

Orano LA Audit Questions
July 14, 2026

Management Measures

MM-1: Construction Phase Organizational Structure

Regulatory basis

10 CFR 70.22(a)(6) requires the technical qualifications, including training and experience of the applicant and members of its staff to engage in the proposed activities in accordance with the regulations in 10 CFR 70.

10 CFR 70.23(a)(2) requires the applicant is qualified by reason of training and experience to use the material for the purpose requested in accordance with the regulations in 10 CFR 70.

10 CFR 70.62(d) requires that each applicant or licensee establish management measures to ensure compliance with the performance requirements of Section 70.61.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 2.4.3, acceptance criteria #A1

A/C #A1 states the applicant should identify and functionally describe the specific organizational groups that are responsible for managing the design, construction, operations, and modifications of the facility or licensed activities. The application also includes organizational charts.

Issue description

In Section 2.1.3 "Transition from EPC phase to Operations," the LA provides a general statement that the applicant is responsible for the full lifecycle of the facility, including design, quality assurance, construction, testing, startup, operation, and decommissioning. As construction progresses, organizational focus will gradually shift from building and commissioning systems to operating the facility. Once a system is built, it will undergo acceptance testing according to procedures. However, the LA does not address how construction will be controlled.

Request

Revise the LA to include a clear description of the construction-phase organizational structure. This should identify all groups involved in the construction phase. It should also state whether a Construction Director exists. Finally, it should explain the roles and responsibilities for oversight, control, coordination, and communication between the applicant, the vendor, and the contractors during the transition from design to construction and then into operation.

Orano Response:

Impacted Sections:

Section 2.1.2 Engineering, Procurement and Construction Phase Organization

Orano Response:

The LA has been revised to clarify that OE does not utilize a standalone Construction Director; instead, ultimate authority for construction phase activities rests with the Project Director.

Furthermore, descriptions have been added to Section 2.1.2 to explicitly define the roles of the EPC Manager and Project Managers in managing oversight, control, and communication between OE, the primary vendor, and contractors. Section 2.1.2 has also been updated to address the organizational controls governing the transition from design to construction, while Section 2.1.3 continues to detail the transition from construction to operations.

As stated in 2.1.2, during the construction phase, “the Project Director is responsible for managing the engineering, construction, and procurement activities.” Section 2.1.2 also includes responsibilities of the EHS&L and QA Manager.

MM-2: Configuration Management – A/C 3

Regulatory basis

10 CFR 70.4 defines Configuration Management (CM) as a management measure that provides oversight and control of design information, safety information, and records of modifications that might impact the ability of Items Relied on for Safety (IROFS) to perform their functions when needed.

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

10 CFR 70.65(b)(1) requires submitting an Integrated Safety Analysis (ISA) summary with the license application with a description of the factors that could affect safety.

10 CFR 70.65(b)(4) requires that the ISA summary describe the IROFS, including the management measures applied.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.1, acceptance criteria #3

A/C #3 states that the ISA summary clearly defines the IROFS to be listed under CM along with the assignment of any grades or quality levels. The applicant should indicate in the ISA summary the CM attributes that will be applied to a particular IROFS. However, in the ISA summary, this indication may consist of only an index or category designation.

Issue description

In the introduction section of Chapter 11 “Management Measures”, the LA provides a description of different quality level (QLs) QL-1 and QL-2 IROFS. In Section 11.1 “Configuration Management” the LA describes the Configuration Management program, including how design and safety basis information is established, maintained and documented. Table 3-1 “Items Relied on for Safety” in the ISA summary provides the Quality Levels for each IROFS, as required. However, neither the ISA Summary nor Chapter 11 of the LA identifies which CM attributes or categorization apply to each IROFS.

Request

Revise the ISA summary or include in Chapter 11 of LA identification of all IROFS assigned to specific MM elements and QLs which includes CM, maintenance, training and qualification, procedures, audits and assessments, incident investigation, records management, and Other QA elements. This could be in the form of a Table in either ISA Summary or in Chapter 11.

Orano Response:

Impacted Sections: Chapter 11 Section preceding 11.1 was updated to have its own section (11.1)

Orano Response:

ISAS Section 3 Table 3-1 shows the Quality Level of the IROFS. The new Section 11.1 outlines how MM and other QA elements are applied to each Quality Level. The QAPD includes a table showing this in further detail. In general, all MM and QA elements are applicable.

MM-3: Temporary Changes to Procedures

Regulatory basis

10 CFR 70.22(a)(8) requires that the application contain procedures to protect public health and safety.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.4, acceptance criteria #10

A/C #10 states that the applicant includes a formal requirement governing the use of temporary procedures. Temporary procedures may be issued only when permanent procedures do not exist to (1) direct operations during testing, maintenance, and modifications, (2) provide guidance in unusual situations not within the scope of permanent procedures, and (3) provide assurance of orderly and uniform operations for short periods when the facility, system, or component is performing in a manner not covered by permanent procedures. The discussion establishes a timeframe for use of the temporary procedure and sets the same level of review and approval as for permanent procedures.

Issue description

In Section 11.4.3 “Changes to Procedures,” of LA, the applicant states that temporary procedures are subject to the same level of review and approval as permanent procedures, are issued only when permanent procedures do not exist, and are limited to a documented timeframe. However, the LA does not fully address all aspects of the acceptance criteria. Specifically, the use of temporary procedures or temporary changes to a procedure to ensure orderly and uniform operations for short-term abnormal conditions, and a complete explanation of conditions under which temporary procedures may be used across all three acceptance criteria scenarios. The LA does not address temporary procedure to provide assurance of orderly and uniform operations for periods of short duration when the facility, system, or a component is performing in a manner not covered by existing permanent procedures or have been modified or extended in such a manner that portions of existing procedures do not apply.

Request

Revise the LA to fully describe the facility’s controls governing temporary procedures, including all conditions under which temporary procedures may be issued, consistent with NUREG-1520 acceptance criteria.

Orano Response:

Impacted Sections: Previously Section 11.4.3 (Now Section 11.5.4)

Orano Response:

The LA has been revised to incorporate a comprehensive, explicit description of the facility’s administrative controls governing temporary procedures. The updated text formally establishes the precise boundary conditions under which temporary procedures may be developed and issued, outlines the mandatory review and approval matrix (including mandatory 10 CFR 70.72 regulatory screenings), defines strict expiration constraints, and outlines the programmatic requirements for period extension or permanent conversion. This provides clear top-tier licensing commitments that ensure temporary work activities do not compromise the availability or reliability of IROFS.

MM-4: Auditor and Lead Auditor Qualifications

Regulatory basis

10 CFR 70.4 defines CM as a management measure that provides oversight and control of design information, safety information, and records of modifications that might impact the ability of IROFS to perform their functions when needed.

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520, Rev. 2, Section 11.4.3.8 states that the license application must describe the QA elements implemented as management measures, including audits.

Section 11.4.3.5 acceptance criteria #6

A/C #6 states that qualified personnel without direct responsibility for the function and area being audited or assessed will perform the audits and assessments.

Issue description

In Section 11.5 “Audits and Assessments” of the LA, the applicant explains that the audit or assessment team members are responsible for conducting assigned portions of the audit or assessment and reporting findings to the lead auditor or assessor. However, the application does not specify the minimum qualifications, training, experience, or competency requirements for individuals who serve as auditors and lead auditors.

Request

Provide clarification of how the applicant will ensure that auditors and lead auditors meet the defined qualification requirements through a structured program that establishes the necessary education, relevant experience, and training for these roles. Or revise the LA to include program or procedures for qualification requirements for an auditor and lead auditors including assessors.

Orano Response:

Impacted Sections: Previously Section 11.5 (Updated to Section 11.6)

Orano Response:

The LA has been revised to incorporate a summary of the structured program utilized to qualify auditors, Lead Auditors, and independent assessors. The updated text details the mandatory requirements for baseline education, technical experience, formal training, and testing. It also establishes the core qualification metrics. It includes the industry-standard scoring system, practical examination criteria, and annual maintenance evaluations. These provisions provide upper-tier regulatory commitments within the body of the LA itself, ensuring that personnel performing oversight have the required objective competence to verify that IROFS remain available and reliable.

MM-5: Other QA Elements Described in LA

Regulatory basis

10 CFR 70.4 defines CM as a management measure that provides oversight and control of design information, safety information, and records of modifications that might impact the ability of IROFS to perform their functions when needed.

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520, Rev. 2, Section 11.4.3.8 requires applicants to describe the “Other QA elements,” that constitute part of the management measures program.

Issue description

In Chapter 11 of the LA, the “Other QA elements” section does not provide a brief description of each required QA element listed in NUREG-1520, Rev. 2, Section 11.4.3.8.

Instead, the applicant only references the Quality Assurance Program Description (QAPD) but does not provide a brief description of each of the QA elements within the LA itself, nor does it clearly identify how each QA element functions as a management measure support the availability and reliability of IROFS.

Request

Provide a brief description of each QA element required under NUREG-1520, Rev. 2, Section 11.4.3.8. For each QA element, describe how it is implemented at the facility and how it functions as a management measure to ensure IROFS remain available and reliable.

Because the acceptance criteria require that the LA itself contain descriptions of these elements, even if further detail resides in the QAPD; the current level of detail in Chapter 11 is not sufficient to demonstrate compliance.

Orano Response:

Impacted Sections: Previous Section 11.8 (Now 11.9)

Orano Response:

LA Chapter 11, Section 11.9 (Other QA Elements) has been expanded and restructured to descriptions for all supplemental QA elements required by NUREG-1520, Rev. 2, Section 11.4.3.8.

To maintain strict cross-reference integrity and eliminate redundancy within the licensing basis, primary management measures and QAPD elements including: Design Control, Instructions/Procedures/Drawings, Test Control, Control of Measuring and Test Equipment, Corrective Action, Records Management, and Audits are fully described within their standalone, dedicated headings throughout the body of Chapter 11.

For the remaining supplementary QA elements that do not map directly to a primary Chapter 11 management measure section, Section 11.9 has been expanded to provide standalone, performance-based descriptions detailing how each element is operationalized and how it functions to ensure IROFS remain available and reliable.

Orano LA Draft RAI / Audit Questions
July 17, 2026

Management Measures

RAI – MM 1 Document Control

Regulatory Requirements

10 CFR 70.4 defines Configuration Management (CM) as a management measure that provides oversight and control of design information, safety information, and records of modifications that might impact the ability of Items Relied on for Safety (IROFS) to perform their functions when needed.

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.1, acceptance criteria #6 and #7

- A/C #6: The application must describe an acceptable method to create and control documents relied on for safety, including design requirements, ISA documentation, as-built drawings, specifications, IROFS procedures, training, QA, maintenance, audits/assessments, emergency procedures, emergency plans, system modification documents, and other CM-controlled documents.
- A/C #7: The application must describe how CM maintains strict consistency among design requirements, physical configuration, and facility documentation.

Description of the Issue

In Section 11.1.3 “Document Control,” the LA provides only a high-level description stating that procedures exist to control the preparation, review, approval, and issuance of documents. Section 11.1.3 also references the QAPD Section 6 for additional detail. The QAPD includes a more complete description of document control requirements, including responsibilities, review and approval processes, revision control, and distribution controls. However, the QAPD is not part of the licensing basis, and information that appears only in the QAPD cannot be used to meet the LA content requirements of NUREG-1520 Section 11.4.3.1 acceptance criteria #6 and #7.

Information Needed

Revise Section 11.3 of the LA to incorporate the detailed document-control program currently described only in QAPD Section 6. This description must be included directly in the LA so that the licensing basis demonstrates compliance with NUREG-1520 acceptance criteria #6 and #7.

Orano Response:

Impacted Sections: Previously Section 11.1.3 (Now Section 11.2.3)

Response:

Section 11.2.3 of the License Application has been completely revised. The high-level summary and external reference to the Quality Assurance Program Description (QAPD) have been expanded into a comprehensive description of the document control program.

RAI – MM 2 Change Control

Regulatory Requirements

10 CFR 70.4 defines Configuration Management (CM) as a management measure that provides oversight and control of design information, safety information, and records of modifications that might impact the ability of Items Relied on for Safety (IROFS) to perform their functions when needed. 10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.1, acceptance criteria #8, #9, and #10

- A/C #8: The application must commit to evaluating, implementing, and tracking each change to site structures, systems, processes, equipment, components, computer programs, and personnel activities.
- A/C #9: The application must describe a process ensuring the ISA is systematically reviewed and updated to reflect design or operational changes, and that all affected documents are properly modified and made available.
- A/C #10: The application must describe the documentation process following changes per 10 CFR 70.72, including prompt updates to avoid use of outdated information.

Description of the Issue

In Section 11.1.4 “Change Control,” the LA describes a structured change control process that includes documentation, cross-functional review, 10 CFR 70.72 screening, approval, and tracking. In Section 1.10.2 “Integrated Safety Analysis” of the ISA Summary, the applicant further describes how proposed facility or process changes are evaluated using ISA methods; how ISA update requirements under 10 CFR 70.72(d)(1) and (3) are met; how accident sequences and IROFS reliability assumptions are reassessed; and how annual ISA Summary revisions are submitted in accordance with regulatory requirements. The QAPD provides additional program-level detail in Section 3 “Design Control,” Section 5 “Instructions, Procedures, and Drawings,” and Section 17 “Quality Assurance Records,” including design change documentation, procedure control, and recordkeeping expectations. However, the QAPD is not part of the licensing basis, and information that appears only in the QAPD cannot be used to meet the LA content requirements of NUREG-1520 Section 11.4.3.1 acceptance criteria #8, #9, and #10.

Information Needed

Revise Section 11.1.4 of the LA to describe a complete change control program that:

- identifies all change categories evaluated under 10 CFR 70.72;
- describes how changes are evaluated, documented, approved, implemented, and tracked;
- incorporates the ISA update process described in ISA Summary Section 1.10.2;
- explains required safety-basis recordkeeping.

Orano Response:

Impacted Sections: Previously Section 11.1.4 (Now Section 11.2.4)

Response:

The amended text formalizes the systematic identification of all change categories, details the step-by-step modification life cycle (evaluation, documentation, approval, implementation, and tracking), permanently integrates the loop to update the ISA safety-basis, and defines specific safety-basis recordkeeping rules.

RAI – MM 3 Defense-in-Depth

Regulatory Requirements

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

10 CFR 70.64(b) requires facility and system design to be founded on defense-in-depth, preferring engineered controls over administrative controls and reducing challenges to IROFS.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.1, acceptance criteria #13

- A/C #13 states that for new facilities or new processes at existing facilities, the application describes facility and system design and facility layout based on defense-in-depth practices, in accordance with 10 CFR 70.64, “Requirements for New Facilities or New Processes at Existing Facilities.” Specifically, 10 CFR 70.64(b) states that facility and system design must be founded on defense-in-depth practices and must incorporate, to the extent practicable: (1) preference for engineered controls over administrative controls and (2) reduction of challenges to IROFS. Thus, facility and system designs relying only on administrative controls, or relying on IROFS that are frequently or continuously challenged, are not acceptable, unless the application provides a justification showing that alternatives to achieve the design criteria are not practicable. Defense-in-depth practices should be applied early through the completion of design by providing successive levels of protection such that health and safety will not wholly depend on any single element of the design, construction, maintenance, or operation of the facility.

Description of the Issue

In Section 6.3.2.3 “Baseline Design Criteria and Defense-in-Depth,” of the LA, the applicant states that the ISA demonstrates compliance with the Baseline Design Criteria (BDC) of 10 CFR 70.64(a) and the defense-in-depth requirements of 10 CFR 70.64(b), including protection against chemical risks and facility conditions affecting licensed material. In Section 1.9 K and Section 3.3.3 of the ISA Summary, the applicant provides detailed information on hazard identification, engineered and administrative IROFS, and facility-wide evaluation of external events, fire hazards, and accident sequences. However, the LA does not describe how CM controls ensure that defense-in-depth design commitments are preserved over time. The LA does not provide enough detail for staff to determine that the applicant’s CM approach satisfies the acceptance criteria of NUREG-1520 Section 11.4.3.1 #13.

Information Needed

Revise the LA to provide a description of how CM controls preserve defense-in-depth design commitments:

- identification of accident sequences that were only prevented or mitigated through administrative IROFS and justification where engineered controls are not practicable;
- description of design approaches that reduce challenges to IROFS, including avoidance of IROFS that are frequently or continuously challenged.

Orano Response:

Impacted Sections: Previously Section 11.1 (Now Section 11.2 – added new section 11.2.8)

Response:

A new Section 11.2.8 has been added directly within the Configuration Management framework. This text details how the Configuration Management change screening process enforces the control hierarchy preferencing engineered over administrative controls, mandates engineering justifications for sole administrative IROFS allocations, and systematically monitors process parameters to minimize operational challenges to safety systems.

RAI – MM 4 Maintenance interfaces with other Management Measures

Regulatory Requirements

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.2, acceptance criteria #A3

- A/C #A3 requires a discussion of how the maintenance function uses, interfaces with, or is linked to the various management measures.

Description of the Issue

In the introduction of Section 11.2.2 “Corrective Maintenance,” of the LA, the applicant states that corrective-maintenance outcomes are evaluated by safety disciplines for CM and ISA impacts, and this evaluation supports maintaining consistency between the physical configuration and the ISA. The ISA Summary further demonstrates that operations and maintenance personnel participate in ISA development and updates and that maintenance activities can affect IROFS performance, accident-sequence assumptions, and safety-basis documentation. For example, Sections 1.3 and 1.4 describe how operations and maintenance expertise is incorporated into ISA hazard identification, accident-sequence evaluation, and IROFS determination. However, the LA does not describe maintenance interfaces with Training and Qualifications, Procedures, Audits and Assessments, Incident Investigation, Records Management, and Other QA Elements. The LA does not provide sufficient detail to meet NUREG-1520 Section 11.4.3.2 acceptance criteria #A3.

Information Needed

Revise the LA to describe how maintenance interfaces with all required management measures, including Training and Qualifications, Procedures, Audits and Assessments, Incident Investigation, Records Management, and Other QA Elements.

Orano Response:

Impacted Sections: Previously Section 11.2 (Now Section 11.3 – added new Section 11.3.5)

Response:

Section 11.3.5 defines how maintenance interfaces with all required management measures, including Training and Qualifications, Procedures, Audits and Assessments, Incident Investigation, Records Management, and Other QA Elements.

RAI – MM 5 Procedures

Regulatory Requirements

10 CFR 70.22(a)(8) requires that the application contain procedures to protect public health and safety.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.4, acceptance criteria #1, #5, and #6

- A/C #1 states that the applicant provides information regarding the procedure categories used at the facility. The categories typically include management control, operating, maintenance, and emergency procedures.
- A/C# 5 states that the applicant has existing or planned procedures to direct the following activities: (1) design, (2) CM, (3) procurement, (4) construction, (5) radiation safety, (6) maintenance, (7) QA elements, (8) training and qualification, (9) audits and assessments, (10) incident investigations, (11) Records Management, (12) criticality safety, (13) fire safety, (14) chemical process safety, and (15) reporting requirements.
- A/C# 6 states, procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA Summary. The applicant provides a list of the types of activities that are covered, or are planned to be covered, by written procedures. The listing includes the topics of administrative procedures; system procedures that address startup, operation, and shutdown; abnormal operation or alarm response; maintenance activities that address system repair, calibration, inspection, and testing; and emergency procedures.

Description of the Issue

In the introduction of Section 11.4 “Procedures Development and Implementation,” of the LA, the applicant provides a general description of the facility’s procedure program and identifies that procedures will be developed for various activities. In Section 11.4.2 “QA and Administrative Procedures,” the LA states that procedures exist to support administrative and programmatic functions. In Section 11.4.2 “QA and Administrative Procedures,” the LA references procedures for normal, abnormal, and emergency operations. The ISA Summary describes how procedures are used in support of ISA methodology (hazard identification, accident sequence development, and IROFS behavior). The QAPD Section 5 “Instructions, Procedures, and Drawings” provides additional program-level details regarding procedure preparation, review, approval, issuance, and change control. However, the QAPD is not part of the licensing basis, and information that appears only in the QAPD cannot be used to meet the LA content requirements of NUREG-1520 Section 11.4.3.4, acceptance criteria #1, #5, and #6.

Information Needed

Revise Section 11.4 of the LA to provide a description of the facility’s procedures program:

- a list of procedure categories and a brief description of how the procedures clearly address each of the 15 functional areas under NUREG-1520 Section 11.4.3.4, acceptance criteria #5;
- a description of operator-action procedures, including a list of activities for which written procedures exist or are planned, that support prevention or mitigation of ISA-identified accident sequences.

Orano Response:

Impacted Sections: Previously Section 11.4.2 (Now Section 11.5.2 – added Section 11.5.3)

Response:

The updated text details the procedure categories and list mapping written implementing procedures across all fifteen (15) functional areas required by NUREG-1520 Section 11.4.3.4 (Acceptance Criterion #5).

Detailed descriptions and a comprehensive list of operator-action procedures and activities (normal, abnormal, alarm response, and emergency) that support the prevention or mitigation of ISA-identified accident sequences.

RAI – MM 6 Audit Program Requirements

Regulatory Requirements

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.5, acceptance criteria #A1

- A/C # A1 states, the LA describes program directives covering the audit and assessment function (i.e., the activities to be audited, audit frequency, guidance in conducting the audit or assessment, assigned responsibilities for each phase of the work, and procedures for recording the results and recommending actions to be taken).

Description of the Issue

In Section 11.5.1 “Audit and Assessment Program,” of the LA, the applicant states that audits and assessments will be performed across multiple disciplines, including security, radiation safety, nuclear criticality safety, chemical safety, fire safety, environmental protection, emergency management, QA, CM, maintenance, training, procedures, Incident Investigation, and Records Management. However, the Licensing Application still lacks sufficient detail for two required program elements: audit frequencies and audit guidance/criteria.

Information Needed

Revise Section 11.5.1 of the LA to describe a complete audit program, including:

- how often each area (e.g., training, maintenance, procedures, incident investigations, Records Management, nuclear criticality safety, fire safety, chemical safety, environmental protection, emergency management, CM, QA elements) is audited;
- the standards, checklists, performance criteria, or procedural requirements auditors use when evaluating program effectiveness.

Orano Response:

Impacted Sections: Previously Section 11.5.1 through 11.5.3 (Now Section 11.6.1, 11.6.2, 11.6.3)

Response:

The revised and added sections establish audit intervals and provide guidance on the standards, checklists, performance criteria, or procedural requirements auditors use when evaluating program effectiveness.

RAI – MM 7 Records Management

Regulatory Requirements

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.7, acceptance criteria #3, # 4, #6, and #7

- A/C# 3 states, the applicant categorizes records by relative safety importance to identify record protection, and storage needs and to designate the retention period for individual kinds of records.
- A/C# 4 states, the applicant protects records against tampering, theft, loss, unauthorized access, damage, or deterioration while in storage.
- A/C# 6 states, the applicant implements procedures that (1) assign responsibilities for Records Management, (2) specify the authority needed for records retention or disposal, (3) specify which records must have controlled access and provide the controls needed, (4) provide for the protection of records from loss, damage, tampering, and theft or during an emergency, and (5) specify procedures for ensuring that the Records Management system remains effective.
- A/C# 7 states, the applicant puts procedures in place to promptly detect and correct any deficiencies in the Records Management system or its implementation.

Description of the Issue

In Sections 2.3.8 “Records Management” and 11.7 “Records Management,” of the LA, the applicant describes record controls, retention periods, authentication, storage controls, and requirements for records to remain legible, traceable, secure, and retrievable. Section 17 “QA Records” describes the responsibilities for Records Management, the requirements for generating, authenticating, receiving, storing, and retaining records, and the requirements for protection against tampering, loss, and unauthorized access. However, although the QAPD contains partial information, it is not part of the licensing basis, and information that appears only in the QAPD cannot be used to meet the LA content requirements of NUREG-1520 Section 11.4.3.7, acceptance criteria #3, #4, #6, and #7.

Because the LA does not sufficiently describe handling, storage, and disposition of contaminated or classified records; the physical-storage characteristics; how effectiveness assessments are performed; and the process for identification of recordkeeping deficiencies, staff cannot determine that the document-control program meets regulatory acceptance criteria.

Information Needed

Revise the LA to provide a Records Management program description that includes:

- handling, protection, storage, and disposition of contaminated and classified records;
- physical storage and environmental controls ensuring preservation;
- methods for periodically evaluating Records Management program effectiveness;
- a defined process for identifying, tracking, correcting, and verifying recordkeeping deficiencies.

Orano Response:

Impacted Sections: Previously Section 11.7 (Now Section 11.8)

Response:

Section 11.8 Elevates programmatic details from the QAPD directly into the licensing basis, providing explicit descriptions of:

- Procedures for handling, decontaminating, storing, and dispositioning contaminated and classified records.
- Physical storage specifications and environmental controls
- Periodic self-assessment methods used to evaluate Records Management effectiveness.
- Corrective Action Program integration for discovering, logging, tracking, and resolving recordkeeping deficiencies.

RAI – MM 8 QA Organizational Authority and Independence

Regulatory Requirements

10 CFR 70.62(d) requires management measures to ensure IROFS remain available and reliable.

NUREG-1520 Revision 2, Guidance

NUREG-1520 Rev. 2, Section 11.4.3.8, acceptance criteria #A1

- A/C #1 Organization —The applicant may describe the organizational structure, functional responsibilities, lines of authority, and lines of communication for control of activities affecting quality. The organization responsible for ensuring that appropriate QA has been established should have sufficient authority, access to work areas, and organizational independence to perform its responsibilities.

Description of the Issue

In Section 2.2.1 “Operating Organization,” of the LA, the applicant describes the functional positions responsible for managing the operation of the facility. However, the LA omits the required QA organizational structure, authority, independence, and verification-separation descriptions. The ISA Summary contains several high-level references to QA standards (e.g., ANSI/ANS-3.2-2012) and QA controls applied to operational activities. However, these references do not include any description of the QA organization’s authority, lines of communication, managerial independence, or organizational autonomy. The QAPD contains substantial QA-program and organizational details. Section 1.0 “Organization” of the QAPD includes the QA Manager responsibilities, QA organizational structure overview, assignment of QA duties, and independence of auditing functions. Section 2.0 “QA Program” of the QAPD describes the responsibilities and authority for QA implementation, the programmatic controls, and the QA functions available during design, construction, and operation. However, the QAPD is not part of the licensing basis, and information that appears only in the QAPD cannot be used to meet the LA content requirements of NUREG-1520 Section 11.4.3.8 acceptance criteria #A1. Because the LA does not describe the QA organization’s authority, independence, access to management, or organizational autonomy, staff cannot determine that the document control program meets regulatory acceptance criteria.

Information Needed

Revise the LA or expand the ISA Summary to include a description of the QA organization’s authority and independence. The description must clearly identify:

- QA independence from production, cost, and schedule pressures;
- QA authority to stop work or prevent use of nonconforming material;
- QA organizational freedom and unrestricted access to all levels of management;
- separation of QA verification functions from the groups performing or directing the work;
- lines of authority and communication necessary for the QA organization to fulfill its responsibilities.

Orano Response:

Impacted Sections: Previously Section 11.8.1 (Now Section 11.9.1)

Response:

The revised text incorporates the core organizational, authority, and independence mandates previously housed only in the QAPD directly into the top-tier licensing basis text. Specifically, the text establishes:

- Absolute QA independence from production cost, schedule, and operational pressures.
- Explicit authority for Quality Assurance personnel to issue Stop Work Orders and block the installation or use of nonconforming items.
- Unrestricted organizational access to all levels of management, up to and including the Company President.
- Strict separation between verification/inspection personnel and line groups performing or directly supervising the work.
- Direct reporting lines and escalation pathways to ensure unbiased quality oversight.