential editorial corrections do not require the same review cycle as the original document. Approved procedures define the types of changes considered minor and the persons who are permitted to make these changes.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Energy*Solutions'* processes ensure procured items and services for important-to-safety and safety-related applications are clearly and adequately specified in procurement documents. Items and services are provided by suppliers and subcontractors who are capable of producing items and furnishing services that conform to procurement document requirements. These procurement methods are controlled by procedures for supplier evaluation, review of procurement requirements, and audit/surveillance of suppliers' facilities.

Commercial grade items may be procured and dedicated for important-to-safety or safety-related applications. Energy*Solutions* identifies the critical characteristics and the method(s) (e.g., special tests and inspections, commercial supplier survey, source verification, and/or acceptable supplier/item performance record) to be used to dedicate commercial grade items. Dedication of commercial grade items is accomplished in accordance with approved procedures.

7.1 Supplier Evaluation

Energy*Solutions* technical, procurement, and QA personnel participate, as appropriate, in evaluation of potential procurement sources. Recommendations of procurement sources are based on these evaluations. Results of supplier evaluations performed prior to contract award are documented and retained. The evaluations cover review of capabilities and facilities for technical, manufacturing, and quality performance, and include any or all of the following, as appropriate:

- Historical performance data, on providing an identical or similar product that performs satisfactorily in actual use;
- Review of supplier's QA Program, including current quality records that provide qualitative and quantitative information that can be objectively evaluated;
- Inspections, audits, or surveillances to verify supplier's QA Program implementation, as required;
- A commercial calibration service accredited by a nationally-recognized accrediting body, using procedures consistent with international standards and guidelines, specifically those found in ISO/IEC 17025. The bodies include National Voluntary Laboratory Accreditation Program (NVLAP) and other accrediting bodies recognized by NVLAP through a Mutual Recognition Arrangement may be used to calibrate Commercial Grade Items (as defined by 10 CFR Part 21, "Reporting of Defects and Noncompliance").

Supplier evaluations include elements of the QAP applicable to the purchased item or services.

A documented evaluation is required annually for suppliers maintained on the Approved Supplier List (ASL). Supplier audits, when required, are conducted triennially in accordance with Section 18.

Engineering and QA identify supplier qualification requirements and documentation in accordance with procedures.

7.2 Bid Evaluation

A documented bid evaluation process has been developed. If bids are solicited, the bids are evaluated to determine the supplier's capability to conform to the technical and quality assurance requirements. Any unacceptable technical or quality assurance condition resulting from the bid evaluation is resolved or a commitment to resolve is obtained, prior to awarding the contract.

7.3 Procurement Requirements

Requirements to be met by the supplier are detailed in the procurement documents, which may include procurement specifications. Procurement specifications detail the supplier quality assurance requirements such as inspection reports, provisions for inspection, equipment calibration prior to use, and provisions for inspection after component repair. The procurement specification may also require the supplier to submit the following for Energy*Solutions*' review:

- Special process procedures for performing welding, heat treatment, and nondestructive examination;
- Recommended inspection point program;
- Appropriate documentation as required by applicable codes, standards, and procurement documents;
- Notices of nonconformances and their disposition;
- Test procedures in accordance with applicable codes and standards.

Documentation provided by the supplier is reviewed against the acceptance criteria.

7.4 Methods of Acceptance

The acceptance methods for an item or service are a Supplier Certificate of Conformance, source verification, receiving inspection, or post installation test at an Energy*Solutions* facility or project site, or a combination of these methods.

When required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements is available at the nuclear facility site prior to installation or use.

7.5 Certificate of Conformance

The process for developing and issuing a Certificate of Conformance is specified and controlled in accordance with approved procedures. The procedures specify the following minimum criteria be met:

- The certificate identifies the purchased material or equipment, such as by the purchase order number.
- The certificate identifies the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of specific requirements or providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified must include any approved changes, waivers, or deviations applicable to the item or service provided.
- The certificate identifies any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformance.
- The certificate is signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the purchaser's or supplier's quality assurance program.
- The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, is described in the purchaser's or supplier's quality assurance program.
- The validity of the supplier certificates and the effectiveness of the certification system are verified during audits of the supplier or independent inspection or test of the items. The verification is conducted at intervals commensurate with the supplier's past quality performance.

7.6 Source Verification

Quality Assurance is responsible for conducting and documenting source verification activities. The activities are performed at intervals consistent with the importance, complexity, and quantity of the items or services procured and may include:

- Witnessing tests, inspections, nondestructive examinations, and various special process operations;

- Monitoring heat treatment, welding, cleaning, preserving, and packaging activities.

Quality Assurance is also responsible for verifying supplier conformance with established procedures such as:

- Energy*Solutions* accepted drawings and procedures;
- Accepted product and process quality planning;
- Document change control;
- Material identification and traceability control;
- Control of welding repairs;
- Control and calibration of measuring and test equipment.

Documentation packages for purchased items, if required, are reviewed by QA or their qualified designee prior to release of the items for use. This documentation may include material test reports, inspection and test reports, NDE reports, and applicable code data reports.

7.7 Receiving Inspection

Receiving inspection is performed for purchased items that are important-to-safety or safety-related (including spare or replacement parts) to ensure that:

- Items are properly identified and correspond to the receiving documentation.
- Inspection records or certificates of conformance attesting to the acceptance of the items are available.
- Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.
- Physical attributes comply with specified requirements.

Receiving inspection is coordinated with review of the supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

7.8 Post Installation Testing

When used, post installation test requirements and acceptance criteria are established with input from the supplier, as required.

7.9 Acceptance of Services Only

Services such as third party inspections, engineering and consulting services, auditing, and installation are accepted by any of the following:

- Technical verification of data produced;
- Surveillance and/or audit of the activity;
- Review of objective evidence for conformance to procurement document requirements.

7.10 Control of Supplier Nonconformances

Energy*Solutions* and the supplier establish and implement methods for disposition of items and services that do not meet the requirements of procurement documents. These methods contain provisions for the following:

- Evaluation of nonconforming items;
- A system to track all nonconformances and resolutions;
- Submittal of nonconformance notices to Energy*Solutions* by the supplier, defining the nonconformance (including a disposition recommended by the supplier) and supporting technical justification for "accept as is" or "repair" dispositions;
- Energy*Solutions* disposition of the supplier's recommendation;
- Verification of the implementation of the disposition;
- Maintenance of records of nonconformances submitted by the supplier.

When required, nonconformances to the procurement documents which consist of one or more of the following are submitted to Energy*Solutions* for approval of recommended disposition:

- Technical or material requirement is violated.
- Requirement in supplier documents, which has been approved by Energy*Solutions*, is violated.
- Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
- The item does not conform to the original requirement such that the capability of the item to function is unimpaired.

7.11 Procurement Records

Records are established and maintained to indicate the performance of the following functions:

- Supplier evaluation and selection;
- Acceptance of items and services;
- Supplier nonconformance to procurement document requirements, including their evaluation and disposition.

7.12 Commercial Grade Items and Services

When commercial grade items or services are utilized in safety class or safety-significant applications, the requirements of Sections 7.12.1 through 7.12.9 are an acceptable alternative to Sections 7.1 through 7.10, except that supplier evaluation and selection may be performed in accordance with Section 7.1 where determined necessary by Energy*Solutions*. The commercial grade dedication process is based on the requirements of NQA-1a-2009, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, and is performed in accordance with implementing procedures.

7.12.1 Utilization

The utilization of commercial grade items or services includes the following:

- Technical evaluation to determine that the item or service performs a safety function;
- Confirmation that the item or service meets the appropriate commercial grade definition criteria established in NQA-1a-2009, Subpart 2.14;
- Identification of critical characteristics, including acceptance criteria;
- Selection, performance, and documentation of the dedication methods for determining compliance with acceptance criteria;
- When one or more critical characteristics for acceptance cannot be verified by the dedication methods, the requirements of this section are not utilized to procure and accept the commercial grade item or service.

Only items or services that perform a safety function and meet the commercial grade definitions are considered for commercial grade dedication. A dedication plan is developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria.

7.12.2 Technical Evaluation

Technical evaluation is performed by the Engineering organization to:

- Determine the safety function of the item or service;
- Identify performance requirements, the component function classification, and applicable service condition;
- Confirm that the item or service meets the commercial grade definition criteria;

- Identify the critical characteristics, including acceptance criteria;
- Identify the dedication method(s) for verification of the acceptance criteria;
- Determine if a replacement item is a like-for-like or equivalent item.

The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function are considered in the technical evaluation for the selection of critical characteristics. Services are evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

Items may be considered identical or like-for-like if one of the following applies:

- The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable) and has not been subject to design, materials, manufacturing, or nomenclature changes.
- The item was purchased at the same time and from the same supplier, as determined by purchase date, date code, or batch/lot identification.
- Evaluation of the item confirms that no changes in the design, materials, or manufacturing processes have occurred since the procurement of the original item.

If it can be demonstrated that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. Verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

When differences exist from the original item, an equivalency evaluation is required. The equivalency evaluation determines if any changes in design, material, manufacturing process, configuration, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function.

The equivalency evaluation is documented and includes the following:

- Identification of the change in design, material, manufacturing process, configuration, form, fit, or function of the replacement item that is different from the replacement item;
- Evaluation of the change;

- Confirmation that the change does not adversely affect the current design or safety function of the original item.

If the change adversely affects or is not bounded by the current design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Section 3.8.

7.12.3 **Critical Characteristics**

Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended function. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part is represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

Critical characteristic selection for acceptance addresses the following:

- Identifiable and measurable attributes or variables appropriate for the safety function;
- Criteria related to the location of the item in the facility or criteria addressing the most severe location of the item in the facility, unless controls are in place to prevent usage in undesignated locations.

To provide reasonable assurance that a commercial grade item or service will perform its intended safety function, Energy*Solutions* verifies that item or service meets the acceptance criteria for the critical characteristics by one or more of the following dedication methods:

- Inspections, tests, or analyses performed after delivery;
- Commercial grade survey of the supplier;
- Source verification of the item or service;
- Acceptable supplier or item performance record.

7.12.4 **Special Tests, Inspections, or Analyses**

Special tests, inspections, or analyses either individually or in combination are conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the critical characteristics. Special tests, inspections, or analyses may include post- installation testing, receipt inspection, or be based on certified material test reports or certificates of conformance.

7.12.5 **Commercial Grade Survey**

A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility that includes or addresses the following:

- Identification of the item(s), or product line, or service included within the scope of the survey;
- Identification of the critical characteristics to be controlled by the supplier;
- Verification of the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics;
- Identification of the survey methods or verification activities performed with the results obtained;
- Documentation of the adequacy of the supplier's processes and controls.

A commercial grade survey is not employed as a supplemental basis for accepting commercial grade items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls. After a supplier's processes and controls have been determined to be adequate, the verified processes and controls are invoked or referenced as part of the purchase order or control requirements for the commercial grade item or service. The supplier is required to provide a certificate of conformance attesting to the implementation of the identified processes and controls.

A survey frequency is established for reconfirming the previous survey information for application to additional purchases and to ensure that process controls continue to be effectively implemented.

7.12.6 ISO/IEC 17025 Accredited Commercial Grade Testing and Calibration Services

7.12.6.1 When purchasing commercial grade testing and calibration services from a laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met (in accordance with EPID L-2020-TOP-0011, Final Safety Evaluation by the Office of the Nuclear Reactor Regulation for the NEI Technical Report 14-05A, Guidelines for the Use of Accreditation in Lieu of Commercial Grade Dedication Surveys for Procurement of Laboratory and Test Services, Revision 1) for use in Safety-Related and Important to Safety applications

- The procurement documents impose additional technical and administrative requirements, as necessary, to comply with the Energy*Solutions* QA program and technical provisions. At a minimum, the procurement documents require that the certificate/report include identification of the laboratory equipment/standard used.

- The procurement documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

• A documented review of the supplier's accreditation is performed and includes a verification of the following The laboratory holds an accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):

  - National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards and Technology;
  - American Association for Laboratory Accreditation (A2LA);
  - ACLASS Accreditation Services (ACLASS);
  - Other NRC-approved laboratory accrediting body.

- The accreditation encompasses ISO/IEC 17025: 2017, *General Requirements for the Competence of Testing and Calibration Laboratories.*
- For procurement of calibration services, the published scope of accreditation for the calibration laboratory

covers the needed measurement parameters, ranges, and uncertainties and cannot be subcontracted.

- For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty and cannot be subcontracted..

- The laboratory has achieved accreditation based on an onsite accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

7.12.6.2 Quality Applications Graded not to be Safety Related or Important to Safety :

- The first three bullet of Sections 7.12.6.1 apply.

- The supplier output (e.g., calibration and test reports) shall be reviewed and accepted by trained and qualified staff using procedures.

7.12.7 **Source Verification**

Source verification is only applicable to the actual items or services that are verified at the supplier's facility or other applicable location. Source verification is performed in accordance with Section 7.6 using an inspection checklist or plan. The documented evidence of the source verification includes or addresses the following:

- Identification of the items or services included within the scope of the source verification;
- Identification of the critical characteristics, including acceptance criteria, to be controlled by the supplier;
- Verification of the supplier's processes and controls are effectively implemented for the identified critical characteristics;
- Identification of the activities witnessed during the source verification and the results obtained;
- Identification of mandatory hold points to verify critical characteristics during manufacture or testing for those characteristics that cannot be verified by evaluation of the completed item;
- Documentation of the adequacy of the supplier's processes and controls.

7.12.8 Acceptable Supplier, Item, or Services Performance Records

Supplier item or service performance records are taken from historical data for identical or equivalent application of the commercial grade item or service. An acceptable supplier, item, or service performance record includes the following:

- Identification of the supplier, item or service being evaluated;
- Identification of previously established critical characteristics specific to the supplier, item or service;
- Identification of industry data examined to evaluate the supplier, item or service;
- Identification of basis for determining that industry data substantiates acceptability of the supplier, item or service;
- Documentation of the adequacy and acceptance of the supplier, item or service performance record.

An acceptable performance record is not employed unless:

- The established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application, i.e., a single source of information is not adequate to demonstrate satisfactory performance.
- The manufacturer or supplier's measures for the control of applicable design, process, and material change have been accepted by Energy*Solutions*, as verified by survey of the supplier.

Continued application of an acceptable performance record includes a documented periodic update and review to ensure the supplier, item or service maintains an acceptable performance record.

7.12.9 Supplier Deficiency Correction

The supplier is required to correct deficiencies identified in their processes and controls if they affect the acceptance criteria for the critical characteristics. The supplier's corrective actions are evaluated for acceptability by Energy*Solutions*.

7.12.10 **Documentation**

Documentation of the commercial grade dedication process contains the following types of documents, depending upon the dedication method(s) used:

- Dedication plans or procedures including the essential elements of the dedication process;
- Commercial grade item or service procurement documents;
- Technical evaluations;
- Critical characteristic identification and acceptance criteria;
- Test reports or results, inspection reports, analysis reports;
- Commercial grade survey reports;
- Source verification reports;
- Historical performance information;
- Dedication reports containing sufficient data to accept the item or service.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND SERVICES

Controls are established in approved procedures to ensure that only correct and accepted items are used or installed. Identification is maintained either on the items or in documents traceable to the items, or in a manner that ensures that identification is established and maintained. When such controls are required, the following methods of identification and control are utilized.

8.1 Identification

Identification such as batch, lot, serial number, or part number is maintained from fabrication or initial receipt up to and including installation. The identification relates the item to the applicable design or other specification document when appropriate. Energy*Solutions* utilizes physical identification when possible. Other means, including separation or procedural control, are used when physical identification is either impractical or insufficient. Physical identification is used to the maximum extent possible.

8.2 Markings

Markings are applied using materials and methods that are clear, legible, and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided. Markings are not obliterated or hidden by surface treatments or coatings unless other identification methods are established.

8.3 Traceability

Energy*Solutions* procedures specify methods for identification of items when codes, standards, or specifications require identification or traceability of an item. Procedures describe how to maintain traceability to a specification, grade of material, heat, batch, lot, part or serial number, or inspection, test, or other records.

8.4 Limited Life Items

Items having limited calendar or operating life or cycles are controlled to preclude use after the shelf life or operating life has expired.

8.5 Maintaining Identification of Stored Items

Provisions are made in Energy*Solutions* procedures for maintenance or replacement of markings and identification records due to damage from handling or aging, excessive deterioration due to environmental exposure, and for updating records while in storage.

9. CONTROL OF SPECIAL PROCESSES

Processes that ensure conformance to customer requirements, quality system requirements, and applicable codes, standards, and regulations are planned and performed under controlled conditions. Verification is provided in accordance with established inspection, audit, assessment, surveillance, and non-destructive examination processes. Management is responsible for ensuring that only properly trained and qualified personnel are assigned to accomplish work activities and that they are provided adequate facilities, equipment, tools, and information to perform their work in compliance with requirements. Managers monitor the quality of activities through the results of in-process checks described in implementing procedures. These checks may be performed by co-workers or supervisory personnel and provide a method of tracking and trending events that affect the quality, safety, or regulatory status of operations, products, and services. Acceptance criteria for the process are identified in or referenced by the applicable procedure.

9.1 Special Processes

Special processes that control or verify quality are performed by qualified personnel using qualified procedures. Personnel, equipment, and procedures used to perform special processes are qualified in accordance with specified requirements. Qualified procedures for special processes include required conditions such as proper equipment, controlled parameters, and calibration requirements. Documentation of personnel, equipment, and process qualifications is maintained in accordance with procedures.

9.2 Special Requirements

For special process not covered by existing codes or standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment are specified or referenced in procedures or instructions.

10. INSPECTION

Quality Assurance, Engineering, and technical support personnel are responsible for ensuring that inspections required to verify conformance of an item or activity to specified requirements are planned, executed, and documented by qualified personnel according to approved procedures. Inspection requirements and acceptance criteria include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

Equipment modifications, repairs, and replacement are inspected in accordance with the original design and inspection requirements unless an approved alternate exists.

10.1 Personnel

Inspection personnel are independent of those who performed the work being inspected. Personnel who verify conformance of work for acceptance are qualified to perform the inspection in accordance with approved procedures. Personnel in training for qualification as an inspector by on-the-job training are directly supervised by a qualified person who verifies the inspection results until qualification is achieved.

10.2 Inspection Hold Points

Responsibilities for identifying and specifying hold points are established in approved procedures. Engineering and technical support representatives are responsible for identifying inspection hold points in appropriate documents to ensure that no further work is performed until a certain inspection has been completed. Work does not proceed beyond hold points without consent from the organization that established them. This consent is recorded prior to continuation of work.

10.3 Inspection Planning

Inspection procedures, instructions, or checklists identify the characteristics and activities to be inspected, the acceptance criteria, the responsible organization for performing inspection; the objective evidence of inspection results. Planning also includes identification of hold or witness points; approval of data by supervisors to ensure that all inspection prerequisites and requirements have been satisfied, including operator and equipment qualifications; and, if applicable, establishment

of sampling methods based on recognized standard practices, in accordance with approved procedures or project plans.

10.4 Sampling

When sampling is used, the sampling procedure is based upon standard statistical methods with engineering approval.

10.5 In-Process Inspection

Inspections are performed, as necessary, to verify conformance to requirements. Indirect control by monitoring may be utilized when direct inspection is impractical. Both inspection and monitoring are performed when control is inadequate without both. A combination of inspection and process monitoring is performed in a systematic manner to ensure that quality is achieved throughout the duration of the process. In-process inspection is performed by qualified personnel or qualified automated means.

10.6 Final Inspection

Final inspection includes a record review of the results of inspection and resolution of nonconformances identified in previous inspections. Items are inspected for completeness, markings, calibration, adjustments, and protection from damage. The acceptance of the item is documented and approved by authorized personnel. Modification, repair, or replacement requires re-inspection or retest to verify acceptability, as appropriate.

10.7 In-Service Inspection

In-service inspection methods are established to verify that the characteristics of an item remain within the specified limits. Inspection methods include routine evaluation of emergency and safety systems, and verification of calibration or integrity of instruments or systems and their maintenance, as appropriate.

10.8 Inspection Records

Inspection records contain, at a minimum, the item inspected, date of inspection, inspector, type of observation, acceptance and rejection criteria, results or acceptability, and reference to nonconformances.

11. TEST CONTROL

Testing to verify conformance of processes, equipment, and products to specified requirements and to demonstrate satisfactory performance is planned and performed by qualified personnel in accordance with approved procedures. Tests required to collect data are planned, executed, documented, and evaluated.

11.1 Test Requirements

Engineering and technical support representatives are responsible to ensure that test requirements and acceptance criteria are developed and incorporated into appropriate test plans, procedures, or checklists. The test methods and acceptance criteria are based on specified requirements contained in design or other technical documents. As appropriate, test plans are established, procedures developed, and results documented on checklists or other suitable records. If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test.

11.2 Test Procedures

Test procedures include or reference characteristics to be tested and test objectives and prerequisites. Prerequisites such as calibrated instrumentation, equipment and its condition, personnel qualification, environmental conditions, and collection and recording of data are taken into consideration during development of test procedures. Test procedures identify required monitoring during the test setup and performance. Test procedures are reviewed and approved by cognizant technical, quality, and management personnel.

As an alternative to Section 11.2, appropriate sections of related documents, such as ASTM methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents include or are supplemented with appropriate criteria from Section 11.2 to ensure adequate procedures for the test.

11.3 Test Results

Test results are documented and evaluated by a responsible authority to ensure that the test requirements were satisfied. Records include, as a minimum, the item tested, date of test, tester, environmental conditions, observations, acceptance and rejection criteria, results and acceptability, action taken for deviations noted, and person evaluating the results.

11.4 Testing after Modifications

Modification, repairs, or replacements are in accordance with the original design and test requirements or acceptable alternatives approved in the same manner as the original design.

11.5 Computer Program Testing

Testing of computer programs is performed in accordance with written plans and/or procedures. Test plans or procedures specify the following as applicable:

- Required tests and test sequence;
- Requires ranges of input parameters;
- Identification of the stages at which testing is required;
- Criteria for establishing test cases;
- Requirements for testing logic branches;
- Requirement for hardware integration;
- Anticipated output values;
- Acceptance criteria;
- Reports, records, standard formatting and conventions.

Computer program tests demonstrate the capability of the computer program to produce valid results for test problems encompassing the range of permitted usage defined by the program documentation. Acceptable test methods include comparison of test results with hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

Testing of computer programs used for operational control demonstrates required performance over the operational range and the adherence of the computer program to documented requirements. Periodic in-use manual or automatic self-check tests are performed for computer programs where operator errors, hardware failure, or instrument drift could affect required performance.

In-use testing is performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. In-use testing demonstrates acceptable performance of the computer program in the current operating system, adherence of the computer program to documented requirements, and assurance that computer programs used in design activities produce correct results.

Test results are documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Test results identify the following:

- Computer program tested and test problems run;
- Computer hardware used;
- Test equipment and calibrations, where applicable;
- Date of test and name of tester or data recorder;
- Simulation models used, where applicable;
- Test problems;
- Results and acceptability;
- Action taken in connection with any deviations noted;
- Person(s) evaluating test results.

Additional requirements regulating the testing of computer programs used for design analysis are contained in Section 3.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Measuring and test equipment (M&TE) used for activities affecting quality is controlled in accordance with approved procedures to ensure accuracy. The calibration process ensures that all measuring instruments used in the acceptance of material, equipment, and assemblies are calibrated and properly adjusted at specified intervals to maintain accuracy within pre-determined limits. These procedures identify the responsible organizations, the devices to be controlled, the controlling and calibration methods, and calibration intervals to maintain accuracy within the necessary limits.

Reference standards have a minimum accuracy of four times greater than that of the measuring and test equipment being calibrated. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard is technically justified.

Management is responsible for selecting the appropriate type, range, accuracy, and tolerance of M&TE to verify conformance to specified requirements. Calibration and control measures are not required for commercially available equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

Measuring and test equipment is calibrated, adjusted, and maintained at scheduled intervals against certified equipment or standards having known valid relationships to nationally recognized standards, standards derived from accepted values for natural physical constants, international standards known to be equivalent to and verified against corresponding nationally recognized standards, or by the ratio type of self-calibration. If no national standard exits, the basis of calibration is documented. The method and interval of calibration for each item is based on the type of device, stability characteristics, required accuracy, purpose, frequency of usage, and environment where it will be used.

Calibration methods are documented and performed by competent personnel in an environment that does not adversely affect the calibration. Special controls for usage, handling, and storage are documented and applied when they are required for environmental conditions such as temperature, humidity, cleanliness, or radiation to maintain accuracy or operating characteristics of the device.

When an M&TE device is lost, damaged or found to be out of calibration, previous test results are validated. Out-of-calibration devices are tagged and/or segregated until repaired and recalibrated or replaced. Any M&TE consistently found to be out of calibration is repaired or replaced.

Record of use and the calibration history is maintained and equipment is marked to indicate calibration status. Documentation includes the equipment identification number, next calibration due date, and inspectors or calibrator's signature or initials attesting to the accuracy and validity of the calibration. Calibration reports and certificates reporting the results of calibration include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

13. HANDLING, STORAGE, AND SHIPPING

Materials considered critical, sensitive, perishable, or of high value are handled, cleaned, stored, packaged, preserved, and shipped in accordance with controls identified in codes, standards, regulations, engineering specifications, or customer requirements to prevent damage or loss and to minimize deterioration. Radioactive waste that is processed and transferred to a disposal facility is handled, characterized, classified, shipped, received, and emplaced in accordance with the requirements specified in 10 CFR 20, Appendix G and 10 CFR 61.

13.1 Instructions

Handling, storage, and shipping processes are conducted in accordance with written procedures, inspection instructions, drawings, specifications, shipment instructions, or other documents, as appropriate. Information pertaining to shelf life, environment, packaging, temperature, cleaning, preservation, etc., is included, as required, to meet design, regulatory, and/or customer requirements.

13.2 Requirements

A special protective environment is provided when specified in instructions or procedures. The use of special handling equipment or techniques is addressed in procedures. Special tools and equipment are inspected and tested in accordance with approved procedures that describe the inspection and test methods, time intervals, maintenance methods, and personnel qualifications and training requirements. When the use of special protective environment and/or special tools and equipment is required, they are provided and their existence is verified.

13.3 **Marking**

Suitable marking or labeling to identify, maintain, and preserve the item is provided during packaging, shipment, handling, and storage, including indication of the presence of special environments or the need for special controls.

13.4 **USNRC-Licensed Packages**

Energy*Solutions* obtains and maintains U.S. NRC approval of the QAP and exercises these commitments to meet the requirements of 10CFR71, Subpart H and 10CFR72, Subpart G.

Transportation cask handling and operation conforms to the handling and operating procedures for each licensed cask.

Prior to the shipment of a transport cask, conditions of the NRC's Certificate of Compliance (specifications, tests, and inspections) are satisfied. Required shipping papers are prepared and accompany the shipment in accordance with regulatory requirements and approved procedures.

Established safety restrictions concerning handling, storage, and shipping are included in the handling and operating procedures for storage and transport casks.

14. INSPECTION, TEST, AND OPERATING STATUS

The status of items can be determined at any point throughout an operational process to prevent inadvertent use, installation, or operation of nonconforming or defective items. Status indicators are required to the extent possible to prevent operation of items that are removed from service for test, calibration, maintenance, or repair, and to ensure that required inspections and tests have been performed.

Operating procedures include reporting requirements that establish the equipment status at key events.

Status is identified by the use of tags, markings, stamps, or travelers. The authority for application and removal of status indicators is identified in approved procedures. Quality Assurance personnel routinely monitor Energy*Solutions* activities to ensure that status indicators are used and removed, as appropriate, in accordance with approved procedures.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Items that do not conform to specified requirements are controlled to prevent inadvertent installation or use in accordance with approved procedures. Procedures include controls that provide for reporting, identifying, documenting, evaluating, segregating (when feasible), disposition of nonconforming items, and notifying affected organizations.

Management is responsible for establishing an environment for identifying potential conditions adverse to quality. Management conducts analysis, as appropriate, to systematically determine significance of these conditions and actions appropriate to the conditions.

All Energy*Solutions* employees are responsible for reporting nonconforming conditions. Energy*Solutions* management, at all levels, fosters a "no fault" attitude toward the identification of conditions that are adverse to quality, such as failures, malfunctions, nonconformances, and out-of-control processes including the failure to follow procedures. Nonconforming items are identified by using legible marking, tagging, or other means that do not adversely affect their end use.

To avoid inadvertent use, nonconforming items are segregated, when feasible, in holding areas. In the case of large items, markings, roping that designates special storage areas, or other precautions are employed.

Conditions that may be reportable in accordance with 10CFR72.242, 10CFR71.95, 10CFR21, or the Price Anderson Amendment Act (PAAA) are reported in accordance with approved procedures.

Disposition of nonconforming items is addressed in a timely manner by management. Further processing, delivery, installation, or use of the nonconforming item is controlled pending the evaluation and approved disposition. Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

Disposition of a nonconformance, involving repair or use-as-is, is based on documented technical justification to ensure continued compliance with design, regulatory, and contractual requirements, and may include provisions for retest or re-inspection to the original acceptance criteria. Any changes to design require the same design controls as those applied to the original design. Accepted deviations are reflected in as-built records.

The disposition of a nonconformance is evaluated and approved by QA personnel. Reworked items are reexamined in accordance with the applicable procedures and with the original acceptance criteria. Repaired items are reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

Nonconformances are closed and documented by QA personnel and records are maintained in accordance with approved procedures. Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance.

16. CORRECTIVE ACTION

Conditions adverse to quality (e.g., nonconformances, failures, malfunctions, deficiencies, defective material, etc.) are promptly identified and evaluated to determine corrective action in accordance with established procedures. The identification, cause, and corrective action for significant conditions adverse to quality are documented and reported to appropriate levels of management.

Corrective action is promptly initiated when it is determined that a condition adverse to quality exists. In cases where it is not possible to accomplish a corrective action immediately, the appropriate management provides a written response describing the cause of the deficiency and the proposed corrective action to be completed within a specified time. Completion of corrective actions is verified.

For significant conditions adverse to quality, procedures provide for the identification of conditions; assignment of responsibility for corrective action; documentation of the cause and corrective action taken; implementation, evaluation, and verification of corrective action to prevent recurrence; and reporting to the appropriate levels of management.

Quality Assurance personnel have the authority to stop work or ensure adequate controls are in place until effective corrective action has been taken and any applicable changes have been incorporated in procedures and communicated to appropriate personnel.

Quality Assurance personnel perform follow-up on corrective actions, when required, to verify that they are effectively implemented and when required, trend adverse conditions to determine quality tendency for management review.

17. QUALITY ASSURANCE RECORDS

17.1 Record Management System

The Record Management System is defined, implemented, and maintained in accordance with established procedures.

The Record Management System provides for the generation, authentication, classification, receipt, retention, and maintenance of records that furnish documentary evidence that items or services meet specified quality requirements, e.g. design documents, fabrication travelers, inspection results, operational outputs, audit results, etc. Requirements and responsibilities for the transmittal, distribution, retention, maintenance, and disposition of records are specified in approved procedures. Quality assurance records are legible, reproducible, accurate, and protected against damage, deterioration, or loss. Records are uniquely identified and traceable to the item or activity to which they apply.

17.2 **Authentication**

Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated, including the use of electronic approval and authorization. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies.

Electronic documents are authenticated with comparable information, as identified above, and identified on the media or with the authentication information contained within or linked to the document itself.

17.3 **Index**

The records indexing system includes records identification, location of the record within the system, and retention time. The records and/or indexing system(s) provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies.

17.4 **Distribution**

The records are distributed, handled, and controlled in accordance with approved procedures.

17.5 **Classification of Records**

Records are classified for retention and storage requirements as either lifetime or nonpermanent. Records that meet any of the following criteria are designated lifetime records and are maintained by or for the owner of the item (or the item affected, in the case of services) or the activity:

- Those that provide significant value in demonstrating the capability for safe operation;
- Those that provide significant value in determining the cause of an accident or the malfunction or failure of an item;
- Those that provide significant value in maintaining, reworking, repairing, replacing, or modifying an item;
- Those that provide required baseline data for in-service inspections.

Energy*Solutions* lifetime records include design specifications, stress reports or stress calculations, as-built and interface control drawings, copies of material test reports, tabulation of materials for as-built configuration, NDE reports including examination reports, and nonconformance reports. Lifetime record retention is based on the life of the program, life of the item, life of the facility, or life of the license, as applicable.

Nonpermanent records are required to show evidence that an activity was performed in accordance with applicable requirements. Retention times are established in writing.

Quality assurance records for packaging and transportation of radioactive materials include instructions, procedures, drawings, and related specifications such as required qualifications, procedures, and equipment. These records are maintained for three years beyond the date Energy*Solutions* last engages in the packaging and transportation of radioactive materials under the rules of 10CFR71. Superseded procedures or instructions are retained for a minimum of three years after the procedure or instruction is superseded.

Quality assurance records for spent fuel storage packaging will be maintained by or under the control of the licensee until the U.S. NRC terminates the license. For all other equipment, quality-related records are retained for a minimum of three years unless otherwise specified by applicable regulatory, code, standard, or contractual requirement.

17.6 Correction

Methods of correcting errors are identified along with a means of documenting the authorized individual who made the corrections and the date.

17.7 Receipt Control

Each organization responsible for the receipt of records designates an individual or organization responsible for receiving the records. Receipt control of records for permanent or temporary storage includes instructions for designating the required records to be controlled, identifying the records received, receiving and inspecting incoming records, determining the status, and forwarding to records storage facilities. Each receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process.

17.8 Storage Requirements

The records are stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies. Prior to storage of records, a written storage procedure is prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure includes, as a minimum:

- A description of the storage facility (single or dual storage);
- The filing system to be used;
- A method for verifying that the records received agree with the transmittal document and that the records are legible;
- A method of verifying that the records are those designated;
- The rules governing access to and control of the files;

- A method for controlling and accounting for records removed from the storage facility; and
- A method for filing supplemental information and disposing of superseded records.

Records are stored to prevent damage from moisture, pressure, or temperature. All records maintained in hard-copy form are firmly attached to binders or placed in folders, envelopes, or boxes for storage in file cabinets or within containers on shelving. Records may be stored in electronic media provided that the process for managing and storing the records is documented in approved procedures. Media used for the retention of records include, but are not limited to, microfilm, compact disks, magnetic media, optical disks, and hard disks. The format used is capable of producing legible and complete documents during the entire retention period.

Records are stored in facilities that minimize the risk of damage or destruction from the following:

- Natural disasters such as wind, flood, or fires;
- Environmental conditions such as high and low temperatures and humidity;
- Infestation by insects, mold, or rodents; and
- Dust or airborne particles.

There are two equally satisfactory methods of providing storage, single or dual.

- Single storage consists of a storage facility, vault room, or container(s) with a minimum two-hour fire rating. The design and construction of a single storage facility, vault room, or container are reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.
- Dual facilities, containers, or combination thereof are at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for dual storage are not required to satisfy the requirements of “single storage” identified above.

17.9 **Temporary Storage**

When temporary storage of records (such as for processing, review, or use) is required, the storage facility or container provides a one-hour fire rating, unless dual storage requirements are met.

17.10 **Authorized Personnel**

Measures are established to preclude the entry of unauthorized personnel into the storage area. These measures guard against larceny and vandalism. Measures are taken to provide for replacement, restoration, or substitution of lost or damaged records.

17.11 **Retrieval**

Storage systems provide for retrieval of information in accordance with planned retrieval times based upon the record type. A list is maintained designating those personnel who have access to the files. Records maintained by the supplier at their facility or other location are accessible to the purchaser or their designated alternate.

17.12 **Disposition**

Records accumulated at various locations other than Energy*Solutions* are made accessible to Energy*Solutions* directly or through the procuring organization. These records are processed in accordance with this QAP when they are transferred to Energy*Solutions*.

Various regulatory agencies have requirements concerning records that are within the scope of the QAP. The most stringent requirements are used in determining the final disposition.

18. AUDITS

Planned internal audits are scheduled and performed in accordance with approved procedures or checklists to provide comprehensive, independent verification, and evaluation of QAP compliance, performance criteria, and program effectiveness. Important to Safety (10 CFR 71 and 72) activities shall be audited based on the activity's importance to safety; however, each applicable quality criterion shall be audited at least once each year. Audit of QAP elements applicable to other activities conducted under the QAP shall be completed for each functional area within a period of 2 years unless a more frequent audit requirement is imposed by regulations. The audit scope encompasses an evaluation of quality system practices and/or procedures and the effectiveness of their implementation, monitoring of operations and activities, and a review of pertinent documents and their control and maintenance. A 90-day grace period may be applied to the scheduled audit intervals, but the periodicity of these audits should be based on the original schedule.

18.1 **Scheduling, Preparation, and Performance**

Internal and external audits are scheduled based on the status and importance of an activity and schedules are updated as necessary to ensure that adequate coverage is maintained.

An audit team, composed of one or more qualified auditors is identified for each audit using personnel who have no direct responsibility for the activity being covered. A lead auditor, as a member of the team, is designated as an audit team leader.

The key elements of the Energy*Solutions* audit program are:

- Scheduling and notifying management of the scope and nature of the audit;
- Team selection, orientation, and planning;
- Entrance conference;
- Exit conference;
- Reporting and response;
- Follow-up action.

18.2 **Reporting, Response, Follow-Up-Action, and Records**

Audit reports are prepared upon completion of the audit and distributed to appropriate management for review and response. Managers of the audited organizations provide a written response to any identified conditions adverse to quality that includes corrective actions (including cause and action to prevent recurrence) and a schedule for completion, when applicable. Audit files are retained as quality records in accordance with approved procedures.

19. ATTACHMENTS

19.1 Attachment 1, Matrix of Quality Assurance Requirements

19.2 Attachment 2, Matrix of QAP Relationship to ISO 9001

19.3 Attachment 3, Glossary of Terms

ATTACHMENT 1

MATRIX OF QUALITY ASSURANCE REQUIREMENTS

ENERGY*SOLUTIONS* QUALITY ASSURANCE PROGRAM CRITERIA	10CFR50 APPENDIX B	10CFR72 SUBPART G	10CFR71 SUBPART H	ASME NQA-1	10CFR830 SUBPART A	DOE O 414.1D
Organization	I	72.142	71.103	R-1	1	1, 10
Quality Assurance Program	II	72.144	71.105	R-2	1, 2, 9	1, 2, 3, 9, 10
Design Control	III	72.146	71.107	R-3	6	6
Procurement Document Control	IV	72.148	71.109	R-4	7	7
Instructions, Procedures, & Drawings	V	72.150	71.111	R-5	5	4, 5
Document Control	VI	72.152	71.113	R-6	4	4
Control of Purchased Material, Equipment, & Services	VII	72.154	71.115	R-7	7	7
Identification & Control of Materials, Parts, & Components	VIII	72.156	71.117	R-8	5	5, 8
Control of Special Processes	IX	72.158	71.119	R-9	5	5
Inspection	X	72.160	71.121	R-10	8	8, 10
Test Control	XI	72.162	71.123	R-11	8	8, 10
Control of Measuring & Test Equipment	XII	72.164	71.125	R-12	5, 8	5, 8
Handling, Storage, & Shipping	XIII	72.166	71.127	R-13	5	5
Inspection, Test, & Operating Status	XIV	72.168	71.129	R-14	8	5
Nonconforming Materials, Parts, or Components	XV	72.170	71.131	R-15	3	3, 10
Corrective Action	XVI	72.172	71.133	R-16	3, 9	3, 10
Quality Assurance Records	XVII	72.174	71.135	R-17	4	4
Audits	XVIII	72.176	71.137	R-18	3, 10	9, 10

ATTACHMENT 2

MATRIX OF QUALITY ASSURANCE PROGRAM RELATIONSHIP TO ISO 9001

ENERGY*SOLUTIONS* QUALITY ASSURANCE PROGRAM CRITERIA	ISO 9001-2015 Clauses
Organization	4.2, 5.1.1
Quality Assurance Program	4.4, 4.3, 6, 7.4, 9.3, 7.1, 7.1.4, 7.1.5, 7.2, 7.5.1, 8.1, 9.1, 9.1.3, 9.3, 10.3
Design Control	8.3, 8.5.2, 8.5.4
Procurement Document Control	8.2, 8.4, 8.4.3, 8.5.1, 8.5.6, 8.6
Instructions, Procedures, & Drawings	8.5.1
Document Control	7.5.2, 7.5.3
Control of Purchased Material, Equipment, & Services	8.4, 8.5.4
Identification & Control of Materials, Parts, & Components	8.5.2
Control of Special Processes	
Inspection	9.1
Test Control	9.1
Control of Measuring & Test Equipment	8.5.2, 7.1.5
Handling, Storage, & Shipping	8.5.5
Inspection, Test, & Operating Status	8.4.2
Nonconforming Materials, Parts, or Components	8.7, 10.2
Corrective Action	10.2, 10.3
Quality Assurance Records	7.5
Audits	9.2

ATTACHMENT 3

GLOSSARY OF TERMS

acceptance criteria: specified limits placed on the performance, results, or other characteristics of an item, process or service defined in codes, standards, or other requirement documents.

audit: a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

audit, external: an audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

audit, internal: an audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Certificate of Conformance: a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

certification: the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

characteristic: any property or attribute of an item, process, or service that is distinct, desirable, and measurable.

commercial grade item:[1, 2] a structure, system, component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

commercial grade item:[1, 3] an item satisfying the following

(a) not subject to design or specification requirements that are unique to those facilities or activities

(b) used in applications other than those facilities or activities

(c) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog)

commercial grade item: [1,4] a structure, system, component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this document.

commercial grade service:[1] a service that was not provided in accordance with the requirements of this document.

computer program:[5, 6, 7] a combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions.

condition adverse to quality: an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

configuration: the physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

configuration item (software):[6] a collection of hardware or software elements treated as a unit for the purpose of configuration control.

configuration management: the process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained.

corrective action: measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

critical characteristics: important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

design, final: approved design output documents and approved changes thereto.

design authority: the organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.

design bases: that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be

(a) restraints derived from generally accepted "state-of- the-art" practices for achieving functional goals; or

(b) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

design change: any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design input: those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

design output: drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

design process: technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

design review: a critical review to provide assurance that the final design is correct and satisfactory.

deviation: a departure from specified requirements.

document: any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record as defined in this document.

document control: the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

electronic document: a document stored in a form (i.e., magnetic or optical media) that is typically accessible only by a computer.

guidance a suggested practice that is not mandatory in programs intended to comply with this document. The word *should* denotes guidance; the word *shall* denotes a requirement.

inspection: examination or measurement to verify whether an item or activity conforms to specified requirements.

inspector: a person who performs inspection activities to verify conformance to specific requirements.

item: an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

measuring and test equipment (M&TE): devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

nonconformance: a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

objective evidence: any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Owner: the organization legally responsible for the construction and/ or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.

procedure: a document that specifies or describes how an activity is to be performed.

procurement document: purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Purchaser: the organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents.

qualification, personnel: the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

qualified automated means: automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits.

qualified procedure: an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

quality assurance (QA): all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

quality assurance record: a completed document that furnishes evidence of the quality of items and/ or activities affecting quality. Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms. The term *record,* as used throughout this document, is to be interpreted as quality assurance record.

quality standard: a code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item.

receiving: taking delivery of an item at a designated location.

repair: the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

rework: the process by which an item is made to conform to original requirements by completion or correction.

right of access: the right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.

safety function: the performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

service: the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

shall: see *guidance.*

should: see *guidance.*

software:[6] computer programs and associated documentation and data pertaining to the operation of a computer system.

special process: a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier: any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

surveillance: the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

testing: an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

traceability: the ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

use-as-is: a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

verification: the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

waiver: documented authorization to depart from specified requirements.

Footnotes

[1] See NQA-1a-2009, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services* for other definitions related to the dedication of commercial grade items.

[2] This definition is applicable to nuclear power plants and activities licensed pursuant to 10 CFR Part 30, 40, 50, 52, or 60.

[3] This definition is applicable to nuclear facilities and activities licensed pursuant to 10 CFR Part 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72.

[4] This definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management.

[5] Computer programs covered by this document are those used for:

(a) design analysis;

(b) operations or process control; or

(c) data base or document control registers when used as the controlled source of quality information for (a) or (b) above.

[6] This definition has been copied from ANSI/IEEE 610.12-1990, Glossary of Software Engineering Terminology, with the permission of IEEE.

[7] To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection systems, digital instrumentation) they are included in the term *item.*