

NRC INSPECTION MANUAL

DANU

INSPECTION PROCEDURE 69021

INSPECTIONS OF QUALITY ASSURANCE PROGRAM IMPLEMENTATION DURING CONSTRUCTION OF NON-POWER PRODUCTION AND UTILIZATION FACILITIES

Effective Date: March 25, 2025

PROGRAM APPLICABILITY: 2550

69021-01 INSPECTION OBJECTIVES

- 01.01 To determine if the holder of a Construction Permit (CP) for a Non-power Production and Utilization Facility (NPUF) has developed quality assurance (QA) procedures, instructions, and other documents (collectively: implementing documents) that are consistent with the licensee's NRC-approved QA program as referenced in the licensee's Safety Analysis Report (SAR).
- 01.02 To determine if the licensee has effectively implemented its QA program during construction activities.

69021-02 INSPECTION REQUIREMENTS

Background. The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(A)(7) require that a QA program be approved by the NRC for CP quality-related activities. Although a QA program is required, the regulations do not invoke 10 CFR, Part 50, Appendix B QA requirements for NPUFs, and NPUF licensees are not required to comply with ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications."

Although not a requirement, it is expected that NPUF licensees will have committed to ANSI/ANS-15.8, "Quality Assurance Program Requirements for Research Reactors," as recommended in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors." This commitment, along with a commitment to implement their NRC reviewed and approved Quality Assurance Program Description (QAPD) should be contained in the Licensee's CP. In preparation for inspection, inspectors should review the QAPD and the applicable revision to the ANSI/ANS-15.8 guidance referenced in the QAPD. These documents should be used in conjunction with the specific guidance and inspection requirements contained in this inspection procedure (IP).

Note 1: The guidance in ANSI/ANS 15.8 is less restrictive than that contained in ASME NQA-1, which is generally used for nuclear power plants. The applicable QA requirements for a specific facility will be based on its approved QAPD. The inspectors should examine and become familiar with the approved QAPD.

Note 2: Throughout this inspection procedure (IP), the terms "applicant" and "permit holder" are used to refer to an operating license applicant and construction permit holder. For the purpose of this IP, these terms are interchangeable with the term "licensee."

General Inspection Requirements

a. Overview

1. The goal of these inspection activities is to examine samples of QA implementing documents and samples of activities that demonstrate the implementation of these documents to provide a comprehensive inspection of the licensee's QA program.
2. The requirements and guidance for inspecting each of the requirements listed in Section 2 of ANSI/ANS-15.8 are contained within Appendix A through Appendix R of this IP, as applicable to the approved QAPD. Guidance and requirements for inspecting the applicable portions of the QA program and its implementation are contained in each appendix. Exhibit 1, "Inspection Frequency for IP 69021 Appendices," provides guidance for inspecting both the program documents and the program implementation.
3. Inspections should be risk-informed and performance based as much as is practical. Inspection sampling recommendations are provided in each of the 18 appendices. However, the inspector should consider the risks at the facility as shown in the CP and the level of inspection effort should be commensurate with the importance of the safety system.
4. The guidance in Exhibit 1 should be considered recommendations and requirements. The NRR NPUF oversight branch will continuously assess licensee performance and will increase/decrease inspection efforts as necessary to respond to licensee performance. While not all samples specified in the appendices are required to be completed, the staff will inspect sufficient samples from each of the applicable appendices to provide adequate assurance that the licensee is effectively implementing their QA program.

b. Requirements for Performance of Inspections

Inspections should be performed in accordance with the inspection plan. Unexpected events after approval of the inspection plan may result in a change of inspection activities.

c. Requirements for the Inspection of QA Implementing Documents

1. Verify that the licensee's QA implementing documents demonstrate compliance with the licensee's QAPD. Select the appropriate appendix or appendices to this IP that address the QAPD requirements that have been assigned in the inspection plan. Use the sections of the appendix or appendices that address the inspection of the QA program implementing documents. Where the licensee has delegated portions of their QA program implementation to other organizations working on behalf of the licensee (as an agent of the licensee), the inspectors should also review the applicable QA program implementing documents for those organizations.
2. Perform the inspection by conducting interviews, reviewing ongoing work activities, and by examining QA program implementing documents and associated records. Inspections should be performed in accordance with the inspection approach described in Exhibit 1.

d. Requirements for the Inspection of QA Program Implementation

Verify that the licensee's QA program is being implemented effectively by the responsible organization(s). Perform the inspection by using direct observations, conducting interviews, and examining QA records. The most efficient way of inspecting QA is through performance-based inspection in conjunction with IP 69020 inspections. The focus of these inspections should be real-time observation of construction activities, including in-process QA records. Inspector judgment should be exercised to focus on those activities that have the highest importance to safety. Inspections should be performed in accordance with the inspection approach described in Exhibit 1.

e. Requirements for Inspection Reporting

An inspection report and any findings will be prepared, approved, and released in accordance with Inspection Manual Chapter 2550, "Non-Power Production and Utilization Facilities (NPUFs) Licensed Under 10 CFR Part 50 Construction Inspection Program (CIP)."

69021-03 INSPECTION GUIDANCE

Construction Inspection Specific Guidance.

- a. In addition to the general inspection requirements identified in Section 2.02 of this IP, the inspection should be conducted in accordance with the specific guidance herein.

As indicated in Exhibit 1, it is recommended that an initial team inspection be conducted to review the QA program implementing documents within the first 6 months after construction has begun. During this initial team inspection, if sufficient activities have been conducted or are in progress, an inspection of the implementation of the QA program could be conducted in specific areas. Any samples completed during the initial team inspection can be credited toward the total sampling requirements for the applicable appendix. After the initial team inspection, periodic inspections of the effective application of the QAPD will be performed using a vertical slice approach and in conjunction with the inspection of the construction of safety significant items (and services) in accordance with IP 69020.

- b. Gather pertinent information and discuss inspection planning and scheduling issues with the appropriate Region II Project Inspector, for example:
1. importance/prioritization of activities.
 2. concurrent inspections to be conducted using other IPs.
 3. 10 CFR Part 21/10 CFR 50.55(e) reporting by licensee.
 4. status of previous NRC findings.
 5. licensee responses to applicable Bulletins, Circulars, and Information Notices sent to licensee.

- c. Contact the licensee for information needed to prepare the inspection plan, for example:
 - 1. status of construction activities (used to focus inspection and determine required sampling during inspection).
 - 2. identification of individuals assigned key positions and functions described by the licensee's QA program.
 - 3. availability of licensee personnel during the period tentatively scheduled for the inspection.
 - 4. changes to QA program since the previous NRC inspection (e.g., QA policy, QA personnel, QA program description, implementing documents).
- d. Utilizing the information gathered in subsections b and c above, determine which activities will be inspected and develop the inspection plan accordingly. Select and use the appropriate appendix or appendices to this IP that address QAPD requirements that are relevant to the activities to be inspected to further develop specific inspection tasks.
- e. During the inspection, the inspector should be asking: What documented process is used for this activity? (This may already be determined during the planning process.) Is there documented, objective evidence for completion of the activity? For example, if the inspector is responsible for inspection of welding activities, then the inspector will use the main body of this IP and Appendix J as the primary tools to conduct the inspection.

The inspector would then perform the following to verify that the licensee's QA program has been implemented effectively in accordance with documented instructions consistent with its approved QAPD

- 1. Determine what implementing documents were used by the licensee to conduct the activity.
 - 2. Observe the activity being performed, if possible, to see that it is conducted in accordance with the licensee's implementing document.
 - 3. Conduct interviews with staff members to determine if they understand the requirements and their responsibilities.
 - 4. Examine the associated records for that activity (it is expected that aspects of other appendices will be applicable during the inspection because several appendices may apply to each construction activity).
- f. To maximize efficiency in the inspection program, implementation of this IP should be coordinated with IP 69020, "Inspection of Safety-Related Items (and Services) During Construction of Non-Power Production and Utilization Facilities." During inspection of structures, systems, and components (SSCs), the inspector should focus on the review and observation of a variety of safety-related construction activities, if available, and use those activities as the starting point for the inspection sample.

For example, if the inspector observes the installation of a component using IP 69020, the inspector may consider additional QA attributes using IP 69021, which may include reviewing the fabrication, procurement, receipt inspection, and qualification and

certification records for the item and verify the upstream records are traceable to the item. Furthermore, the inspector may review the training and qualification records for the construction, inspection, and test personnel associated with the item's inspection and installation in the plant. The inspector could review the associated design documents for that item and verify that the as-built condition of the SSC is consistent with the original design, and that any design changes were properly controlled. The inspector may also review any associated nonconformance reports or other corrective action records associated with the activity. This scope of review is not necessary for every inspection but is included here to illustrate that many sections of this procedure can be accomplished for almost any safety-related construction activity. The inspections of these items should be reviewed against the approved QAPD.

This IP should also be performed in conjunction with IP 69022, "Inspections of Operational Readiness During Construction of Non-Power Production and Utilization Facilities," as applicable.

69021-04 RESOURCE ESTIMATE

Completion of this inspection procedure requires of 40–80 hours of direct inspection. This is inclusive of applicable appendices or sections of the appendices and will vary depending on the specific facility design. Inspection preparation, including review of applicable licensing basis, safety analysis report (SAR), and codes and standards, is not included in this estimate.

For a site working under a Limited Work Authorization (LWA), safety-related construction activities may be constrained and not moving at the pace that would likely occur if the site worked under a CP. Within this limited safety-related work scope, the resource estimate should be adjusted accordingly to the QA safety-related work activities allowed under the LWA.

69021-05 PROCEDURE COMPLETION

This IP supplements IP 69020 to support the vertical slice approach for inspection of construction and operational readiness activities. Implementation of this IP is considered complete when the requirements in the inspection procedure and the applicable appendices are complete.

69021-06 REFERENCES

10 CFR Part 21, "Reporting of Defects and Noncompliance"

10 CFR 50.34, "Contents of applications; technical information"

10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses"

ANSI/ANS 15.8, "Quality Assurance Program Requirements for Research Reactors"

END

List of Exhibits:

Exhibit 1: Inspection Frequency for IP 69021 Appendices

List of Appendices:

IP 69021.A: Inspection Guide for Requirement 2.1–Organization
IP 69021.B: Inspection Guide for Requirement 2.2–Quality Assurance Program
IP 69021.C: Inspection Guide for Requirement 2.3–Design Control
IP 69021.D: Inspection Guide for Requirement 2.4–Procurement Document Control
IP 69021.E: Inspection Guide for Requirement 2.5–Procedures, Instructions, and Drawings
IP 69021.F: Inspection Guide for Requirement 2.6–Document Control
IP 69021.G: Inspection Guide for Requirement 2.7–Control of Purchased Items and Services
IP 69021.H: Inspection Guide for Requirement 2.8–Identification and Control of Items
IP 69021.I: Inspection Guide for Requirement 2.9–Control of Special Processes
IP 69021.J: Inspection Guide for Requirement 2.10–Inspection
IP 69021.K: Inspection Guide for Requirement 2.11–Test Control
IP 69021.L: Inspection Guide for Requirement 2.12–Control of Measuring and Test Equipment
IP 69021.M: Inspection Guide for Requirement 2.13–Handling, Storage, and Shipping
IP 69021.N: Inspection Guide for Requirement 2.14–Inspection, Test, and Operating Status
IP 69021.O: Inspection Guide for Requirement 2.15–Control of Nonconforming Items and Services
IP 69021.P: Inspection Guide for Requirement 2.16–Corrective Actions
IP 69021.Q: Inspection Guide for Requirement 2.17–Quality Records
IP 69021.R: Inspection Guide for Requirement 2.18–Assessments

List of Attachments:

Attachment 1: Revision History Sheet for IP 69021

Exhibit 1: Inspection Frequency for IP 69021 Appendices.

Initial Team Inspection (QA Program Implementing Documents):

It is recommended that an initial team inspection be conducted to review the QA program implementing documents within the first 6 months after construction has begun. This inspection should cover QA program implementing document requirements for all applicable appendices to this IP. During this initial team inspection, if sufficient activities have been conducted or are in progress, an inspection of the implementation of the QA program could be conducted in specific areas. Any samples completed during the initial team inspection can be credited toward the total sampling requirements for the applicable appendix.

QA Program Implementation Follow-up Inspections:

Follow-up inspections of QA Program implementation should be performed in conjunction with IP 69020 SSC inspections, concentrating on the applicable QA attributes for that SSC using a vertical-slice inspection approach.

Vertical-Slice Inspection Approach:

To attain reasonable assurance in each inspection area, the inspection scope for each inspection includes a “vertical-slice” inspection for construction and operational readiness activities. Under a vertical-slice inspection, not only is the SSC inspected in accordance with the inspection area procedure, to verify the SSC meets the licensing requirements; an inspection is also performed to verify the applicable 10 CFR Appendix B quality assurance program (QAP) attributes are adequately implemented. QAP attributes include, but are not limited to, the following:

- design control of process changes and modifications,
- instructions, procedures, and drawings
- procurement and control of purchased material and equipment,
- identification and storage,
- installation,
- testing,
- identification and resolution of nonconformances and compliance issues (and associated documentation).

Appendix A: Inspection of Requirement 2.1–Organization

69021A-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for the organization are consistent with the NRC-approved QAPD and commitments in the safety analysis report (SAR).
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for the organization.

69021A-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

- a. Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for the organization.
- b. Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents address QA functions and responsibilities.

02.02 Inspection of QA Program Implementation

- a. Determine if changes to the organizational structure have occurred, including changes to the relationship between the licensee upper management and the organization(s) responsible for QA oversight functions. Review changes to the organizational structure and verify that these changes do not adversely impact the ability of the licensee to effectively implement the QA program. Discuss the changes with project and QA management. The QA functions may be performed by various sub tier organizations, such as engineering, field QC, and procurement.
- b. Examine the organizational description and, if available, the organizational chart to determine if the personnel that perform QA oversight functions are sufficiently independent from the work being performed.
- c. Determine if changes in personnel authorities, responsibilities and functions have occurred. Discuss the changes with the licensee's management to determine why the changes were made (e.g., reassignment of staff, departure of staff from the organization).
- d. Interview a sample of personnel that perform QA oversight functions to determine if they have an adequate understanding of the QA program, focusing on roles and responsibilities. If it is not apparent that a staff member has a clear understanding, then the inspector should examine documents to determine if requirements for training or qualification are sufficient (reference Appendix B for additional information on training and qualification). Verify that they are sufficiently independent and have organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and verify implementation of solutions.

- e. Interview a sample of staff that perform activities in support of quality objectives to determine if they have an adequate understanding of the QA program, focusing on roles and responsibilities. If it is not apparent that a staff member has a clear understanding, then the inspector should examine documents to determine if requirements for training or qualification are sufficient (reference Appendix B for additional information on training and qualification). Determine if staff members are aware of the levels of management to which the staff would elevate awareness of a quality issue. Verify that personnel responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed have sufficient authority, access to work, and freedom to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation.
- f. Interview personnel to determine how delegation of authority is documented. Examine a sample of documentation of the most recent delegations, such as memoranda and e-mails.

69021A-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address the licensee's organizational structure, responsibilities, and authorities. The licensee's staff, including contractors (e.g., subcontractors, agents, suppliers, vendors), is responsible for performing activities that meet quality objectives that affect safety-related items (and services).

In addition, the licensee should have specific staff members who have been designated to perform QA oversight functions that are independent of the work being performed. These personnel need sufficient authority, access to work, and freedom to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation.

Inspection of the licensee's organization may require more in-depth interviews of staff and management than other appendices. The inspection of implementation in this area should be directed at verifying that the overall QA program is established and clear, that personnel responsible for performing QA oversight functions are truly independent, that delegation of work to others (including internal to the licensee and to contractors) is at the appropriate reporting level within the organization, and that staff understand their responsibilities and the lines of authority. At the conclusion of the inspection of the QA program implementation portion of this IP appendix, the inspector should be able to conclude if the licensee's staff members understand their roles and responsibilities, including the importance of their compliance with the licensee's QA program in the effective implementation of the QA program.

The inspector should also perform a detailed review of the licensee's delegation of QA program implementation to contractors acting as an agent to the licensee, if applicable to this section. The inspector should verify if the licensee has delegated responsibilities through the purchase order and if the contractor QA program would be followed or if the contractor has committed to implementing the licensee's QAPD. The licensee should verify that the contractor follows the licensee's QAPD or the contractor's QAPD through the licensee's external assessment process, where applicable.

Appendix B: Inspection of Requirement 2.2–Quality Assurance Program

69021B-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for establishing the QA program for activities affecting the quality of identified items (and services) are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for the QA program.

69021B-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

- a. Review applicable sections of the licensee's QAPD and SAR. Ensure that policies and appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for revising and modifying the QAPD.
- b. Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for establishing the QA program, ensuring indoctrinated and trained personnel conduct quality-affecting activities.

02.02 Inspection of QA Program Implementation

- a. Examine the structure of the licensee's QA program (QAPD, policies, implementing documents). Verify that items and activities subject to the QA program are identified.
- b. Examine the most recent revision of the QAPD. Verify that revisions to the QAPD were reviewed and approved in accordance with established requirements.

NOTE 1: The provisions of 10 CFR 50.54(a) regarding reductions in commitments in the QAPD do not apply to NPUFs.

NOTE 2: The QAPD will have already been reviewed by the NRC to verify that the identification of safety-related items and activities are specified. The licensee also needs to establish measures to identify the extent to which the QA Program applies to the items and activities. Designated functions may be described in more detail in the licensee's implementing documents for Appendix A – Organization.

- c. Select a sample of staff from various disciplines (e.g., administrative, QA, engineering, training, and craft, from both the licensee and contractors):
 - 1. Conduct interviews to determine if staff members understand which items (and services) are covered by the QA program they support. If it is not apparent that a staff member has a clear understanding, then the inspector should examine documents to determine if requirements for training or qualification are sufficient.

2. Verify that personnel performing quality-affecting activities are qualified in accordance with standards established by the licensee. Review changes of key positions to determine if the minimum qualifications have been met. Compare the qualification requirements with the associated qualification verification documentation for the personnel.
3. Select the names of a sample of staff from various disciplines (may be from same sample as Section 02.02.c above):

Verify that staff performing quality-affecting activities received required indoctrination and training. Examine training requirements for those positions and verify that orientation and training were completed within the specified time frame.

69021B-03 INSPECTION GUIDANCE

General Guidance

The inspector should find policies and implementing documents that specifically address the establishment of the QA program, including personnel training and indoctrination, planning work, and evaluation of the status and adequacy of the QA program. Effective implementation of the QA program ensures that activities affecting quality are accomplished under controlled conditions, including use of appropriate equipment, conduct of work under suitable environmental conditions, and fulfillment of prerequisites. The QAPD is the licensee's documented basis for its QA program, and it is reviewed as part of the NRC's evaluation of the licensee's SAR.

Appendix C: Inspection of Requirement 2.3–Design Control

69021C-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for design control are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee is effectively implementing its design control program.

69021C-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

- a. Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for design control. Ensure that the licensee's implementing documents provide a sufficient level of detail to allow licensee staff to perform design/engineering work and maintain control of the plant design in accordance with the requirements as specified in the SAR. For design work being performed by the design authority or other outside contracted organization, ensure that the licensee has invoked applicable portions of its QAPD.
- b. Review implementing documents that govern the performance of design calculations and analyses. Ensure that the implementing documents adequately describe the process for the review and approval of such documents.
- c. Review implementing documents that govern the review, approval, and process for controlling changes to design documents.
- d. Review implementing documents that cover the turnover of the design information from the design authority to the licensee. Ensure that adequate implementing documents are in place to maintain the design basis.

02.02 Inspection of QA Program Implementation

- a. Select a sample of design documents and design changes. To the extent practical, the samples chosen for review should involve multiple systems and organizations (e.g., electrical, mechanical, maintenance, etc.). These samples may include work performed directly by the licensee, the construction design authority, or through contracted design organizations.

Obtain and review the licensee's procedure(s) for design control to ensure that the design conforms to the NRC approved licensing basis. Verify that applicable procedures for design control, (including design changes, design verification, and commercial grade items) were followed.

If available, the sample should include changes requested by field installation personnel. Such changes might involve requested changes to piping or cabling runs, requested deviations from construction drawings, etc. Ensure that the field changes receive the

proper level of engineering review in accordance with licensee procedures. Ensure that all affected calculations, drawings, and analyses are identified. Verify that affected design documents are reviewed to ensure their continued applicability and that all design input assumptions remain valid.

- b. Ensure that proper verification, validation, and version control of all quality related computer software used in the performance of design work.
- c. Verify that design and licensing documents have either been updated or are in the process of being updated to reflect the design changes. Examples of design documents that could be affected by design changes are: SAR, Technical Specifications, drawings, supporting calculations and analyses, plant equipment lists, maintenance instructions, and vendor manuals.
- d. Ensure that the licensee is appropriately implementing its documents that govern the turnover and control of design information from the design authority.

NOTE: This inspection requirement may need to be completed towards the end of the construction cycle.

69021C-03 INSPECTION GUIDANCE

General Guidance

Inspection of the licensee's implementation of design control can also be reviewed through structure, system, and component (SSC) inspection. For example, SSC inspections could assess the processes being used by the design authority to translate the higher-level design into detailed design drawings, construction drawings, and procurement specifications for the SSC being inspected.

Appendix D: Inspection of Requirement 2.4–Procurement Document Control

69021D-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee’s QA implementing documents for procurement document control are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA program implementing documents for procurement document control.

69021D-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee’s QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for procurement document control for purchases of safety-related items and services.

02.02 Inspection of QA Program Implementation

Review a sample of recently issued purchase documents for safety-related items and services. Select a representative sample from the following categories: mechanical, electrical, instrument/electronic, and consumables (e.g., chemicals, reagents, lubricants, filters). Verify the Procurement documents were prepared and processed in accordance with licensee’s implementing documents.

69021D-03 INSPECTION GUIDANCE

General Guidance

The inspection in this area should be directed at assuring that procurement of material and equipment (collectively referred to as “items”), and services from contractors, subcontractors, agents, vendors, and suppliers (collectively referred to as “contractors”) will be accomplished in accordance with the licensee’s documented controls. The licensee may define two types of procurement controls: one for purchase of non-safety-related items and services and one for safety-related items and services. If this is the case, it is important to recognize that the defined methods of control must be sufficiently definitive to prevent the non-conservative method of controls from being used for purchasing safety-related items and services.

Appendix E: Inspection of Requirement 2.5—Procedures, Instructions, and Drawings

69021E-01 INSPECTION OBJECTIVE

- 01.01 Verify that the licensee's QA program documents for preparing and revising implementing procedures, instructions, and drawings that prescribe activities affecting quality are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA program implementing instructions, procedures and drawings for revising implementing documents.
- 01.02 Verify that licensee personnel are trained to follow safety-related instructions and procedures.

69021E-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate QA program documents have been developed to address the QAPD requirements and SAR commitments for preparation of implementing documents (e.g., preparation of administrative procedures or work instructions).

02.02 Inspection of QA Program Implementation

Select a sample of controlled implementing documents. Select a mixed sample of implementing documents, such as procedures, design drawings, and engineering specification. Verify that procedure content is in accordance with QAPD requirements (e.g., inclusion or reference to appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactory accomplished), and that procedures are being used.

69021E-03 INSPECTION GUIDANCE

General Guidance

The inspector should find QA program documents that specifically address preparation and modification of the implementing documents that establish requirements for conducting quality-affecting activities involving safety-related items (and services). For example, the licensee may have a QA program document (e.g., administrative level procedure) that describes how an administrative-type implementing document (e.g., training) is to be prepared. Additionally, the licensee may have a separate QA program document that addresses preparation of technical-type implementing documents, such as work instructions.

The licensee is required to have implementing documents that describe activities addressing applicable safety-related activities. These implementing documents are required to be in place prior to the commencement of work. The records that are generated as a result of implementing

the documents provide objective evidence that the plant has been constructed to design specifications and in accordance with regulations and implementing documents.

The inspector should select for review those implementing documents that are representative of the QAPD. As a result of this inspection, the inspector should develop an overall assessment of the licensee's implementing documents that control the performance of quality-affecting activities during construction.

Appendix F: Inspection of Requirement 2.6—Document Control

69021F-01 INSPECTION OBJECTIVE

- 01.01 Verify that the licensee's QA program documents for the preparation, issuance, and change of implementing documents that prescribe activities affecting quality are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA program documents related to document control.

69021F-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for review, approval and issuance of controlled documents.

02.02 Inspection of QA Program Implementation

- a. Verify that the licensee has an electronic or paper copy system for issuing, distributing, and cancelling controlled documents. Obtain access to the list(s) of currently controlled documents. Verify that the documents are available to personnel by accessing the documents electronically or by examining a sample of controlled paper copies that have been issued to personnel. Compare the master-controlled list(s) to the electronic controlled documents or the sample of paper copy controlled documents to verify that the document titles, identifiers, and revision levels are identical. Verify that the paper copies are indicated as controlled copies.
- b. Select a sample from the list(s) of controlled documents. Verify that the controlled documents were developed in compliance with QAPD and implementing document requirements.
- c. Select a sample of revised controlled documents. Verify that the controlled documents were developed in compliance with QAPD and implementing document requirements.
- d. Select various work locations (e.g., administrative office, warehouse, shop floor, contractor field trailer). Interview a sample of personnel at these locations to verify that they have access to the current controlled implementing documents that they need to conduct the activity.
- e. Obtain a list of the most recently cancelled/rescinded implementing documents. Select a mixed sample of documents, such as procedures, design drawings, and engineering specifications. Verify that the documents are no longer available at the work site.

General Guidance

The inspector should find implementing documents that specifically address review, approval, distribution, and modification of controlled documents. Other controlled documents may include design drawings, design requirements documents, engineering specifications, calculations, and procurement documents that provide specific instructions to the licensee. The inspector should select for review those controlled documents associated with activities that have high safety significance.

Inspections of document control should focus on ensuring that current work controlling documents are made available promptly to licensee staff and that all quality-affecting work is being conducted in accordance with current revisions of approved documents.

Inspection of implementation will include an examination of the actual controlled documents and the document review records. Although this aspect of the inspection is important, more significant is the verification that the personnel have direct access to the correct (e.g., current revision) documents that apply to the activities they are performing.

Appendix G: Inspection of Requirement 2.7–Control of Purchased Items and Services

69021G-01 INSPECTION OBJECTIVE

- 01.01 Verify that the licensee's QA implementing documents for control of safety-related, purchased material and equipment (collectively referred to as "items"), and services are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for control of safety-related, purchased items and services, including acceptance of items and services.

69021G-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

- a. Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for evaluation and selection of contractors.
- b. Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for acceptance of items and services.

02.02 Inspection of QA Program Implementation

Inspect a sample of safety-related items and services that were procured from contractors. Select a representative sample from the following categories: mechanical, electrical, and instrument/electronic items; consumables and services that require only documentation as the deliverable (i.e., no tangible item was procured). Verify that the safety-related item or service is accepted in accordance with QAPD and implementing document requirements, including (as appropriate):

- Supplier was selected in accordance with applicable requirements.
- Measures were established to control the supplier's performance.
- Supplier verified and provided evidence of the quality of the product.

69021G-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address acceptance of safety-related procured items and services. It is important to verify that implementing documents provide controls that assure that items or services meet the procurement requirements and are accepted prior to its use.

Various methods may be used to accept items and services, such as certificate of conformance, source verification, surveillance, receiving inspection, dedication of commercial grade item, or a combination thereof.

The inspector should also review a sample of item acceptance activities (e.g., receipt/source inspection) performed on behalf of the licensee by those contractors acting as an agent to the licensee.

Appendix H: Inspection of Requirement 2.8—Identification and Control of Items

69021H-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for the identification and control of safety-related materials, parts, and components (collectively referred to as "items") are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for the identification and control of items.

69021H-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for the identification and control of safety-related items.

02.02 Inspection of QA Program Implementation

- a. Inspect a sample of safety-related items that are installed, in use, or stored. Examine associated records and other documentation (e.g., tracking systems) that identify these items. Verify that the items are properly identified and controlled in accordance with implementing documents.
- b. Observe the licensee's installation or use of an item. Verify that the item is properly identified and that the associated documentation is accurate and traceable and that the correct item is being installed or used.
- c. Examine items that require inspection or tests (requirement may be indicated on the item or its associated documentation). Verify that the status of the inspection or test as indicated on the item and/or in the documentation is current and accurate.
- d. Examine items that are indicated as incorrect or defective (e.g., nonconformance, corrective action). Verify that the associated documentation and records are in agreement with the indicated item.
- e. Examine items with a limited operating or calendar life. Verify that controls are in place to preclude the use of expired items.

69021H-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address the identification and control of items that are manufactured, procured, installed, and/or used.

The inspection of implementation in this area should be directed at assuring the traceability of items that are procured, installed, and used. Establishing traceability of an item is key to ensuring that the proper item is used, and its pedigree can be verified; that the final assembled component is comprised of the appropriate parts; and that correct spare parts can be acquired and installed, as necessary. Traceability can be established and maintained using physical markings and by associated documentation. When physical marking is impractical or insufficient, other appropriate means (e.g., physical separation, procedural control) must be used. Only items that have undergone required inspection and testing should be used. It is also important to determine if accepted items are controlled adequately to ensure that they are not used if a nonconformance or corrective action is identified.

Appendix I: Inspection of Requirement 2.9—Control of Special Processes

69021I-01 INSPECTION OBJECTIVES

Verify that the licensee's QA implementing documents for the control of special processes are consistent with the NRC-approved QAPD and commitments in the SAR. Special processes include welding, nondestructive testing (NDT), heat treatment, and coatings.

69021I-02 INSPECTION REQUIREMENTS AND GUIDANCE

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for control of special processes.

02.02 Inspection of QA Program Implementation

Implementation of control of special processes should be verified as a part of SSC inspections. For example, inspections of SSCs that involve welding should include verification that QAPD and implementing document requirements for NDT have been met for the specific SSC being inspected.

69021I-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address the control of special processes during construction to demonstrate that items that are important to safety will perform satisfactorily in service. It is important to verify that implementing documents provide controls that assure that special processes are conducted by qualified personnel using qualified procedures and tools, and that the special processes are performed in accordance with specified applicable codes, standards, specifications, and other special requirements.

Examples of welding include: piping, support and component welding; structural welding and component support welding; and storage tank fabrication welding. NDT may include radiographic, liquid penetrant, magnetic particle, and ultrasonic. Examples of special processes include post-weld heat treatment and application of fire-retardant coatings. Heat treatment may be required pre-welding and/or post-welding. Coatings may be applied to protect structural and mechanical components.

Appendix J: Inspection of Requirement 2.10—Inspection

69021J-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for conducting inspections of materials, parts, equipment and components (collectively referred to as "items") are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for inspection of items.

69021J-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for conducting inspections to ensure quality.

02.02 Inspection of QA Program Implementation

- a. Evaluate a sample of inspection documentation for safety-related items that require inspection. Select a representative sample from the following categories: mechanical, electrical, instrument/electronic, and consumables (e.g., reagents, lubricants, filters), and conduct the following:
 - 1. Verify that inspections were performed by qualified individuals other than those who performed or directly supervised the work being inspected.
 - 2. Confirm inspection of item was performed at required frequency for each work operation (including in-process inspections and final inspections), as described in the implementing document. Inspection may include verification of completeness, markings, installation, adjustments, protection from damage, or other characteristics.
 - 3. If modifications, repairs, or replacements of items were performed subsequent to final inspection, then verify that appropriate re-inspections were performed.
- b. Observe the licensee's inspection of an item. Select a sample of licensee inspections that the NRC inspector is able to witness. Verify that the person conducting the inspection is qualified and/or authorized to conduct the inspection and to update markings (e.g., tags) or documentation subsequent to the inspection. Verify that the inspector has the current implementing document and appropriate tools to conduct the inspection.

General Guidance

The inspector should find implementing documents that specifically address inspection of safety-related items during construction to demonstrate the conformance of an item or activity to requirements. It is important to verify that implementing documents provide controls that assure that only items that have undergone required inspections, and have passed or been determined to be acceptable, are installed and used. Items may undergo inspection on a one-time-only basis, or periodic inspections may be required.

Appendix K: Inspection of Requirement 2.11–Test Control

69021K-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for the control of testing are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for test control.

69021K-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for testing.

02.02 Inspection of QA Program Implementation

Evaluate a sample of documentation for safety-related items that require testing. Select a representative sample from the following categories: mechanical, electrical, instrument/electronic, and pre-op. Either directly observe tests (or portions of tests), or review completed test documentation to verify that QA Program implementing documents for testing have been correctly implemented. If applicable, also verify that computer programs used for operational control are tested in accordance with an approved verification and validation plan, and that they demonstrate required performance over the range of operation of the controlled function or process.

69021K-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address testing during construction to demonstrate that safety-related items will perform satisfactorily in service. These implementing documents should include the requirements and acceptance limits contained in applicable design documents.

It is important to verify that implementing documents provide controls that assure that only items that have undergone required testing, and have passed or been determined to be acceptable, are used. The acceptability of items prior to use is addressed in Appendix N. Inspectors should consider including applicable portions of Appendix N during inspections of Appendix K.

Construction testing includes provisions for pre- or post-installation operational and other construction tests and generally verifies that certain components pass specific test parameters. Examples of tests that may be performed include quality acceptance tests (e.g., concrete testing), baseline data checks (e.g., PSI), and field tests (e.g., hydrostatic test) or any other similar construction testing activities. Items may undergo a test on a one-time-only basis, or periodic tests may be required.

Appendix L: Inspection of Requirement 2.12—Control of Measuring and Test Equipment

69021L-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for controlling measuring and test equipment (M&TE) used during inspections, tests, and determinations of status of materials, parts, equipment and components (collectively referred to as "items"), are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA program implementing documents for control of M&TE.

69021L-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for control of M&TE.

02.02 Inspection of QA Program Implementation

Select a sample of calibrated M&TE used to conduct an activity (e.g., test and inspection procedures). Verify that the M&TE met QAPD and implementing requirements. Examine the related calibration documentation to verify that it meets the requirements of the implementing document(s).

69021L-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address the control of M&TE that helps to demonstrate that safety-related items will perform satisfactorily in service. These implementing documents should include the requirements and acceptance limits contained in applicable design documents.

M&TE, including tools, gages, instruments, and other devices used in activities affecting quality, must be properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. The M&TE program for assuring and testing equipment applies to both on-the-shelf and installed gages, indicators, and other devices. M&TE need not be calibrated for all ranges; however, this is rarely noted on the calibration sticker. Therefore, the licensee's identification system should note this situation, and the program shall provide sufficient control to prevent use outside the calibrated ranges.

Calibration and control are not required for rulers, tape measures, levels, and other normal commercial equipment that provide adequate accuracy. The inspection of the implementation of this appendix is closely related to inspections of several other appendices, as described in this paragraph. M&TE may be calibrated by a contractor (Appendices D and G). M&TE is identified,

handled, stored (Appendices H, M, and N). M&TE also is used to conduct inspections, tests, and special processes (Appendices I, J, and K). This IP appendix describes inspection activities that address all of the above-mentioned appendices. Therefore, the inspector should use the appendices in this paragraph for additional guidance and requirements within this area. Coordinated use of the appendices minimizes the duplication of inspection requirements in this IP appendix.

The use of out-of-calibration M&TE (i.e., calibration due date or interval has passed without recalibration; or device produces results known or suspected to be in error) may result in invalid resultant data and in the loss of critical information. The test, inspection, or other activity that requires the use of calibrated M&TE may have to be repeated. Therefore, it is important to verify that only items that have undergone and passed required periodic calibration are used.

Recalibration frequency of M&TE equipment should be established based on factors such as equipment experience, inherent stability, manufacturer's recommendation, purpose of use, and required accuracy. If historical information is used to evaluate and adjust calibration intervals, the inspector should review this information to verify that the newly determined calibration frequency is justified by knowledgeable personnel and by the data from which it is derived.

Appendix M: Inspection of Requirement 2.13—Handling, Storage, and Shipping

69021M-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for storage, handling, and shipping of equipment, materials, and spare parts (collectively referred to as "items") is consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for handling, shipping, and receiving.

69021M-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for the handling, storage, and shipping of safety-related items.

02.02 Inspection of QA Program Implementation

- a. Inspect a sample of safety-related items that have been received on site. Tour the onsite and offsite warehouse facilities to verify the items are being properly stored in accordance with licensee implementing documents. Examine records and other documentation (e.g., tracking systems) that support the implementation of storage requirements of items.
- b. Observe the licensee's handling of items. Verify the licensee is properly implementing its implementing documents for handling items. Special handling is sometimes required because of the weight, size, and configuration of certain items.

69021M-03 INSPECTION GUIDANCE

General Guidance

It should be noted that all safety-related items are not necessarily stored on site. Rather, they may be in storage areas near the site. Items may also be stored in temporary staging areas. The inspector should therefore verify that the licensee's program for handling, storage, and shipping covers offsite, as well as onsite, safety-related items.

The inspector should find written storage, handling, and shipping requirements that specifically address those items associated with safety-related items.

Appendix N: Inspection of Requirement 2.14—Inspection, Test, and Operating Status

69021N-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for the inspection, test, and operating status of materials, parts, equipment and components (collectively referred to as "items") are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for indicating inspection, test, and operating status of items.

69021N-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for indicating the inspection, test and operating status of safety-related items.

02.02 Inspection of QA Program Implementation

- a. Evaluate a sample of safety-related items that require inspection or test. The licensee should be able to provide a list of items that require inspection or test. Select a representative sample from the following categories: mechanical, electrical, instrument/electronic, and consumables (e.g., reagents, lubricants, filters). Verify that these items have physical markings (e.g., tags) or have related documentation, if physical marking is not feasible (e.g., travelers). Markings and related documentation must clearly show the acceptance status of the item.
- b. Observe the licensee's testing or inspection of an item and verify that implementing document requirement for Inspection Test and Operating Status are followed.
- c. Select items marked/documented as out of service from the lists of open NCRs or corrective action reports (CARs). The appropriate sample of items may be selected by examining the actions described in open NCRs or CARs. Examine the selected items to verify that each item:
 - 1. Was documented as out of service or for limited use.
 - 2. Cannot be inadvertently used while out of service or used beyond its limited use determination.

General Guidance

The inspector should find implementing documents and instructions that specifically address the inspection, test, and operating status of items. Examples of items that might require inspection and testing and the resultant operating status include pumps, pipes, circuit breakers, valves, safeguards instrumentation, and balances. It is important to verify that implementing documents provide controls that assure that only items that have undergone required inspection and testing, and have passed or been determined to be acceptable, are used. Items may undergo an inspection or test on a one-time-only basis, or periodic inspections and tests may be required.

The inspection of implementation in this area should be directed at assuring that items have been appropriately marked and/or documented to indicate their current status for present or future use. Use of items that are not suitable may result in an installation that does not meet specifications, installation of a component that does not meet design requirements, or measurements that are inaccurate.

Appendix O: Inspection of Requirement 2.15—Control of Nonconforming Items and Services

69021O-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for the control of nonconforming material, parts, and components (collectively referred to as "items") are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for the control of nonconforming items.

69021O-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for the control of nonconforming items.

02.02 Inspection of QA Program Implementation

- a. Select a representative sample of safety-related items that have been identified to be in nonconformance with specified requirements. Ensure that the items are being processed and controlled in accordance with implementing document requirements.
- b. Nonconformance was reported to NRC (IAW 10 CFR 21.21(d)(1) and 10 CFR 50.55(e), if applicable).

Note: Inspectors may refer to IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance's," for additional information related to reporting requirements.

69021O-03 INSPECTION GUIDANCE

General Guidance

During the review of the requirements established for the disposition of safety-related nonconforming items, the inspector should find provisions to assure that: (1) nonconforming items will be reviewed and then accepted, rejected, repaired or reworked in accordance with implementing documents; (2) repaired and reworked items will be re-inspected in accordance with applicable implementing documents; (3) a description of the change, waiver, or deviation that has been accepted for "use as is" items will be documented; (4) the responsibility and authority for the disposition of nonconforming items will be clearly defined in writing; and (5) that items dispositioned as "repair" and "use as-is" are subjected to documented design controls commensurate with those applied to the original design. It is extremely important that nonconforming safety-related items are properly controlled to prevent their inadvertent use or installation.

Appendix P: Inspection of Requirement 2.16–Corrective Actions

69021P-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for the identification, evaluation, and corrective action of conditions adverse to quality are in accordance with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its corrective action program (CAP).

69021P-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

The first annual CAP team inspection will be conducted either shortly before or just after construction begins. During that inspection, the team shall verify that the licensee's QA implementing documents for the identification, evaluation, and correction of conditions adverse to quality are in accordance with the NRC-approved QAPD and commitments in the SAR. The team should review applicable sections of the licensee's QAPD and SAR and ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for the identification, evaluation, and resolution of conditions adverse to quality.

02.02 CAP Implementation

Inspectors will conduct the initial team inspection in accordance with Section 02.01. If there is enough CAP activity at the time of the first team inspection, the inspectors can also review CAP implementation. CAP implementation will also be inspected on an annual basis. For the annual inspection, select a representative sample of between four and six significant conditions adverse to quality or 10 CFR 50.55(e) reportable events and between four and ten conditions adverse to quality. If the minimum number of samples is not available, the inspectors will review all of the available samples. For each condition/problem selected for review, ensure that the licensee has appropriately followed its implementing documents.

The use of NCVs for self-revealing and NRC-identified violations as part of the enforcement process is predicated on a licensee having an adequate CAP into which identified issues are entered and effectively resolved in a timely manner. Because the CAP at construction sites will be new and implemented initially by individuals with limited experience with the new program and because construction will involve program implementation by contractors, the NRC will delay the use of NCVs for self-revealing and NRC-identified violations pending confirmation, via the inspections described in this appendix, that the new program is adequate and being effectively implemented. Inspection reports documenting inspections described in this appendix should include a clear statement addressing the adequacy and effectiveness of the licensee's CAP.

General Guidance

Reviews under this IP appendix will apply to both the licensee and its contractors that implement their own QA programs. This IP appendix should be implemented for contractors participating in the construction phase, regardless of geographic location.

The licensee may use multiple processes to accomplish its CAP, or it may employ a single process. The processes should ensure that all conditions adverse to quality are processed in accordance with implementing document requirements, and that significant conditions adverse to quality receive investigations for cause and are provided actions to preclude recurrence.

Licensees may choose to process issues that are not conditions adverse to quality through alternative means. In such cases, inspectors should sample these alternative systems to ensure that conditions adverse to quality have not been mischaracterized and inappropriately handled outside the CAP.

Appendix Q: Inspection of Requirement 2.17–Quality Records

69021Q-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for creating and controlling QA records are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for QA records.

69021Q-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for creation, maintenance, and disposition of QA records.

02.02 Inspection of QA Program Implementation

- a. Obtain a sample of completed individual records from the implementing documents. Verify that they have been developed and maintained in accordance with licensee implementing documents.
- b. Visit a sample of temporary records storage areas, e.g., designated location, filing area. Interview staff and verify that records (including in-process records and electronic records) are being maintained in accordance with applicable licensee implementing documents.
- c. Visit a sample of main records storage facilities that are for express purpose of long-term storage of records. Examine the facility and interview records personnel to verify that the facility meets Licensee QAPD and implementing document requirements.

69021Q-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address creation and control of QA records related to safety-related items (and services). Records furnish evidence of activities affecting quality during construction. Implementation of the QAPD will result in the creation of numerous QA records during the construction phase. These records are created to support objective evidence that the NPUF has been constructed to design specifications and in accordance with regulations and implementing documents. Inspections within this appendix will verify that adequate procedural controls have been established to maintain quality-affecting records and assure proper identification and retrievability of these records.

Emphasis during inspection should be placed on confirming the adequacy of records related to safety-related items and design control activities during the construction phase. Permanent

records and short-term records need to be identified and stored in location(s) that protect them from damage from moisture, temperature, and pestilence. Additional provisions need to be made for special processed records (e.g., radiographs, photographs, negatives, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

For records maintained in electronic media, rapid changes in computer software, hardware, and storage media necessitate providing for migration of electronic records to other media if degradation or obsolescence of the media is identified.

Appendix R: Inspection of Requirement 2.18—Assessments

69021R-01 INSPECTION OBJECTIVES

- 01.01 Verify that the licensee's QA implementing documents for conducting assessments are consistent with the NRC-approved QAPD and commitments in the SAR.
- 01.02 Verify that the licensee has effectively implemented its QA implementing documents for conducting assessments.

Note: ANSI/ANS 15.8, "Quality Assurance Program Requirements for Research Reactors," uses the term assessment rather than audit.

69021R-02 INSPECTION REQUIREMENTS

Inspection Requirements

02.01 Inspection of QA Implementing Documents

Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and SAR commitments for conducting assessments.

02.02 Inspection of QA Program Implementation

Select a sample of the recently completed assessment reports and verify that they have been scheduled and performed in accordance with implementing document requirements. Verify that the qualifications of personnel performing the assessments were in accordance with implementing document requirements, and that follow-up to assessment findings were performed in accordance with implementing requirements. Verify that assessment results were documented and reviewed by management personnel who have responsibility for the area assessed. Verify that conditions requiring prompt corrective action are reported immediately to the appropriate management of the assessed organizations. Inspection of the implementation of the assessment program should also be performed on annual basis, with the same sample size as established in Section 04.02 of this appendix.

69021R-03 INSPECTION GUIDANCE

General Guidance

The inspector should find implementing documents that specifically address the conduct of assessments by the licensee. Verify personnel conducting assessments evaluate programmatic compliance and effectiveness of the implementation of the QA program. Inspectors should verify licensee assessments are appropriately planned and documented evaluations are performed by trained personnel.

Verify internal assessments conducted by the licensee focus on activities performed by the licensee and by contractors that work to the licensee's QA program. External assessments conducted by the licensee should focus on safety and quality related activities performed by

contractors that work to their own QA programs or that provide commercial grade items for dedication.

Verify assessment teams consist of personnel who have undergone training to be recognized as qualified. The assessment team may include specialists in specific areas, in addition to the qualified assessment personnel. This is common when the area to be assessed is of a more technical or complex nature.

Attachment 1: Revision History for IP 69021

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML15083A164 12/14/15 CN 15-029	Initial Issue to provide guidance for the QA inspections of Non-power Production and Utilization Facilities licensed under Part 50.	Briefing for inspectors – prior to performing inspections covered by this IP	ML15190A088
N/A	ML17213A959 09/12/17 CN 17-018	This is the initial issuance to provide guidance for the QA inspections of Non-Power Production and Utilization Facilities licensed under Part 50.	N/A	ML17213A961
N/A	ML24264A207 Date 03/25/25 CN 25-005	Inspection procedure was rewritten for conformance with changes to IMC 2550.	N/A	N/A