

Chapter 11 – Management Measures

TABLE OF CONTENTS

	Page
11.0 MANAGEMENT MEASURES	11-1
11.1 GRADED APPROACH.....	11-1
11.2 CONFIGURATION MANAGEMENT.....	11-6
11.2.1 Configuration Management Program.....	11-6
11.2.2 Design Requirements	11-7
11.2.3 Document Control	11-7
11.2.4 Change Control	11-9
11.2.5 Assessments.....	11-10
11.2.6 Interface Control.....	11-11
11.2.7 Procurement Controls.....	11-11
11.2.8 Preservation of Defense-in-Depth Practices	11-11
11.3 MAINTENANCE.....	11-12
11.3.1 Surveillance and Monitoring	11-13
11.3.2 Corrective Maintenance.....	11-13
11.3.3 Preventive Maintenance	11-14
11.3.4 Functional Testing	11-15
11.3.5 Interfaces with Other Management Measures	11-15
11.4 TRAINING AND QUALIFICATIONS.....	11-16
11.4.1 Position Training Requirements.....	11-17
11.4.2 Bases and Objectives for Training	11-18
11.4.3 Training Guides	11-18
11.4.4 Training Evaluations.....	11-18
11.4.5 On-the-Job Training	11-18
11.4.6 Training Program Assessments.....	11-19
11.4.7 Personnel Qualification.....	11-19
11.5 PROCEDURES DEVELOPMENT AND IMPLEMENTATION	11-20
11.5.1 Procedures.....	11-20
11.5.2 QA and Administrative Procedures.....	11-20
11.5.3 Operator Action Procedures for Accident Sequences	11-22
11.5.4 Changes to Procedures.....	11-22

11.5.5	Maintenance and Testing Procedures	11-23
11.6	AUDITS AND ASSESSMENTS.....	11-24
11.6.1	Audit and Assessment Program	11-24
11.6.2	Audit Guidance, Standards, and Performance Criteria	11-24
11.6.3	Audit Frequency	11-25
11.6.4	Independence	11-26
11.6.5	Qualification Requirements for Auditors, Lead Auditors, and Assessors	11-26
11.6.6	Results and Corrective Action	11-27
11.6.7	Graded Approach to Oversight	11-27
11.6.8	Self-Assessment Program	11-27
11.6.9	Audit and Assessment Process	11-28
11.7	INCIDENT INVESTIGATIONS AND CORRECTIVE ACTION PROGRAM	11-29
11.8	RECORDS MANAGEMENT	11-30
11.8.1	Records Categorization and Retention	11-31
11.8.2	Handling and Storage of Contaminated and Classified Records.....	11-31
11.8.3	Physical Storage Facilities and Environmental Controls	11-32
11.8.4	Program Effectiveness Evaluations and Deficiency Correction.....	11-32
11.9	OTHER QA ELEMENTS	11-32
11.9.1	Organization	11-32
11.9.2	Quality Assurance Program.....	11-34
11.9.3	Design Control.....	11-34
11.9.4	Procurement Document Control	11-34
11.9.5	Instructions, Procedures, and Drawings	11-34
11.9.6	Document Control	11-35
11.9.7	Control of Purchased Items and Services.....	11-35
11.9.8	Identification and Control of Items	11-35
11.9.9	Control of Special Processes.....	11-36
11.9.10	Inspection.....	11-36
11.9.11	Test Control.....	11-36
11.9.12	Control of Measuring and Test Equipment.....	11-36
11.9.13	Handling, Storage, and Shipping	11-36
11.9.14	Inspection, Test, and Operating status	11-36
11.9.15	Control of Nonconforming Items	11-36

11.9.16 Corrective Action 11-37

11.9.17 Quality Assurance Records 11-37

11.9.18 Audits 11-37

11.9.19 QA Element Table 11-37

11.0 MANAGEMENT MEASURES

The management measures adopted by Orano Enrichment USA, LLC (OE) to ensure the availability and reliability of items relied on for safety (IROFS) integrate lessons learned from GB2 Enrichment Facility. Management measures described in this application are applied to IROFS or other items or activities designated by OE. IROFS are those items (Configuration Items, CI) or activities of personnel which are relied on to prevent potential accidents at a facility that could exceed the performance requirements in 10 CFR 70.61 or to mitigate their potential consequences. Non-IROFS are those CI or activities of personnel which are not designated as IROFS. Management measures shall be applied to the IROFS in a graded approach allowing OE to strategically allocate resources while providing reasonable assurance that IROFS are available and reliable to perform their intended function(s) when needed.

OE has elected to classify CI and personnel activities as one of three quality levels (Quality Level 1, Quality Level 2, and Quality Level 3). IROFS are classified as QL-1 or QL-2 using a risk-informed methodology contained in the Integrated Safety Analysis (ISA). Non-IROFS are designated as QL-3. The classification methodology, including the scoring criteria used to assign quality levels to each CI and personnel activity, is described in Section 3 of the ISA Summary submitted as part of this License Application.

Quality level 1 and 2 CI and personnel activities are designated as IROFS due to their contribution to prevent or mitigate potential accidents. Quality Level 3 is the designation for those CI and personnel activities that are not designated as IROFS. Management measures and additional QA elements are outlined in the OE Quality Assurance Program Description (QAPD). These measures are applied to Quality Level 1 and 2 IROFS and other CI or personnel activities as designated, commensurate with the complexity of the IROFS, the level of safety significance, and importance to safety, providing reasonable assurance that they are available and reliable to perform their functions when needed.

Management measures are implemented through a quality assurance (QA) program described in OE's QAPD. The use of the QAPD ensures that the design, implementation, construction, operation, and decommissioning of IROFS are controlled in accordance with management measures and other QA elements, commensurate with the complexity of the service, the level of safety significance, and importance to safety.

OE maintains full responsibility for ensuring that the Facility is designed, constructed, tested, operated, and decommissioned in conformance with good engineering practices, applicable regulatory requirements, and specified design requirements and in a manner to protect the health and safety of the public. Management measures applicable to IROFS during the operational phase of the Facility shall continue to be applied during decommissioning activities that involve IROFS, commensurate with the risk significance of the decommissioning activity and the IROFS quality level classification.

11.1 GRADED APPROACH

Management measures are applied to QL-1 and QL-2 IROFS in a graded manner commensurate with the complexity of the IROFS, their level of safety significance, and their importance to safety. The graded application of management measures tailors the rigor of implementation to the safety significance of the item without compromising the availability or reliability of IROFS. The following describes how each management measure is differentiated between QL-1 and QL-2 IROFS:

Configuration Management: QL-1 IROFS require a greater level of design control rigor, with approval and verification consistent with NRC regulations, applicable codes, and consensus

standards. QL-2 IROFS rely on more general commercially recognized codes and consensus standards. Changes to both QL-1 and QL-2 IROFS shall be subject to review in accordance with 10 CFR 70.72.

Maintenance: QL-1 IROFS typically require more frequent surveillance and monitoring than equivalent QL-2 IROFS. Maintenance frequencies for all IROFS shall be commensurate with manufacturer recommendations and facility operating experience and are adjusted based on trended surveillance results and incident investigation root causes.

Training and Qualifications: Personnel activities designated as QL-1 IROFS may require more stringent minimum qualification requirements than QL-2 IROFS, addressed on a case-by-case basis and documented by OE. Personnel activities designated as either QL-1 or QL-2 IROFS shall undergo initial and periodic task-based qualifications, not to exceed a two-year interval, to verify performance of safety functions. Extended qualification intervals for QL-2 IROFS may be approved by the Quality Assurance Manager if justified and documented.

Procedures: The level of detail and rigor of procedures for both QL-1 and QL-2 IROFS shall be commensurate with the IROFS level of safety significance and complexity. QL-1 IROFS procedures shall be subject to a higher level of validation prior to use.

Audits and Assessments: QL-1 IROFS and associated personnel activities shall be assessed at a higher frequency than equivalent QL-2 IROFS. Both QL-1 and QL-2 IROFS shall be subject to the audit and assessment program described in Section 11.6.

Incident Investigations: All failures of both QL-1 and QL-2 IROFS shall be documented in the Corrective Action Program (CAP) at the time of discovery in accordance with 10 CFR 70.62(a)(3). Root cause analysis shall be required for all QL-1 IROFS failures. Root cause analysis for QL-2 IROFS failures shall be performed at the discretion of the Quality Assurance Manager based on risk significance.

Records Management: Records for both QL-1 and QL-2 IROFS shall be retained for the life of the Facility in accordance with 10 CFR Part 70 and Section 11.8 of this application.

Table 11.1-1: Management Measures Criteria Mapping by Quality Level

Management Measures	Quality Level 1	Quality Level 2
Configuration Management	Oversight and control of design/safety information is handled under Other Quality Assurance Elements, "Design Control". Modifications – changes are reviewed, approved, documented, and controlled. Changes to IROFS shall be reviewed and approved commensurate with the original design review and approval.	
Maintenance	IROFS are maintained at a frequency commensurate with manufacturer recommendations and facility operating experience. Maintenance frequencies will be adjusted based on trended surveillance results and incident investigations root causes.	
	QL-1 IROFS typically will require more frequent	QL-2 IROFS will require less frequent surveillance/monitoring.

Table 11.1-1: Management Measures Criteria Mapping by Quality Level

Management Measures	Quality Level 1	Quality Level 2
	surveillance/monitoring than an equivalent QL-2 IROFS.	
Training and Qualifications	Personnel Activities on QL-1 vs QL-2 IROFS may require different minimum requirements but will be addressed on a case-by-case basis. Personnel Activities designated as IROFS shall undergo initial and periodic task-based qualification to verify performance of safety functions. See Other Quality Assurance Elements, "Organization".	
Procedures	See Other Quality Assurance Elements, "Instructions, Procedures, and Drawings".	
Audits and Assessments	Audits are handled under Other Quality Assurance Elements, "Audits". Assessments – both QL-1 and QL-2 IROFS are assessed following the same guidance. Inspections of IROFS are handled under Other Quality Assurance Elements, "Inspections".	
	QL-1 IROFS may be assessed at a higher frequency than an equivalent QL-2 IROFS.	QL-2 IROFS typically require a lower assessment frequency.
Incident Investigations	See Other Quality Assurance Elements, "Control of Nonconforming Items and Corrective Action"	
Records Management	See Other Quality Assurance Elements, "Quality Assurance Records".	
Other Quality Assurance Elements		
Organization	Not subject to grading.	
Quality Assurance Program	Program will ensure that management measures are applied to IROFS commensurate with the IROFS' level of safety significance.	
Design Control	Approval and verification typically require a greater level of rigor from federal NRC regulations, codes, and consensus standards.	Reliant on more general and commercially recognized codes and consensus standards.
Procurement Document Control	QL-1 IROFS specific requirements are outlined in PO/contract.	QL-2 IROFS typically have less stringent requirements.

Table 11.1-1: Management Measures Criteria Mapping by Quality Level

Management Measures	Quality Level 1	Quality Level 2
Instructions, Procedures, and Drawings	Level of detail is commensurate with the IROFS' level of safety significance and complexity.	
Document Control	Level of review shall be commensurate with the IROFS' level of safety significance and complexity.	
Control of Purchased Items and Services	Certificate of Conformance (CoC) + onsite audit (onsite expected unless basis for not doing so is justified) Source inspections / surveillances expected unless basis for not doing so is justified	Accreditation/certificate in lieu of onsite Audit CoC + ASL Source inspections / surveillances typically not required
Identification and Control of Items	Not subject to grading.	
Control of Special Processes	Approved and reviewed prior to use.	Not required to be reviewed prior to use if done per code/standard requirements.
Inspection	High rigor (more characteristics, high sampling)	Low rigor (less characteristics, low sampling)
Test Control	Approved and reviewed prior to use. Higher sampling rate.	Not required to be reviewed prior for use if done per code/standard requirements. Lower sampling rate.
Control of Measuring and Test Equipment	Calibration shall be done in accordance with design documents. All calibrations shall be done by approved suppliers. QL-2 IROFS may have an extended calibration interval (not to exceed manufacturer recommendation), while QL-1 IROFS may have shorter intervals between calibrations.	
Handling, Storage, and Shipping	Requirements shall be commensurate with the IROFS' level of safety significance and complexity.	
Inspection, Test, and Operating status	Not subject to grading.	

Table 11.1-1: Management Measures Criteria Mapping by Quality Level

Management Measures	Quality Level 1	Quality Level 2
Control of Nonconforming Items	Approval is commensurate with the IROFS' level of safety significance and complexity.	
Corrective Actions	Approval is commensurate with the IROFS' level of safety significance and complexity.	
Quality Assurance Records	Not subject to grading, however, document retention will be in accordance with applicable laws and regulations.	
Audits	Internal audits are not graded; frequency of audits and assessments will depend on the quality program of the supplier and the IROFS they are providing.	

OE shall periodically review and assess the application of management measures to all IROFS to ensure that the quality level classifications and assigned management measures remain appropriate and continue to provide reasonable assurance of IROFS availability and reliability. This review shall be conducted as part of the Configuration Management Program periodic assessment described in Section 11.2.5, at a frequency not to exceed 24 months. The results of incident investigations, root cause analyses, and operational experience shall be evaluated to determine if quality level classifications require adjustment, if management measures need to be added, removed, or modified, and if maintenance and surveillance frequencies require adjustment based on trended reliability data. Proposed changes to quality level classifications or management measures resulting from these evaluations shall be reviewed by a cross-functional team to ensure consistency with the ISA and the Facility design basis prior to implementation.

The ISA Summary, submitted as part of this license application, contains the complete inventory of IROFS identified for the OE Facility, the quality level assigned to each IROFS, and the basis for that assignment. The application of the Management measures to each IROFS is commensurate with its quality level classification. OE maintains design basis documentation for each IROFS that identifies its safety function, critical characteristics (as applicable), and applicable management measures. This documentation shall be maintained as a lifetime record and shall be subject to the change control requirements described in Section 11.2.4 and the periodic assessment requirements described in Section 11.2.5.

11.2 CONFIGURATION MANAGEMENT

This section discusses oversight, control, and documentation of design and safety information including the changes or modification of IROFS that may impact their ability to be available or reliable to perform their intended function(s) when needed. OE's QAPD, Section 3, Design Control, discusses the design process, design inputs, design verification, configuration management, interface control, and the resulting records.

11.2.1 Configuration Management Program

The Configuration Management Program ensures that the initial design and safety bases are established, maintained, and documented. This program ensures the integrity of the design and safety bases of the Facility. The different elements of the program shall be systematically applied and graded to the IROFS, as appropriate, ensuring that the IROFS are available and reliable to perform their intended function(s) when needed. Design and safety bases are established using the guidance of the QAPD, Section 3, Design Control. As part of establishing these bases, each of the design documents shall be prepared in accordance with approved procedures and shall undergo interdisciplinary reviews during the initial release and subsequent revisions to ensure alignment of design and safety bases. The Configuration Management Program ensures strict consistency among Facility design and operational requirements, the physical configuration, and Facility documentation. Facility documentation shall be periodically assessed, at a frequency not to exceed 24 months, for discrepancies between the design and safety bases. This assessment shall ensure that changes are appropriately documented, and any corrective and preventive measures are taken. OE maintains the physical configuration of the Facility in strict alignment with design and safety bases through a combination of post-modification testing, periodic assessments, audits, walkdowns, and robust change control procedures described in Section 11.2.4.

The Configuration Management Program maintains the linkage between each IROFS and its applicable management measures as part of the design basis documentation. Changes to an IROFS that affect its quality level classification, critical characteristics, or applicable management measures shall require a revision to the applicable documents, subject to the same review and approval process as the original classification. The Configuration Management Program ensures that the design documents for each IROFS remain current and consistent with the ISA and the Facility design basis throughout the life of the Facility.

Deviations to the design bases shall be analyzed by a cross-functional team (typically composed of the design and ISA teams) to determine if there are any impacts to the ISA. Changes or impacts to the ISA shall be tracked, documented, reviewed, and approved prior to implementing a change. Changes that are approved by the cross-functional team are reviewed to determine whether NRC approval is required prior to implementation.

Changes that do not decrease the level of safety do not need to be reviewed by the NRC prior to implementation. However, changes that decrease the level of safety or that are otherwise required to be reviewed by NRC shall be submitted to the NRC for review and approval prior to implementation. All cross-functional team approved changes, regardless of whether they require NRC approval, shall be documented in accordance with approved procedures and reported at least annually to the NRC in accordance with 10 CFR 70.72(d).

11.2.2 Design Requirements

Design requirements and associated design bases are established and maintained by the Engineering department through a design process that proceeds logically from the design basis to drawings and other technical or design documents. All design documents, including software, are subject to design control requirements. The design process ensures that safety commitments in the ISA are translated into the detailed design and technical documents via a documented engineering workflow, ensuring that final design and technical documents accurately represent the established design basis. Design Control is outlined in the QAPD, Section 3, Design Control. These requirements include personnel training and qualification, control of inputs, process control (e.g., procedures), verification (e.g., independent reviewer, cross-functional review), and validation.

Software used in the design, analysis, or operation of IROFS is subject to design control requirements commensurate with its quality level classification. Software controls include configuration identification, version control, validation prior to use, and change control through the Configuration Management Program. Software that performs or supports an IROFS safety function is subject to the same change control requirements as hardware IROFS, including 10 CFR 70.72 screening for changes that may affect the design or safety basis. Procedures are established for maintaining the readability and usability of software and computerized data as computing technology changes, in accordance with the records management requirements of Section 11.8.

11.2.3 Document Control

Document Control is an integral element of the Configuration Management Program that prescribes an acceptable, rigorous method to create, review, approve, issue, and control documents. Document Control ensures that personnel performing IROFS activities utilize only correct, approved, and up-to-date documentation, maintaining strict consistency among design requirements, physical configuration, and facility documentation. Document Control is addressed further in the QAPD, Section 6, Document Control.

11.2.3.1 Program Scope and Controlled Categories

Document Control applies to all documents that describe, specify, or govern activities affecting IROFS. The specific categories of documents controlled under this program include, but are not limited to:

- Design requirements, technical specifications, and engineering calculations.
- ISA documentation and supporting summaries.
- As-built facility drawings, piping and instrumentation diagrams (P&IDs), and electrical schematics.
- Procurement documents, specifications, and supplier quality manuals.
- Operating, maintenance, modification, and test procedures.
- Training and qualification program records and instructions.
- Audits, assessments, nonconformance reports, and corrective action tracking records.
- Emergency procedures, emergency plans, and physical security plans.

11.2.3.2 Document Preparation, Review, and Approval

Document Control measures are implemented through approved administrative procedures that establish clear lines of responsibility and authority:

- Preparation: Documents are drafted by qualified individuals possessing technical competency in the subject matter.
- Interdisciplinary Review: Before issuance, documents are reviewed by qualified individuals other than the preparer. This review evaluates technical adequacy, accuracy, compliance with regulatory commitments, and potential impacts on the ISA safety basis. Review matrices ensure that all affected technical and functional disciplines (e.g., Nuclear Criticality Safety, Fire Protection, Chemical Safety, Operations, and Quality Assurance) provide independent oversight.
- Approval: Documents are formally authorized and signed by the designated functional Manager (or authorized designee) responsible for the activity prior to issuance and implementation. The Quality Assurance Manager reviews and approves lower-tier quality program instructions to verify adherence to upper-tier requirements.

11.2.3.3 Distribution and Revision Control

Distribution of documents is controlled to ensure that authorized documents are available at the appropriate work locations where activities are performed.

- Revision Control: Changes to controlled documents (except for minor editorial corrections) are subject to the same level of preparation, independent review, and formal approval as the original document. Revisions are clearly identified within the document text or accompanying revision logs.
- Obsolescence Prevention: Administrative controls are maintained to identify the current revision status of all facility documents. Superseded or obsolete documents are promptly removed from work areas or clearly marked as "SUPERSEDED" to prevent inadvertent operational use.

11.2.3.4 Maintaining Design and Baseline Consistency

Document Control actively interfaces with the broader Configuration Management process to maintain absolute alignment between the physical plant configuration and the engineering design baseline. Whenever a modification is processed through the Change Control program, the impacted documents are tracked and controlled. These changes are made prior to the physical implementation and operational readiness review of the change, ensuring only approved documents are utilized.

11.2.4 Change Control

Change Control is established to systematically evaluate, document, approve, implement, and track each modification to the facility. Change Control applies to all lifecycle phases of the facility and ensures that changes do not degrade safety baselines or compromise the availability and reliability of IROFS.

11.2.4.1 Scope and 10 CFR 70.72 Change Categories

Change Control is applicable to all physical, operational, and administrative modifications. Prior to implementation, any proposed change within the following categories must be formally evaluated under the 10 CFR 70.72 regulatory framework:

- Modifications to facility CI including structures, systems, processes, equipment, and components (including temporary modifications).
- Alterations to the engineering design basis, calculations, drawings, and technical specifications.
- Changes to facility computer programs, software codes, and automation systems that control or monitor IROFS functions.
- Revisions to standard operating, maintenance, emergency, and quality program procedures.
- Significant organizational adjustments, changes to key functional personnel positions, or modifications to personnel training and qualification activities.

11.2.4.2 Change Control Process

Proposed changes are controlled through a structured administrative process:

- Initiation and Identification: Changes are initiated via a formal Configuration Change Request. The request identifies the proposed change target, technical justification, affected CI and administrative activities, and preliminary impact assessments.
- Interdisciplinary Evaluation: Configuration Change Requests are routed to a designated Configuration Control Board consisting of qualified technical representatives from Engineering, Operations, Licensing, Quality Assurance, and safety disciplines (Nuclear Criticality Safety, Fire Protection, Chemical Safety, and Radiation Safety). This review evaluates the modification's impact on facility operations, procurement, training requirements, and upper-tier quality criteria.
- Approval and Authorization: Modifications classified as IROFS require formal approval by the Design Authority (Engineering Manager) and the Configuration Management Manager prior to execution. If a modification requires prior NRC approval under 10 CFR 70.72(c), a formal License Amendment Request is prepared and submitted, and physical implementation is barred until NRC approval is granted.
- Implementation and Tracking: Approved modifications are executed via formal Design Change Notices and tracked. Closeout requires validation that physical field installation matches the approved design, post-modification functional testing is successfully completed, and personnel training has been updated.

11.2.4.3 Systematic ISA Updates

To prevent any disconnect between operational configurations and safety-basis analyses, the Change Control process directly integrates with the ISA update loop as described in ISA Summary Section 1.10.2:

- 10 CFR 70.72 Regulatory Screening: Every Configuration Change Request undergoes a documented safety evaluation against the five (5) distinct licensing criteria of 10 CFR 70.72(c) to verify whether the change creates unanalyzed accident sequences, alters existing accident frequencies, decreases IROFS reliability assumptions, or introduces novel chemical/radiological hazards.
- Safety-Basis Reconciliation: If the screening indicates an impact on the ISA, the facility's quantitative probabilistic models, preliminary hazard analyses, and event tables are updated concurrently with the design phase. Affected documentation is modified to reflect revised accident-sequence timelines or updated IROFS boundary definitions before operational readiness is declared.
- Annual Transmittal Loop: All changes implemented under 10 CFR 70.72 that do not require prior NRC approval are logged, compiled, and submitted to the NRC as part of the mandatory annual ISA Summary revision within 12 months of the change.

11.2.4.4 Recordkeeping

Complete documentation of the change control process is maintained as permanent, auditable records in accordance with records management controls:

Documented packages (Initial request (Configuration Change Request), engineering calculations, multi-disciplinary review comments, 10 CFR 70.72 screenings/evaluations, approved Design Change Notices, and post-modification test data) are maintained as authenticated lifetime facility records. The Records Management System maintains traceability of design changes, ensuring that historical engineering justifications remain retrievable throughout the facility's operating life.

11.2.5 Assessments

As part of establishing a Configuration Management Program, OE shall conduct an assessment to ensure the program provides adequate oversight and control of design and safety information, and records of temporary and permanent modifications that may affect the ability of IROFS to be available and reliable to perform their intended safety functions. Both the initial and periodic assessments of the Configuration Management Program shall be conducted to determine the program's effectiveness and to rectify deficiencies. Periodic assessments shall include review of the adequacy of documentation and system walkdowns of the as-built Facility. Such assessments shall be conducted and documented in accordance with procedures and scheduled as discussed in the QAPD, Section 18, Audits.

Periodic assessments of the Configuration Management Program and of the design shall confirm that the program meets its goals and that design and safety information and records of modifications are consistent with the design and safety bases. Incident investigations shall occur in accordance with the QAPD, Section 16, Corrective Action, in the event problems are encountered. Prompt corrective actions shall be developed as a result of incident investigations or in response to adverse audit or assessment results, in accordance with the QAPD.

11.2.6 Interface Control

OE establishes and maintains interface control to ensure that design requirements and safety commitments are communicated and controlled across organizational, system, and contractor boundaries. Interface requirements for IROFS are identified during the design process and documented in design basis documents maintained by the Configuration Management Program. Interface control ensures that changes made to one system or component that may affect another IROFS are evaluated for impacts prior to implementation. Contractors and suppliers performing work on IROFS are provided with applicable interface requirements through procurement documents and are required to communicate any identified interface conflicts to OE for resolution prior to implementation. Interface control is addressed further in the QAPD, Section 3, Design Control.

11.2.7 Procurement Controls

Design requirements and quality level classifications established for IROFS are flowed down to suppliers and contractors via procurement documents to ensure that IROFS meet the applicable design basis and quality requirements. Procurement documents for IROFS identify the applicable quality level, design requirements, critical characteristics (as applicable), applicable codes and standards, and any special requirements including 10 CFR Part 21 obligations. The level of procurement control applied to IROFS is commensurate with the quality level classification of the CI or service being procured, as described in the graded approach in Section 11.1. Procurement controls for IROFS are addressed further in the QAPD, Section 4, Procurement Document Control, and Section 7, Control of Purchased Items and Services.

OE establishes controls to prevent the procurement and use of suspect or counterfeit items in IROFS applications. Procurement documents identify requirements for item traceability, certification, and source verification commensurate with the quality level classification of the CI. IROFS and other designated CI shall be subject to receipt inspection to verify conformance with procurement requirements and to identify potential suspect or counterfeit conditions. CI identified as potentially suspect or counterfeit shall be immediately segregated and controlled to prevent inadvertent use and shall be evaluated for 10 CFR Part 21 reportability. These controls are described further in the QAPD, Section 7, Control of Purchased Items and Services, and Section 15, Control of Nonconforming Items.

11.2.8 Preservation of Defense-in-Depth Practices

The Configuration Management Program establishes mechanisms to ensure that the facility's defense-in-depth design practices, founded in accordance with 10 CFR 70.64(b), remain fully preserved throughout the operational life of the facility. Configuration Management controls govern modifications to prevent programmatic degradation of successive, overlapping layers of protection.

11.2.8.1 Configuration Control Board Review Hierarchy

The Configuration Change Request screening and technical evaluation process enforces a strict design hierarchy during any process modification or system realignment:

- Engineered Control Preference: Modifications prioritize passive engineered features (such as overflow lines, structural barriers, or fixed geometry) or active engineered features (such as automated interlocks or hardwired isolation valves) over administrative operator actions to mitigate identified process hazards.

- Justification for Administrative Controls: For bounding accident sequences where an engineering change results in prevention or mitigation relying solely on an administrative IROFS, a formal engineering and human factors evaluation must be compiled. This evaluation must prove that alternative engineered options are not practicable due to technical, centrifuge layout, or process limitations, and must mandate enhanced management measures to ensure baseline control reliability.

11.2.8.2 Prevention of Frequent Challenges to IROFS

To satisfy defense-in-depth design criteria and prevent premature safety system degradation, the CM program screens proposed design inputs against operational parameters:

- Challenge Avoidance Screening: Design Change Notices are reviewed to confirm IROFS are configured with operational boundaries wider than the credited safety boundaries. This ensures routine operational transients are fully absorbed before an IROFS actuation setpoint is reached.
- Operational Escalation Loop: Any IROFS that undergoes frequent or unexpected operational actuations or demands repeated corrective maintenance is entered into the CAP. The Configuration Management Program requires a prompt technical evaluation to realign setpoints or optimize design interfaces, restoring the safety-basis margins established in the ISA.

11.3 MAINTENANCE

This section outlines the maintenance and functional testing programs to be implemented for the construction, pre-operational, and operations phases of the Facility. Preventive maintenance activities, surveillance, and performance trending provide reasonable assurance that IROFS will be available and reliable to perform their functions.

The purpose of planned and scheduled maintenance for IROFS is to ensure that the equipment and controls are kept in a condition of readiness to perform the planned and designed functions when required. The maintenance group plans, schedules, tracks (documents), and maintains records for maintenance activities. All maintenance (preventive, corrective, functional testing, and surveillance and monitoring) shall be performed and documented in accordance with approved maintenance procedures. The degree of maintenance performed is ascertained as part of the design process, or as a result of monitoring, an audit or assessment finding, incident investigation, corrective action, or a lesson learned.

Personnel performing maintenance on IROFS shall be qualified commensurate with the complexity of the maintenance activity and the quality level of the IROFS. Qualification requirements for maintenance personnel are established through the training and qualification program described in Section 11.4 and the QAPD, Section 2, Quality Assurance Program. Maintenance activities on QL-1 IROFS shall be performed by personnel who have demonstrated competency in the applicable maintenance task through initial qualification and periodic requalification not to exceed a two-year interval. Maintenance activities on QL-2 IROFS shall be performed by qualified personnel with competency requirements commensurate with the complexity and safety significance of the task.

11.3.1 Surveillance and Monitoring

Surveillance and monitoring are utilized to detect degradation and adverse trends of CI so that action may be taken prior to the CI failure. The monitored parameters are selected based upon their ability to detect the predominant failure modes of the CI. Surveillance, monitoring, and reporting of results are required for CI that are designated as IROFS. The level of surveillance and monitoring for IROFS, like the degree of maintenance, is ascertained as part of the design process and is dependent on the complexity of the service, the level of risk, the level of safety significance, and importance to safety.

Plant performance criteria shall be established to monitor plant performance and to monitor IROFS functions and component parameters. These criteria are established and documented using industry experience, operating data, surveillance data, and plant equipment operating experience. These criteria ensure the reliability and availability of IROFS. The performance criteria are also used to demonstrate that the performance or condition of an IROFS is being effectively controlled through appropriate predictive and repetitive maintenance strategies so that they are available and reliable to perform their intended function(s) when needed.

Surveillance of IROFS is performed at specified intervals. The purpose of the surveillance program is to measure the degree to which IROFS meet performance specifications and to determine if the controls applied to the IROFS (administrative or otherwise) are adequate. The results of surveillances are trended, and when the trend indicates potential performance degradation, preventive maintenance frequencies are adjusted, or other appropriate corrective action is taken. As part of the corrective actions, modifications to the preventive maintenance scope and frequency are required to ensure safe and reliable operation of IROFS.

OE shall verify administrative controls identified as IROFS are available and reliable through periodic procedural audits, assessments, training proficiency evaluations, and performance monitoring as part of the surveillance function to ensure they are available and reliable during extended periods of operation.

Incident investigations may identify root causes of failures that are related to the type or frequency of maintenance. The lessons learned from investigations are incorporated into the surveillance, monitoring, and preventive maintenance programs as appropriate.

Maintenance procedures prescribe compensatory measures, if appropriate, for surveillance tests of IROFS that can be performed only while equipment is out of service.

Records showing the current surveillance schedule, performance criteria, and test results for all IROFS shall be maintained and retained in accordance with the records management system.

Results of surveillance and monitoring activities related to IROFS via the Configuration Management Program shall be evaluated by all safety disciplines to determine if there are any impacts on the ISA.

11.3.2 Corrective Maintenance

Corrective maintenance involves repair or replacement of equipment that has unexpectedly degraded or failed. Corrective maintenance of IROFS restores the equipment to acceptable performance through a planned, systematic, controlled, and documented approach for the repair and replacement activities. As part of the investigation, scheduled maintenance activities and their frequency shall be evaluated for adequacy or to determine whether maintenance or lack thereof was the cause or contributing cause of premature degradation or failure.

Following corrective maintenance on an IROFS, and before returning it to operational status, functional testing, if necessary, shall be performed by qualified maintenance personnel to ensure the IROFS is available and reliable to perform its intended function(s) when needed.

Results of corrective maintenance activities related to IROFS via the Configuration Management Program shall be evaluated by applicable safety disciplines to determine any impact on the ISA and any updates needed.

Corrective maintenance activities involving the replacement of IROFS components shall be conducted as like-for-like replacements whenever possible, maintaining the original design and safety basis. In instances where a like-for-like replacement is not practicable, the proposed replacement is treated as a Facility change and evaluated and screened per 10 CFR 70.72 as described in Section 11.2.4. This ensures that any modification to the physical configuration resulting from corrective maintenance is systematically evaluated for its impact on the Integrated Safety Analysis (ISA) and that the IROFS remains available and reliable to perform its intended safety function before being returned to operational status.

11.3.3 Preventive Maintenance

Preventive maintenance (PM) includes preplanned and scheduled periodic refurbishment, partial or complete overhaul, or replacement of IROFS, if necessary, to ensure their continued safe operation. Planning for preventive maintenance includes consideration of results of surveillance and monitoring, including failure history. PM also includes instrument calibration and testing.

The PM program procedures and calibration standards (traceable to the national standards system or to nationally accepted calibration techniques, as appropriate) enable the Facility personnel to calibrate equipment and monitoring devices important to plant safety and safeguards. Testing performed on IROFS that are not redundant shall provide for compensatory measures to be put into place to ensure that the IROFS function is maintained until it is returned to operational status. Graded maintenance for IROFS may include extended calibration intervals, provided that such intervals do not exceed manufacturer recommendations or accepted industry standards and are justified by established performance data.

Industry experience, operating data, surveillance data, and plant equipment operating experience are used to determine initial PM frequencies and procedures. In determining the frequency of PM, consideration is given to appropriately balancing the objective of preventing failures through maintenance against the objective of minimizing unavailability of IROFS because of PM. In addition, feedback from PM and corrective maintenance and the results of incident investigations and identified root causes are used, as appropriate, to modify the frequency or scope of PM. The rationale for deviations from industry standards or vendor recommendations for PM is documented.

Results of PM activities related to IROFS via the Configuration Management Program shall be evaluated by all safety disciplines to determine impact on the ISA and any updates needed.

The PM program incorporates aging management considerations for IROFS. The effects of aging on IROFS, including degradation mechanisms such as corrosion, erosion, fatigue, and material embrittlement, are identified during the design process and addressed through preventive maintenance frequencies, surveillance parameters, and replacement criteria. Aging-related degradation trends identified through surveillance and monitoring are evaluated and addressed through the CAP described in Section 11.7. Where industry operating experience identifies aging mechanisms applicable to IROFS at the OE Facility, that experience is incorporated into the PM program.

11.3.4 Functional Testing

Functional testing of IROFS is performed appropriately, following initial installation, as part of periodic surveillance testing, and after corrective or preventive maintenance or calibration to ensure that the IROFS meets its original design requirements and safety parameters defined in the ISA and is available and reliable to perform its intended function(s) when needed.

Results of surveillance and monitoring activities related to IROFS via the Configuration Management Program shall be evaluated by all applicable safety disciplines to determine any impact on the ISA and any updates needed.

Testing (preoperational, operational, maintenance required, periodic, and special) of IROFS is performed and controlled in accordance with the QAPD, Section 11, Test Control. All testing modes — preoperational, operational, maintenance required, periodic, and special — shall be conducted to ensure safe and reliable operation of the Facility. For new processes or during Facility startup, functional tests shall be designed to include all operational aspects of the IROFS's intended safety functions. Records showing the functional test schedule and results for all IROFS shall be maintained and retained in accordance with the records management system.

If testing is performed during operation and an IROFS is out of service, localized outages may be utilized to ensure the impacted IROFS are isolated. Lock Out Tag Out and testing procedures may be utilized to ensure that personnel are aware of localized outages and which equipment is unavailable. Localized outages and other compensatory measures ensure continued safe operation of the Facility.

11.3.5 Interfaces with Other Management Measures

Maintenance activities as described above do not operate in isolation. The maintenance function is programmatically linked to all other management measures to provide reasonable assurance that IROFS remain available and reliable to perform their intended safety functions when needed.

11.3.5.1 Configuration Management

- Design Alignment: Maintenance work packages and field modifications are evaluated to verify that replacement parts and maintenance activities conform to approved design baselines.
- Post-Maintenance Testing: Physical changes or major repairs to IROFS trigger Configuration Management reviews and post-maintenance testing to confirm configuration equilibrium prior to declaring the system operable.

11.3.5.2 Training and Qualifications

- Personnel Qualification: Personnel performing maintenance or surveillance activities on IROFS shall be formally qualified and certified in accordance with the Training Program prior to initiating work.
- Feedback Loop: Identified human performance trends or post-maintenance testing failures are provided to the Training organization to update training requirements and criteria.

11.3.5.3 Procedures

- Work Execution: Maintenance and surveillance on IROFS are performed using approved, written procedures or work instructions that incorporate human factors engineering principles.
- Procedure Feedback: Maintenance technicians work with their management and Document Control to update procedures whenever field conditions or equipment manual revisions demand technical updates.

11.3.5.4 Audits and Assessments

- Internal Oversight: The maintenance organization, including work-package planning, tool calibration, and field execution, is subject to periodic independent audits and management self-assessments to verify program effectiveness.
- Material Condition Audits: Quality Assurance conducts field surveillances of active work areas to confirm compliance with quality and technical standards.

11.3.5.5 Incident Investigation and Corrective Action Program

- Deficiency Reporting: Equipment failures, unanalyzed degradation, or IROFS performance deviations uncovered during maintenance activities are immediately entered into the CAP.
- Causal Analysis: Maintenance subject matter experts participate in Apparent Cause Analyses or Root Cause Analyses to evaluate failure modes, establish corrective actions, and prevent recurrence.

11.3.5.6 Records Management

- Quality Records Generation: Completed work orders, surveillance data sheets, calibration logs, and post-maintenance test results are authenticated and transmitted to Records Management.
- Retention: Documentation validating the operational readiness and historical integrity of IROFS is maintained as permanent Lifetime Facility Records.

11.3.5.7 Other Quality Assurance Elements

- Procurement and Receipt: Replacement parts and spare components for IROFS are procured from qualified suppliers on the Approved Supplier List or dedicated via Commercial Grade Dedication plans under QA oversight.
- Measuring and Test Equipment Calibration: Measuring and Test Equipment utilized during maintenance calibrations or post-maintenance functional tests are strictly controlled, calibrated, and traceable to national standards.

11.4 TRAINING AND QUALIFICATIONS

The Training Program requirements apply to those plant personnel who perform activities that are classified as IROFS. Each type of training shall be conducted in accordance with reviewed and approved training materials (guides, courses, lesson plans, etc.). Training materials shall clearly document the purpose of the training, training and learning objectives, relevant details (such as job performance requirements), standards of performance, and standards for evaluating acceptable trainee performance.

The principal objective of the OE Training Program is to ensure job proficiency of all Facility personnel involved in IROFS activities through effective training and qualification. The Training Program is structured to accommodate future growth and meet commitments to comply with applicable established regulations and standards. In some circumstances, exemptions from training may be granted when the need is justified, documented, and approved by the applicable department manager or Operations Manager.

Qualification is indicated by successful completion of prescribed training, demonstration of the ability to perform assigned tasks and where required by regulation, maintaining a current and valid certification. Training is designed, developed, and implemented according to a systematic approach. Employees are provided with formal training to establish the foundation of knowledge and on-the-job training to develop work performance skills. Continuing training is provided, as required, to maintain proficiency in these knowledge and skill components, and to provide further employee development.

OE's Training Program is organized under the direction of the Operations Manager. Line management is responsible for the content and conduct of training. OE utilizes performance-based training as the primary management tool for developing, conducting, and evaluating training. Training and qualification records, including exemptions, shall be documented and retained for traceability.

Initial qualification requirements for each position performing IROFS activities are established through a systematic job task analysis that identifies the knowledge, skills, and abilities required to perform each task safely and effectively. The job task analysis considers the safety significance of the task, the complexity of the IROFS involved, the consequences of human error, and the Human Factors Engineering assumptions established in the ISA. Position-specific qualification requirements shall be documented and maintained as part of the Training Program records. Changes to IROFS that affect the knowledge, skills, or abilities required to perform associated tasks shall result in a review and update of the applicable qualification requirements.

11.4.1 Position Training Requirements

Each discipline shall have their own curated training modules or guides. These modules and guides provide the trainee(s) with an understanding of the work within their purview. Minimum qualification requirements are developed and included in Chapter 2 of this License Application for those who perform regulated activities and other personnel as required. Initial identification of job-specific training requirements is based on experience. The objective of the training shall be to ensure safe and efficient operation of the Facility and compliance with applicable established regulations and requirements. Training requirements shall be applicable to, but not necessarily restricted to, those personnel within the Operations Group who have a direct relationship with the operation, maintenance, testing, or other technical aspect of IROFS. Training courses shall be kept up to date to reflect plant modifications and changes to procedures when applicable. Relevant trainings are linked in the Configuration Management Program to ensure that the training accurately reflects Facility modifications and design changes in a timely manner.

Periodic retraining courses shall be established when applicable to ensure that personnel remain proficient. Periodic retraining generally is conducted to ensure retention of knowledge and skills important to Facility operations. The training may consist of periodic retraining exercises, instruction, and review of subjects as appropriate to maintain proficiency of all personnel assigned to the Facility.

11.4.2 Bases and Objectives for Training

The Training Program incorporates insights from the ISA and Human Factors Engineering (HFE). Objectives shall be developed to address error-likely situations and human-to-system interfaces for IROFS, ensuring that personnel qualifications account for the cognitive and physical demands identified during the safety analysis process.

Learning objectives identify the training content, as established by job analyses and position-specific requirements. The task list from the job analysis is used to develop action statements that describe the desired post-training performance. Objectives include the knowledge, skills, and abilities the trainee shall demonstrate; the conditions under which required actions take place; and the standards of performance the trainee shall achieve upon completion of the training activity.

11.4.3 Training Guides

Training guides shall be developed and maintained under the direction of the Operations Manager. These guides ensure that trainees have a good understanding of the task and can perform tasks competently. Training guides are records that are controlled in accordance with the QAPD.

11.4.4 Training Evaluations

Trainee understanding and command of learning objectives are evaluated through observation and demonstration or oral and written tests as appropriate. Such evaluations measure the trainee's skills and knowledge of job performance requirements.

Qualified personnel shall be evaluated to identify the Training Program's strengths and weaknesses. OE uses feedback from trainee performance during training and former trainees and their supervisors to evaluate and refine training.

Training evaluations are one of the mechanisms used to retrain or requalify personnel. Alternatively, periodic or repeat training or qualifications may be used to ensure personnel are comfortable and competent in their job duties.

Requalification frequencies for personnel performing IROFS activities are established based on the safety significance of the activity, the frequency with which the task is performed, the consequences of performance error, and the results of training evaluations and performance monitoring. Personnel activities designated as QL-1 IROFS shall be requalified at a frequency not to exceed two years. Personnel activities designated as QL-2 IROFS shall be requalified at a frequency not to exceed two years unless an extended interval is justified based on task frequency, demonstrated proficiency, and documented approval by the Quality Assurance Manager. Requalification frequencies shall be reviewed annually as part of the Training Program Assessment described in Section 11.4.6 and adjusted based on identified human performance trends.

11.4.5 On-the-Job Training

On-the-job training in conjunction with classroom training (or assigned reading) shall be used for tasks that require a higher level of control or for IROFS that require or need specific on-the-job training. Designated personnel, competent in the program standards and methods of conducting the training, conduct on-the-job training using current performance-based training materials. Completion of on-the-job training is demonstrated by actual task performance or performance of

a simulation of the task with the trainee explaining task actions using the conditions encountered during the performance of the task, including references, tools, and equipment reflecting the actual task to the extent practical.

11.4.6 Training Program Assessments

The Training Program shall be assessed annually per QAPD, Section 18, Audits. The assessment shall ensure that personnel are properly trained, certified, qualified, and competent in performing their assigned activities. The assessments shall also identify the need for retraining or requalification of personnel. If the assessment discovers a shortcoming, the shortcoming shall be documented (utilizing the CAP as necessary) and remedial steps shall be taken to ensure that impacted IROFS are still available to reliably perform their intended functions.

The annual assessments shall ensure alignment with the design and safety bases. Changes to either the design or safety basis shall result in an investigation to determine if training is impacted as part of the Configuration Management Program. Additionally, the assessments shall verify that training materials remain consistent with the HFE assumptions used in the ISA and that any identified human performance trends are incorporated into the continuing training cycle.

11.4.7 Personnel Qualification

The QAPD, Section 2, Quality Assurance Program provides training and qualification requirements for personnel performing IROFS work activities; for nondestructive examination, inspection, and test personnel; and for QA auditors. Other personnel that are required to be qualified for work activities shall conduct the applicable training as outlined above.

Contractors and vendor personnel performing activities on IROFS shall be qualified in accordance with requirements established in procurement documents. OE shall verify contractor and vendor personnel qualifications prior to permitting work on IROFS commensurate with the quality level of the IROFS. For QL-1 IROFS activities, OE shall verify that contractor and vendor personnel hold applicable certifications, licenses, or demonstrated qualifications consistent with the applicable code or standard. For QL-2 IROFS activities, qualification verification requirements are commensurate with the complexity and safety significance of the work. Contractor qualification records shall be maintained in accordance with the records management requirements of Section 11.8.

11.5 PROCEDURES DEVELOPMENT AND IMPLEMENTATION

Procedures are prepared, maintained, and implemented per OE's QAPD, Sections 5, Instructions, Procedures and Drawings, and 6, Document Control. OE shall have procedures that protect the public's health and safety. Measures including the Configuration Management Program and Training Program shall ensure that the latest revision of procedures is available and utilized. Personnel performing activities on IROFS shall adhere to applicable approved procedures. Departures from approved procedures during IROFS activities are not permitted without authorization from the appropriate level of management and shall be documented and evaluated through the CAP described in Section 11.7.

11.5.1 Procedures

Procedures are governed by a master procedure which establishes methodology for the preparation, review, approval, revision, cancellation, and control for policies, procedures, plans, guides, manuals, and forms. Procedures shall be reviewed prior to release and periodically reviewed to ensure that they can be performed as written, are technically accurate, and aligned with the QAPD and industry best practices.

Procedures shall be developed based on the needs of the organization. The ISA, QAPD, management measures, operations, and other applicable sources shall be utilized to determine if a procedure is needed. Prior to implementation, procedures shall be validated using mechanisms such as field testing.

Procedures shall include the following elements as applicable:

- Title, document number, revision and date
- Purpose and scope (limitations) of the procedure
- References
- Responsibilities (who is responsible and accountable for the actions)
- Background (including prerequisites and precautions)
 - Actions for normal and off-normal conditions of operation
- Procedural steps (including human actions and limitations)
- Acceptance criteria
- Check lists
- Operating limits and IROFS
- Safety checkpoints

11.5.2 QA and Administrative Procedures

To develop a QA Program, procedures shall be developed for the relevant QA elements, management measures, construction (as applicable), radiation safety, criticality safety, fire safety, chemical process safety, and other applicable safety areas. Written implementing procedures are established, maintained, and controlled to support the QAPD and to direct activities across the fifteen (15) specific functional areas required by NUREG-1520:

1. Design: Controls engineering calculations, design inputs/outputs, design verification, and modification design packages.
2. Configuration Management: Governs change screening under 10 CFR 70.72, Configuration Management reviews, and approved document and drawings list updates.
3. Procurement: Regulates purchase requisitions, flow-down of quality and technical requirements, supplier evaluations, and Commercial Grade Dedication.

4. Construction: Controls field installation, structural checks, receipt inspection, and turnover of completed systems.
5. Radiation Safety: Directs radiation work permits, air sampling, contamination monitoring, and dosimetry.
6. Maintenance: Establishes PM schedules, work order planning, post-maintenance testing, and tool/M&TE calibration.
7. QA Elements: Governs Nonconformance Reports (NCRs), CAP entry, stop-work orders, and control of special processes.
8. Training and Qualification: Controls job task analyses, classroom and on-the-job-training curricula, qualification tracking, and requalification cycles.
9. Audits and Assessments: Directs internal quality audits, independent safety assessments, supplier audits, and management self-assessments.
10. Incident Investigations: Regulates corrective action logging, Apparent Cause Analyses, Root Cause Analyses, and reportability evaluations.
11. Records Management: Governs receipt, authentication, indexing, physical/electronic vaulting, and retention schedules for Quality Records.
12. Nuclear Criticality Safety: Controls double-contingency verification, mass/geometry tracking limit compliance, and CAAS alarm response.
13. Fire Safety: Governs hot work permits, fire barrier inspections, transient combustible controls, and pre-fire plan maintenance.
14. Chemical Process Safety: Directs hazardous chemical handling, hazardous material monitoring, ventilation system controls, and chemical isolation checks.
15. Reporting Requirements: Regulates mandatory regulatory transmittals under 10 CFR 70.50, 10 CFR 70.74, 10 CFR Part 21, and annual ISA Summary updates.

Facility administrative procedures are written by each department as necessary to control activities that support process operations, including management measures. Listed below are several areas for which administrative procedures are written:

- A. Operator's authority and responsibility
- B. Activities affecting Facility operation or operating indications
- C. Manipulation of Facility control
- D. Relief of Duties
- E. Equipment control
- F. Master surveillance testing schedule
- G. Control Room Operations
- H. Fire Protection Procedures
- I. Abnormal Events

Facility administrative procedures establish departmental governance, whereas step-by-step operator actions required to prevent or mitigate ISA-identified accident sequences during normal, abnormal, and emergency operations are executed via operational procedures detailed in Section 11.5.3. Administrative procedures and controls are determined as part of the ISA evaluation and may be augmented or changed due to the CAP, lessons learned, or updates to the design or safety basis (communicated via the Configuration Management Program). These procedures and controls shall be evaluated for effectiveness as part of internal audits and assessments. The audits and assessments shall evaluate the administrative procedures and controls to ensure they support the IROFS being reliable and available when needed. The application of these

procedures and controls is supported by the Training Program to ensure that the controls and procedures are up to date and accurately implemented.

Activities involving licensed materials, IROFS, or both shall be conducted in accordance with approved procedures. These procedures are intended to provide a pre-planned method of conducting operations of systems to eliminate errors due to on-the-spot analysis and judgments. These procedures, like administrative procedures, shall be reviewed to ensure that they are aligned with the QAPD and industry best practices, and capture lessons learned. By using industry best practices and incorporating lessons learned, the use of procedures shall eliminate or mitigate the risk associated with these activities.

11.5.3 Operator Action Procedures for Accident Sequences

Emergency and abnormal operating procedures for IROFS shall be developed based on the accident sequences identified in the ISA, including initiating events, event sequences, and the credited operator actions identified as IROFS. Written operator-action procedures are planned to cover the following operational evolutions and activities:

- Standard System Operations: Step-by-step procedures covering system startup, normal operations, enrichment operational transitions, feed/withdrawal line-ups, and planned system shutdown.
- Administrative IROFS Execution: Operator-action procedure steps that execute administrative IROFS (e.g., manual valve isolations, cylinder weight/fill verification checks, enrichment limit validations, and mass tracking validation) formatted with mandatory "Hold Points" or sequential sign-offs to guarantee positive human verification before proceeding.
- Abnormal Operation and Alarm Response: Dedicated procedures prescribing immediate operator actions upon receipt of control room alarms or local annunciators (e.g., UF6 release detection alerts, high-temperature/high-pressure trips, loss of ventilation, or criticality alarm activation) to safely trip or isolate processes prior to exceeding safety margins.
- System Maintenance Support: Operating procedures governing line-breaking, equipment lock-out/tag-out, system evacuation, and purge sequences prior to maintenance.
- Emergency Response Procedures: Action-oriented procedures directing control room and field operators during potential accident sequences to execute immediate equipment trips, place systems into safe trip configurations, and initiate containment or evacuation steps.

Emergency and abnormal operating procedures shall be validated through tabletop exercises or walk-throughs prior to initial use and shall be reviewed and updated following any change to the ISA, Facility design basis, or IROFS that affects the credited operator action. Human Factors Engineering (HFE) principles are applied during procedure development to ensure operator steps are unambiguous and physically executable within credited ISA timeline constraints. The adequacy of emergency and abnormal operating procedures shall be verified as part of the audit and assessment program described in Section 11.6.

11.5.4 Changes to Procedures

Temporary procedures are subject to the same level of review and approval as permanent procedures. The use of temporary procedures is limited to a documented timeframe, and they are issued only when permanent procedures do not exist to direct operations during testing, maintenance, and modifications, or to provide guidance in unusual situations. Temporary changes to procedures shall not involve a change to the ISA and shall not alter the intent of the original procedure.

Temporary procedures may be issued to direct activities that are short-term in nature or not covered by existing permanent procedures. These procedures are developed, reviewed, approved, and controlled in accordance with a structured administrative process to ensure facility safety and regulatory compliance are maintained.

- Conditions for Issuance: Temporary procedures may only be issued under the following specific operational conditions:
 1. To direct non-routine, temporary operational evolutions.
 2. To execute specialized, one-time tests, inspections, or operational commissioning sequences.
 3. To support unique post-maintenance testing or troubleshooting activities on facility hardware.
 4. To provide urgent operational or administrative guidance during a temporary or unusual plant configuration, or to resolve an emergent technical condition while a permanent procedure change is being prepared.
- Review and Approval Requirements: Temporary procedures affecting IROFS shall undergo a level of technical and safety review equivalent to that required for permanent procedures. Prior to authorization and use, a temporary procedure shall:
 1. Receive a multi-disciplinary technical review by qualified personnel from affected organizations (e.g., Operations, Engineering, and EHS&L as appropriate).
 2. Undergo a formal regulatory screening in accordance with the 10 CFR 70.72 facility change process to ensure the temporary activity does not require prior NRC approval or a License Amendment.
 3. Be approved by the designated functional Manager (e.g., Operations Manager or Maintenance Manager) or higher authority matching the approval level of a permanent procedure in that discipline.
- Time Limits and Expiration Constraints: Temporary procedures are strictly time-bounded and cannot be utilized as an open-ended substitute for a permanent procedure.
 1. Each temporary procedure shall explicitly document its expiration criteria on its cover sheet, defined by a specific calendar date or a clearly identifiable operational milestone/event (e.g., "valid only until the completion of testing on Train A").
 2. Temporary procedures shall not remain active for more than a maximum period specified in administrative procedures (typically up to 6 months for long-term test evolutions) without a formal management re-review and re-authorization.
- Extensions and Conversions: If a temporary procedure must be extended past its documented expiration boundary, it shall undergo a complete technical re-review and formal re-approval under the same controls as its initial issuance. If the temporary activity is determined to be a routine or recurring function, the temporary procedure shall be formally processed, formatted, and approved as a permanent facility procedure prior to any subsequent execution.

11.5.5 Maintenance and Testing Procedures

Maintenance of Facility CI is performed in accordance with written procedures, documented instructions, checklists, or drawings appropriate to the circumstances that conform to applicable codes, standards, specifications, and other appropriate criteria. Maintenance procedures shall include steps for a pre-maintenance review and inspection, required stop work notifications, impact to surrounding CI, maintenance personnel requirements, configuration management requirements, testing requirements, documentation requirements, and safe work requirements, as applicable.

Testing conducted on a periodic basis to determine various Facility parameters and to verify the continuing capability of IROFS to meet performance requirements is conducted in accordance with approved written procedures. Periodic test procedures are utilized to perform such testing and are sufficiently detailed that qualified personnel can perform the required functions without direct supervision. When testing is performed on IROFS that are not redundant, compensatory measures shall be established to ensure that the IROFS safety function is maintained until the IROFS is returned to operational status.

Procedures shall include provisions for operations to stop and place the process in a safe condition if a step of a procedure cannot be performed as written. In the event of unexpected incidents (such as an accident, unexpected transient, significant operator error, or equipment malfunction), procedures shall be reviewed to determine if a modification is needed.

Maintenance procedures describe the controls for the procurement and use of replacement components to ensure like-kind replacement and adherence to 10 CFR Part 21 requirements for IROFS.

11.6 AUDITS AND ASSESSMENTS

OE utilizes a tiered approach to verifying compliance with procedures and the effectiveness of management measures. The system of audits and assessments is designed to provide comprehensive program oversight and ensure that IROFS are available and reliable to perform their intended safety functions. Audits, assessments, and their graded application are described in OE's QAPD, Section 18, Audits.

11.6.1 Audit and Assessment Program

A comprehensive audit and assessment Program is established to verify that management measures including facility operations, safety management programs, and QA elements are implemented in accordance with licensing commitments, regulatory requirements, and internal procedures, and to confirm that IROFS remain available and reliable. The program encompasses both internal audits conducted by independent qualified personnel and management self-assessments.

Audits and assessments shall be conducted in the areas of security and safeguards, radiation safety, nuclear criticality safety, chemical safety, fire safety, environmental protection, emergency management, QA, configuration management, maintenance, training and qualification, procedures, incident investigation, and records management.

11.6.2 Audit Guidance, Standards, and Performance Criteria

Audits and assessments are conducted in accordance with approved administrative procedures using pre-planned, structured plans and objective evaluation criteria.

- Governing Baseline Standards: Auditor evaluations are performed against explicit technical and regulatory baselines, including:
 - Title 10 of the Code of Federal Regulations (e.g., 10 CFR 70, 10 CFR 21, 10 CFR 19/20).
 - Approved License Application commitments and the ISA Summary.
 - Approved facility policies, quality program instructions, operating procedures, and technical specifications.

- **Audit Checklists:** Prior to executing an audit, the assigned Lead Auditor prepares a documented Audit Plan and structured Audit Checklists. Checklists incorporate specific performance criteria, physical field verification requirements, sampling sizes, and procedural compliance points to ensure objective and repeatable reviews.
- **Scope of Evaluation:** Auditors evaluate both administrative compliance (document reviews) and operational effectiveness (field walkdowns, direct observation of work, operator interviews, and M&TE/hardware inspections).
- **Reporting and Action Guidance:** Audit findings are categorized by severity (e.g., Nonconformance, Finding, Observation, Recommendation). All identified deficiencies are formally documented in an Audit Report transmitted to senior management and the Company President, and are immediately entered into the CAP for causal evaluation and corrective action tracking.

11.6.3 Audit Frequency

Audits of activities affecting safety and quality are scheduled at defined intervals based on the status, complexity, and safety significance of the activity, not to exceed the maximum frequencies specified below. Internal audits of all key functional and safety areas are conducted on a rolling cycle such that all areas are evaluated at least once within a 24-month period (or annually as mandated for specific technical disciplines). Audit schedules are continuously evaluated and may be accelerated or increased in frequency based on adverse quality trends, major facility changes, or performance issues identified through the CAP.

Program / Functional Area	Maximum Audit Frequency¹
Nuclear Criticality Safety (NCS)	Annual (not to exceed 12 months)
Radiation Safety / Protection	Annual (not to exceed 12 months)
Chemical Process Safety	Annual (not to exceed 12 months)
Fire Safety / Fire Protection	Annual (not to exceed 12 months)
Emergency Management	Annual (not to exceed 12 months)
Environmental Protection	Biennial (not to exceed 24 months)
Configuration Management (CM)	Biennial (not to exceed 24 months)
Maintenance & Functional Testing	Biennial (not to exceed 24 months)
Training and Qualifications	Biennial (not to exceed 24 months)
Procedures Program	Biennial (not to exceed 24 months)
Incident Investigation / CAP	Biennial (not to exceed 24 months)
Records Management & Document Control	Biennial (not to exceed 24 months)
Security & Safeguards	Biennial (not to exceed 24 months)
Quality Assurance Program Elements	Biennial (not to exceed 24 months)

Note 1: Audit Schedules are subject to standard audit schedule grace periods defined in the QAPD.

11.6.4 Independence

Qualified personnel without direct responsibility for the function and area being audited or assessed shall perform the audits and assessments. To ensure objective oversight, independent assessments shall be conducted by offsite groups or individuals not involved in the licensed activity to verify that the health, safety, environmental compliance, and security and safeguards functions are effectively achieving their intended purposes.

The following responsibilities are assigned for each phase of the audit and assessment process:

- The Quality Assurance Manager is responsible for overall management of the audit and assessment program, assignment of lead auditors and assessors, approval of audit and assessment plans and reports, review and approval of corrective action responses, and tracking of open findings to closure.
- The Lead Auditor or Assessor is responsible for preparation of the audit or assessment plan, conduct of the audit or assessment in accordance with approved procedures, preparation of the draft and final audit or assessment report, and communication of findings to the audited or assessed area.
- The audit or assessment team members are responsible for conducting assigned portions of the audit or assessment, gathering objective evidence, and reporting findings to the lead auditor or assessor.
- The manager of the audited or assessed area is responsible for facilitating access to personnel, documents, and records during the audit or assessment; reviewing preliminary findings for factual accuracy; developing corrective action responses for identified findings; and ensuring timely implementation of approved corrective actions.
- The Company President and Senior Management are responsible for receiving and reviewing audit and assessment reports and for ensuring that systemic issues identified through the audit and assessment program receive appropriate organizational attention and resources.

11.6.5 Qualification Requirements for Auditors, Lead Auditors, and Assessors

Personnel performing independent audits and assessments of facility activities affecting management measures and IROFS shall be qualified prior to executing oversight functions. Qualifications are established through a documented program managed by the Quality Assurance organization that details mandatory baseline education, relevant experience, training, and objective evaluation.

Auditor Qualifications: Prospective Auditors shall participate in formal training and practical orientations that encompass facility safety design bases, the ISA framework, applicable parts of 10 CFR Part 70, the Quality Assurance Program Description (QAPD), and audit performance methodologies (including planning, executing, reporting, and tracking corrective actions). Competence is verified by the QA organization through written examination or documented technical performance metrics.

Lead Auditor Qualifications: Prospective Lead Auditors must achieve a minimum proficiency score evaluated on a defined point-scoring system that credits:

- Education: Technical, engineering, or baseline scientific academic credentials.
- Experience: Documented nuclear, industrial, or technical engineering quality experience, with a portion of that experience concentrated in nuclear quality assurance or high-consequence safety oversight fields.

- **Audit Participation:** Documented active participation in formal nuclear or safety program audits within a defined period prior to certification.
- **Examination:** Successful completion of a comprehensive practical examination (written, oral, or performance-based) testing the candidate's operational knowledge of codes, standards, audit techniques, and facility licensing commitments.

Oversight Assessors: Technical Subject Matter Experts (SMEs) or Independent Assessors who participate in audit equivalents (such as technical assessments or programmatic surveillances) shall be selected based on documented professional experience and demonstrated technical expertise in the targeted safety or engineering discipline being evaluated. When performing independent assessments or technical oversight of the Quality Assurance organization itself, the plan and final reports are routed directly to the Company President to ensure uncompromised organizational independence and objective oversight.

Records and Maintenance: Lead Auditor certifications are formally documented, signed by the Quality Assurance Manager, and maintained as permanent, auditable facility records. To maintain active certification, Lead Auditors are evaluated annually by QA management to confirm ongoing proficiency via active audit participation, review of current regulatory standards, or management safety evaluations. Certified personnel who fail to maintain annual proficiency metrics are placed in an inactive status and must satisfy a documented re-qualification plan prior to performing subsequent IROFS independent oversight.

11.6.6 Results and Corrective Action

Audit and assessment results shall be documented and reported to the Company President, senior management, and relevant safety committees. The results shall be used to generate lessons learned that are communicated to the workforce to drive future improvements. Findings and recommendations shall be tracked, and corrective actions shall be implemented in accordance with the CAP to rectify deficiencies and mitigate or eliminate recurrence.

11.6.7 Graded Approach to Oversight

Audit and assessment activities are applied in a graded manner based on safety significance.

Audit and assessment frequency shall be commensurate with the safety significance of the activities being assessed. QL-1 IROFS and high-risk activities shall be subject to more frequent oversight than equivalent QL-2 IROFS, which may be subject to reduced audit and assessment frequencies. Assessments associated with graded IROFS may be performed by personnel knowledgeable of the specific trade or skill involved in the activity in lieu of personnel with specific training in the conduct of formal assessments.

11.6.8 Self-Assessment Program

Line management is responsible for conducting ongoing self-assessments of activities under their supervision to verify that work is being performed in accordance with approved procedures and that management measures are achieving their intended purpose. Self-assessments shall be conducted at a frequency commensurate with the safety significance of the activity and the results of previous assessments. Self-assessment results shall be documented and reported to senior management. Deficiencies identified through self-assessments shall be entered into the CAP in accordance with Section 11.7. Self-assessment results shall be considered during the planning of formal audits and independent assessments to focus oversight resources on areas of greatest safety significance.

11.6.9 Audit and Assessment Process

Audits and assessments shall be conducted in accordance with the following process:

11.6.9.1 Planning Phase

The Quality Assurance Manager or designee shall assign a lead auditor or assessor and, where necessary, a team of qualified personnel to conduct the audit or assessment. The lead auditor or assessor shall prepare an audit or assessment plan that identifies the scope, objectives, schedule, applicable requirements, and personnel to be interviewed. The audit or assessment plan shall be approved by the Quality Assurance Manager prior to initiation. The area or function to be audited or assessed shall be notified of the planned activity in advance in accordance with approved procedures.

11.6.9.2 Conduct Phase

Audits and assessments shall be conducted using approved checklists, procedures, or criteria documents developed from applicable regulatory requirements, license commitments, and program procedures. Evidence shall be gathered through document review, record review, observation of activities, and interviews with personnel. The lead auditor or assessor shall maintain an objective and factual basis for all findings. Preliminary findings shall be discussed with the cognizant supervisor or manager of the area being audited or assessed prior to the exit meeting to ensure factual accuracy.

11.6.9.3 Reporting Phase

The lead auditor or assessor shall prepare a written audit or assessment report documenting the scope, objectives, methodology, findings, observations, and conclusions. The report shall identify each finding with a reference to the applicable requirement or commitment that was not met. Audit and assessment reports shall be issued within a timeframe established in approved procedures and shall be approved by the Quality Assurance Manager. Reports shall be distributed to the Company President, senior management, the manager of the audited or assessed area, and relevant safety committees, as described in Section 11.6.6.

11.6.9.4 Corrective Action Phase

Each finding identified in an audit or assessment report shall be entered into the CAP in accordance with the Corrective Action and Incident Investigations procedure. The manager of the audited or assessed area shall be responsible for developing a corrective action response that identifies the root cause, proposed corrective actions, and the scheduled completion date. The Quality Assurance Manager shall review and approve the corrective action response for adequacy. Corrective actions shall be tracked to completion in the CAP.

11.6.9.5 Closure Phase

The Quality Assurance Manager or designee shall verify that corrective actions have been effectively implemented prior to closing audit or assessment findings. Objective evidence of corrective action implementation shall be documented in the CAP. Audits or assessments with open findings shall remain open in the tracking system until all findings are closed. Overdue corrective actions shall be escalated to senior management in accordance with CAP procedures.

11.6.9.6 Records

Completed audit and assessment packages, including the audit plan, checklists, working papers, the final report, and corrective action responses, shall be maintained as quality assurance records in accordance with Section 11.8 and the records retention requirements of 10 CFR Part 70.

11.7 INCIDENT INVESTIGATIONS AND CORRECTIVE ACTION PROGRAM

The incident investigation process is an accessible mechanism available for use by any person at the Facility for reporting deficiencies, abnormal events and potentially unsafe conditions or activities. Abnormal events that potentially threaten or lessen the effectiveness of health, safety or environmental protection shall be identified and reported to and investigated by the EHS&L Manager. The investigation shall determine the specific or generic root cause(s), generic implications, and risk significance of the event to facilitate the application of lessons learned. Each event shall be considered in terms of its requirements for reporting in accordance with regulations and shall be evaluated to determine the level of investigation required. Potential defects and failures to comply shall be evaluated in accordance with 10 CFR Part 21 to determine whether a substantial safety hazard exists or potentially exists. These investigations, including the process of incident identification, root cause analysis, environmental protection analysis, recording, reporting, and follow-up, are governed by and performed in accordance with the CAP procedures. Radiological, criticality, hazardous chemical, and industrial safety requirements are addressed. Guidance for classifying occurrences is contained in CAP procedures, including examples of threshold off-normal occurrences. The depth of the investigation depends upon the severity of the classified incident in terms of the levels of uranium released or the degree of potential for exposure of workers, the public, or the environment. Investigations include a comparison of the event sequence with accident sequences already considered in the ISA. The ISA summary shall be modified in accordance with approved procedures to include evaluation of the risk associated with accidents of the type actually experienced to ensure safety significance is correctly characterized. Lessons learned from these investigations shall be proactively disseminated to relevant Facility personnel through the Training Program, updated procedures, or safety bulletins to prevent recurrence and enhance the overall safety culture.

The level of investigation required for each incident is determined based on the safety significance of the involved IROFS and the severity of the event. Events involving QL-1 IROFS or events with potential consequences approaching the performance requirements of 10 CFR 70.61 shall require a formal root cause analysis conducted by a cross-functional team. Events involving QL-2 IROFS shall be evaluated by the Quality Assurance Manager to determine whether a formal root cause analysis or a cause evaluation is appropriate based on the risk significance of the event. Events not involving IROFS or events with negligible safety significance shall require documentation in the CAP and a cause evaluation sufficient to prevent recurrence. The criteria for classifying events and determining the level of investigation required are contained in the CAP procedures.

The discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.) or incidents involving licensed material shall be evaluated immediately (as soon as practical) by the EHS&L Manager, reporting individual, and the relevant stakeholders. This immediate evaluation shall ensure that "1 hour" or "4 hour" notifications are made within the required timeline. Other issues shall be evaluated to ensure compliance with applicable notification requirements. If a notification is deemed necessary, the EHS&L Manager shall provide notification to the NRC within the required timeline.

The OE QAPD identifies the responsibilities and establishes the authority for those individuals involved in quality activities to identify any condition adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective materials and equipment, and nonconformances. These individuals shall identify and document conditions adverse to quality, analyze and determine how the conditions can be corrected or resolved, and take such steps as necessary to implement corrective actions in accordance with documented procedures. The rigor of the incident investigation process, including the size and composition of the investigation team, is commensurate with the risk significance of the incident and the safety significance of the involved IROFS.

Regularly scheduled audits and assessments shall be conducted to ensure that the corrective actions needed are identified. OE employees shall have the authority and responsibility to initiate corrective actions if they discover deficiencies. Procedures shall be established for identifying, reporting, resolving, documenting, and analyzing conditions adverse to quality. Reports of conditions adverse to quality shall be analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends shall be reported to senior management in accordance with CAP procedures.

OE maintains a trending program as part of the CAP to identify recurring quality issues, adverse trends in IROFS performance, and programmatic weaknesses that may not be apparent from individual events. Trend codes are assigned to closed corrective action records to categorize the type of condition and the affected program area. Trend data shall be reviewed at least quarterly by the Quality Assurance Manager and reported to senior management. When a trend indicates a potential adverse condition, a cause evaluation shall be initiated, and corrective actions shall be implemented to address the programmatic root cause. Trending results shall be considered during the planning of audits and assessments and during the periodic review of management measures described in Section 11.1.

OE personnel have the authority and the obligation to stop work when an activity presents an immediate threat to the safety of personnel, the public, or the environment, or when a condition is identified that could compromise the safety function of an IROFS. Stop work authority applies to all OE personnel and to contractor personnel performing work on IROFS. When work is stopped, the condition shall be immediately reported to the relevant supervisor and the EHS&L Manager and documented in the CAP. Work shall not resume until the condition has been evaluated and resolved in accordance with approved procedures and authorization to resume has been provided by the appropriate level of management.

Conditions adverse to quality or failure of an IROFS or CI, the cause of the conditions, and the corrective action taken to mitigate repetition shall be documented, recorded, and reported to management for review and assessment in accordance with CAP procedures. Documentation related to abnormal events shall be maintained for the life of the Facility.

The QAPD, Section 16, Corrective Action, provides additional details regarding the CAP requirements.

11.8 RECORDS MANAGEMENT

The Records Management program is established to control the generation, authentication, indexing, receipt, physical and electronic storage, protection, retrieval, and final disposition of records. The program provides documented evidence that CI and activities affecting safety conform to specified technical, design, quality, licensing, and regulatory requirements.

QAPD, Section 17, Quality Assurance Records, provides additional details regarding records management requirements.

11.8.1 Records Categorization and Retention

Records are categorized upon generation by relative safety importance and retention requirements in accordance with approved administrative procedures:

- Life of Facility Records: Maintained for the life of the Facility
- Nonpermanent Records: Retained for specific periods defined in implementing procedures, typically 3 to 10 years).

Records shall be retained to ensure conformance with 10 CFR Part 70. The table below highlights the minimum retention period for each type of document. OE shall ensure that these records retention requirements meet or exceed these requirements. In addition to being retained, records shall be legible, easily traceable, categorized by safety importance, and linked back to specific IROFS.

Record Type	Minimum Retention Period
IROFS	Life of the Facility
Safety Program Records (ISA and IROFS failures etc.)	Life of the Facility
Decommissioning	Until license termination
Material Control and Accounting Changes	5 years after each change
Visitor Registers and Access Logs	3 years after last entry
Accidental Criticality Reports	Until license termination
Alarm and Security Incident Logs	3 years after each change
Waste Disposal Records	Until license termination
Superseded Security Procedures	3 years after each change
Effluent Monitoring Report	Until license termination

11.8.2 Handling and Storage of Contaminated and Classified Records

Specific administrative and physical controls govern records with specialized handling or security constraints:

- Contaminated Records: Physical records originating from radiologically controlled areas or chemical processing zones are screened prior to receipt processing. Contaminated documents are decontaminated or duplicated (e.g., via digital scanning or photocopying) by Radiological Protection personnel. The clean duplicate is authenticated and vaulted as the permanent record, while the contaminated original is dispositioned as radiological waste.
- Classified and Safeguards Information (SGI): Records containing Classified National Security Information (NSI), Restricted Data (RD), or Safeguards Information are processed, stored, and dispositioned in strict accordance with the Security Plan, 10 CFR Part 95, and 10 CFR 73.21. Storage is restricted to approved, GSA-rated security containers or classified computing environments located within secure, access-controlled facility areas.

11.8.3 Physical Storage Facilities and Environmental Controls

Records are protected against tampering, theft, physical damage, deterioration, fire, water, and environmental extremes during lifetime storage. Electronic records are stored in enterprise software systems featuring access-control security matrices, automated audit logging, write-once-read-many storage architecture, and daily offsite encrypted backup routines.

11.8.4 Program Effectiveness Evaluations and Deficiency Correction

The effectiveness of the Records Management system is verified through structured administrative mechanisms:

Periodic Self-Assessments and Audits: Internal audits and management self-assessments are conducted at least biennially to evaluate records legibility, index accuracy, retrieval speed, vault environmental logs, and system adherence.

Deficiency Identification and CAP Integration: Any identified recordkeeping deficiency (e.g., missing authentication signatures, unreadable attachments, or indexing errors) is entered into the CAP. The issue is tracked, evaluated for systemic root causes, corrected, and verified prior to closure.

11.9 OTHER QA ELEMENTS

The OE QAPD is structured around 18 QA elements that are consistent with the criteria of ANSI/ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications, but is not committed to full NQA-1 compliance. The QAPD establishes QA requirements commensurate with the specific regulatory framework of 10 CFR Part 70 and the performance-based approach of NUREG-1520, which allows for graded application of quality requirements based on safety significance rather than the uniform application required by NQA-1. Where NQA-1 criteria are applied, they are applied in a graded manner consistent with the quality level classification of the affected IROFS. OE has determined that this approach provides reasonable assurance that IROFS are designed, procured, constructed, operated, and maintained across the Facility life cycle in a manner that protects the health and safety of workers, the public, and the environment in accordance with the performance requirements of 10 CFR 70.61.

The QAPD establishes 18 QA elements which are applied to management measures, IROFS, and other designated CI and personnel activities in a graded manner. The selection of quality levels is commensurate with the risk involved and specifically parallels the risk-informed grading established for maintenance, training, and surveillance to ensure a consistent, integrated safety approach across the Facility life cycle. The QA elements described below and in the QAPD are applied to provide reasonable assurance that IROFS are designed, procured, constructed, operated, and maintained in accordance with the performance requirements of 10 CFR 70.61 for the protection of workers, the public, and the environment.

11.9.1 Organization

The facility organization structure establishes clear lines of authority, functional responsibilities, and reporting channels for personnel performing activities affecting quality and safety. The Quality Assurance (QA) organization is structured to ensure that oversight and verification functions remain completely independent of direct operational, schedule, and cost considerations.

The QA organization operates with complete organizational autonomy. The QA Manager reports directly to senior executive management (the Company President) on all quality program matters.

This administrative reporting alignment guarantees that QA personnel are free from direct line pressure, financial constraints, or scheduling conflicts associated with production targets, construction milestones, or operational throughput.

11.9.1.1 Stop Work Authority

All personnel have the right and ability to stop work. QA personnel have explicit, legally protected organizational authority to execute quality controls across all project phases:

- Stop Work Authority: The QA Manager and designated Quality Assurance/Quality Control (QC) personnel possess the direct authority to issue formal Stop Work Orders whenever an activity violates quality requirements, threatens hardware integrity, or compromises the availability or reliability of IROFS. Work cannot resume until the nonconforming condition is resolved and formally closed out by the QA organization.
- Control of Nonconforming Materials: QA/QC inspectors possess the authority to apply physical "HOLD" or "REJECTED" tags and segregate nonconforming equipment, components, or raw materials, preventing their inadvertent installation, processing, or operational use.

11.9.1.2 Organizational Freedom and Executive Access

QA personnel are granted unrestricted access to all facility work areas, construction sites, technical documentation, operational records, and supplier manufacturing facilities to perform audits, surveillances, and inspections. The QA Manager maintains direct, unhindered access to all levels of facility management, up to and including the Company President, to escalate quality concerns, adverse trends, or unresolved safety issues.

11.9.1.3 Functional Separation of Verification Activities

To preserve objective verification, individuals performing quality verification functions (such as audits, receipt inspections, source surveillances, receipt testing verification, and post-maintenance testing sign-offs) are organizationally independent of the individuals or groups responsible for performing, directly directing, or managing the specific work activity being evaluated. Verification personnel do not evaluate their own work or work for which they had direct operational responsibility.

11.9.1.4 Communication and Reporting Lines

Formal lines of communication are established between the QA organization, Engineering, Operations, Maintenance, Procurement, and Licensing:

- Quality concerns identified during work execution are documented and communicated via approved administrative procedures (e.g., Nonconformance Reports and Condition Reports).
- The QA Manager periodically compiles independent quality metrics, CAP trends, and audit summaries for executive management review, providing reasonable assurance that the Quality Assurance Program remains effective and compliant with regulatory commitments.

11.9.2 Quality Assurance Program

The Quality Assurance Program is addressed throughout this Chapter.

11.9.3 Design Control

This Quality Assurance element is implemented to ensure that technical requirements, safety baselines, and 10 CFR Part 70 licensing commitments are correctly translated into design outputs, specifications, drawings, procedures, and instructions.

Description and Implementation: Primary design control commitments are described in Section 11.2.2 (Design Requirements) and Section 11.2.4 (Change Control).

Function: Design control measures ensure that changes to facility CI and personnel activities undergo technical and interdisciplinary reviews prior to implementation. This guarantees that design modifications do not degrade the availability or reliability of IROFS or alter the ISA baseline without proper 10 CFR 70.72 regulatory screening.

11.9.4 Procurement Document Control

In addition to the baseline procurement configuration controls described in Section 11.2.7 (Procurement Controls) and maintenance replacement parts controls in Section 11.3.5.7 (Other QA Elements / Procurement & Receipt), measures are established to ensure that applicable regulatory requirements, technical design bases, quality program criteria, and documentation expectations are explicitly incorporated or referenced in procurement documents for IROFS.

Procurement document control measures are implemented through approved administrative procedures and ensure that:

- Technical and Quality Flow-Down: Procurement packages specify technical specifications, drawings, codes, standards, inspection/test requirements, and supplier QA program requirements commensurate with the safety classification of the CI or service.
- 10 CFR Part 21 Applicability: Procurement documents for applicable IROFS explicitly invoke the reporting requirements of 10 CFR Part 21 (Reporting of Defects and Noncompliance), legally binding suppliers to notify OE of potential defects affecting IROFS reliability.
- Access and Audit Rights: Procurement documents mandate supplier provisions for right-of-access to supplier and subcontractor facilities, records, and activities for OE source inspections, surveillances, and audits.
- Documentation Submittals: Suppliers are required to submit objective evidence of quality (e.g., Certified Material Test Reports [CMTRs], Certificates of Conformance [CoCs], special process certifications, and test data) for review and acceptance prior to item installation or commercial use.
- Interdisciplinary Review and Approval: Procurement packages undergo documented technical and QA reviews prior to issuance to verify that quality and engineering requirements are accurately specified and complete. Changes to procurement documents undergo the same level of review and approval as the original document

11.9.5 Instructions, Procedures, and Drawings

This QA element is fully detailed in Section 11.5.

11.9.6 Document Control

This QA element is fully detailed in Section 11.2 and 11.5.

11.9.7 Control of Purchased Items and Services

In alignment with the Configuration Management procurement interfaces in Section 11.2.7 and maintenance receipt processes in Section 11.3.5.7, the control of purchased items and services ensures that items and services credited as, or supporting, IROFS conform to procurement documentation requirements prior to being placed into service.

These controls include the following core elements:

- **Supplier Evaluation and Selection:** Suppliers of IROFS are evaluated and qualified prior to contract award or work initiation. Qualified suppliers are placed on OE's Approved Supplier List, which is maintained and updated under independent QA oversight based on periodic audits, source evaluations, and performance trending.
- **Acceptance of Purchased Items:** Purchased items are accepted through one or a combination of the following methods:
 - **Certificate of Conformance (CoC):** Evaluated against minimum verification requirements and traceable to the specific shipment and purchase order.
 - **Source Verification / Source Inspection:** Conducted at the supplier's facility during manufacturing, testing, or packaging.
 - **Receiving Inspection:** Performed upon arrival at the facility using approved checklists to verify physical condition, dimensions, marking/tagging, documentation completeness, and freedom from damage or suspect/counterfeit items (S/CI).
 - **Post-Installation Testing:** Conducted after installation under controlled test procedures before declaring the item operable.
 - **Commercial Grade Dedication (CGD):** When QL-1 or QL-2 items or services are sourced from commercial suppliers not on the nuclear ASL (Procurement Level 3 crossover), a formal Commercial Grade Dedication process is executed in accordance with EPRI NP-5652. Qualified engineers develop a documented Dedication Plan specifying critical characteristics, which are independently verified through special tests, inspections, supplier surveys, or performance evaluations prior to safety-basis reliance.
- **Acceptance of Services:** Supplier-provided services that impact IROFS (e.g., engineering analysis, auditing, calibration, non-destructive examination [NDE], or specialized maintenance) are accepted through documented reviews of technical submittals, vendor audits, and direct verification of personnel qualifications.

11.9.8 Identification and Control of Items

Description and Implementation: Controls are established to identify and track IROFS materials, parts, and components from initial receipt through fabrication, installation, and use. Physical identification is used wherever practical, and traceability is maintained through recorded documentation.

Function: This prevents the incorrect use or inadvertent installation of unverified, incorrect, or defective CI into the facility, ensuring the physical configuration of the facility remains in absolute agreement with the design basis.

11.9.9 Control of Special Processes

Description and Implementation: Special processes affecting IROFS, such as welding, non-destructive examination (NDE), and heat treating, are controlled and performed by qualified personnel using approved procedures in accordance with applicable codes and standards.

Function: Because the quality of special processes is highly dependent on the skill of the operator or the control of process parameters, this element ensures that structural and pressure-retaining boundaries supporting IROFS maintain their design integrity and do not fail prematurely under accident conditions.

11.9.10 Inspection

Description and Implementation: Independent inspections are planned and executed to verify that activities affecting IROFS conform to documented instructions, procedures, and drawings. Inspections are performed by qualified individuals other than those who performed the work being inspected.

Function: Inspection provides physical verification of IROFS integrity and installation conformity, identifying construction or maintenance deficiencies before the system is operational.

11.9.11 Test Control

This QA element is addressed in Section 11.3.

11.9.12 Control of Measuring and Test Equipment

This QA element is addressed in Section 11.3.

11.9.13 Handling, Storage, and Shipping

Description and Implementation: Procedures control the cleaning, packaging, handling, shipping, and preservation of IROFS to prevent damage, loss, or degradation caused by environmental conditions like moisture or extreme temperatures.

Function: This ensures that sensitive IROFS, such as electronic interlocks or chemical detectors, do not experience environmental degradation prior to installation, maintaining the components in a pristine state of operational readiness.

11.9.14 Inspection, Test, and Operating status

Description and Implementation: Measures are established to clearly indicate the status of inspections and tests performed on IROFS, using indicators such as tags, labels, markings, or log sheets. These controls prevent the bypass of required inspections or the accidental operation of unverified or failed IROFS.

Function: It ensures that personnel are immediately aware of whether a CI is fully functional, undergoing maintenance, or failed, eliminating human error associated with operating IROFS that are not currently capable of performing their intended safety functions.

11.9.15 Control of Nonconforming Items

This QA element is addressed in Section 11.7.

11.9.16 Corrective Action

This QA element is addressed in Section 11.7.

11.9.17 Quality Assurance Records

This QA element is addressed in Section 11.8.

11.9.18 Audits

This QA element is addressed in Section 11.6.

11.9.19 QA Element Table

QAPD Section Number	Section Title	NUREG-1520 / 10 CFR Part 70 Management Measure	Primary Purpose in 10 CFR Part 70 Context
1	Organization	11.9.1 (Organization) / Chapter 2 (Org)	Independence of QA from Production
2	Quality Assurance Program	11.0 (Management Measures) and 11.1 Graded Approach	Establishes the Graded Approach (QL-1, 2, 3)
3	Design Control	11.2 (Configuration Management)	Maintains the Design Basis and 10 CFR 70.72 controls
4	Procurement Document Control	11.2 (Configuration Management) / 11.9 (Other QA)	Flow down of IROFS & 10 CFR Part 21 requirements
5	Instructions, Procedures, and Drawings	11.5 (Procedures)	Ensuring work is performed via approved methods
6	Document Control	11.2 (Configuration Management) / 11.5 (Procedures)	Controlling revisions of the design and safety basis
7	Control of Purchased Items and Services	11.3 (Maintenance) / 11.9 (Other QA)	Acceptance of Items
8	Identification and Control of Items	11.2 (Configuration Management) / 11.3 (Maintenance)	Traceability of IROFS from receipt to install
9	Control of Special Processes	11.3 (Maintenance)	Qualification of IROFS welding/NDE
10	Inspection	11.3 (Maintenance)	Verification of IROFS physical condition
11	Test Control	11.3 (Maintenance)	Functional Testing post- maintenance/install
12	Control of Measuring and Test Equipment	11.3 (Maintenance)	Accuracy of IROFS calibration & monitoring

QAPD Section Number	Section Title	NUREG-1520 / 10 CFR Part 70 Management Measure	Primary Purpose in 10 CFR Part 70 Context
13	Handling, Storage, and Shipping	11.3 (Maintenance)	Preserving IROFS reliability before use
14	Inspection, Test, and Operating status	11.3 (Maintenance)	Preventing use of unverified/failed IROFS
15	Control of Nonconforming Items	11.7 (Incident Investigation/CAP)	Controlling IROFS that fail to meet spec
16	Corrective Action	11.7 (Incident Investigation/CAP)	10 CFR Part 21 Evaluations & Root Cause Evaluations
17	Quality Assurance Records	11.8 (Records Management)	Documentary evidence of IROFS reliability
18	Audits	11.6 (Audits & Assessments)	Periodic verification of program effectiveness