INSPECTION PROCEDURE 69021

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

PROGRAM APPLICABILITY: 2550

69021-01 INSPECTION OBJECTIVES

01.01 To verify that 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 verify that the licensee has effectively implemented its QA program implementing documents during construction activities.

69021-02 INSPECTION REQUIREMENTS AND GUIDANCE

02.01 Background. The regulations in 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) would 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: 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.

02.02 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 in order 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. Contained within each appendix are guidance and requirements for inspecting the applicable portions of the QA program and its implementation. Exhibit 1, "Inspection Frequency for IP 69021 Appendices," provides a separate periodicity for inspecting both the program documents and the program implementation for each of the 18 appendices. At this time, NPUFs are not expected to be performing activities that would require the implementation of Requirement 2.19, "Experimental Equipment." If this changes, an additional appendix may need to be added to this IP to address those requirements.

3. The actual planning and scheduling of these inspections should factor in the importance to safety of the ongoing activities. Sampling recommendations for conducting the inspections are provided in each of the 18 appendices. However, the inspector should take into account the risks at the facility as shown in the CP and focus the level of effort commensurate with the importance of the safety system. The inspection team leader should coordinate with the Region 2 RPI in the development of its inspection plan and sample sizes for a QA inspection.

4. The inspection schedules and sample sizes provided in Exhibit 1 and in each of the appendices to this IP are to be used as guidance and should not be construed as requirements. The NPUF Facility Specific Assessment and Review Group (FSARG) 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.

The inspection will be performed in accordance with the inspection plan. Unexpected events subsequent to approval of the inspection plan, for example, a delay in construction materials delivery or change in inspection dates, may result in changes to the inspection when conducted.

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 portion(s) of their QA program implementation to other organization(s) working on behalf of the licensee (as an agent of the licensee), the NRC 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 schedule illustrated in Exhibit 1.

d. Requirements for the Inspection of QA Program Implementation.

Verify that the licensee's QA program has been implemented effectively by the responsible organization(s). Perform the inspection by using direct observations, conducting interviews, and examining QA records. Although examination of completed records is essential to a thorough inspection, 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 schedule illustrated 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.

02.03 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 six 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 will be performed of selected appendices, at a periodicity as indicated in Exhibit 1.

b. Gather pertinent information and discuss inspection planning and scheduling issues with the appropriate Region II RPI, 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 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 in order to further develop specific inspection tasks.

e. During the conduct of the inspections, 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 in order 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 have an understanding of 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 course of the inspection because several appendices may apply to each construction activity).

f. During inspection of structures, systems, and components (SSC), IP 69020, 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. If the inspector observes the installation of a component, the inspector should consider 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 should 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 should 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.

69021-03 RESOURCE ESTIMATE

The resource estimate for conducting inspections during the first 12 months of construction is approximately 128 hours of direct inspection effort. This is based upon 64 hours of review of the QA program documents and 64 hours of inspection of QA program implementation over a period of 12 months.

The resource estimate for conducting inspections of QA program implementation during each remaining 12-month period of construction is approximately 64 hours of direct inspection effort per year.

For a site working under an 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 reduced to the QA safety-related work activities allowed under the LWA.

69021-04 REFERENCES

NOTE: Additional references specific to Appendix A through Appendix R are included in the Reference section of that appendix.

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.”

69021-05 PROCEDURE COMPLETION

For construction activities, implementation of this IP is considered complete when the applicable appendices are complete for the designated periodicity presented in Exhibit 1.

END

Exhibit:

1. Inspection Frequency for IP Appendices.

Appendices:

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

Attachment:
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 six 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 scheduled for those implementation activities that could not be completed during the Initial Team Inspection (e.g., due to insufficient activities being completed at the time of the initial team inspection). The goal is to cover all applicable QA Program implementation guidance described in the appendices to this IP during the first year of construction, however this might not be practical based on the type and amount of construction completed during the first year (e.g., there might not be enough testing work being performed to complete the QA Program Implementation inspections described in Appendix K). To the extent practicable, follow-up QA Program implementation inspections should be performed in conjunction with SSC inspections described in IP 69020.

Annual QA programmatic inspection

Annual QA Program Implementation inspections should usually address the requirements in the following appendices:

- Appendix C, Inspection Guide for Requirement 2.3 - Design Control
- Appendix O, Inspection Guide for Requirement 2.15 - Control of Nonconforming Items and Services
- Appendix P, Inspection Guide for Requirement 2.16 - Corrective Actions
- Appendix R, Inspection Guide for Requirement 2.18 - Assessments

The scope of the annual QA Inspection should be adjusted to include additional Appendices if appropriate. Additionally, the inspection should consider what other appendices should be evaluated during the annual inspection with the goal of examining each applicable appendix over a number of years or annual inspections.

Examples of when an expanded annual inspection scope would be appropriate include:

- Major changes to the Licensee's organizations (Appendix A)
- Major changes to the Licensee's QAPD (Appendix B)
- NRC management has determined that specific aspects of the Licensee's program require greater inspection attention (e.g., multiple findings or an adverse trend related to procurement activities might result in an expansion of the scope to include Appendices D and G)
- QA Program Implementation for a specific Appendix has not yet been covered under other inspections

Appendix A. Inspection of Requirement 2.1 – Organization

69021-A1.01 INSPECTION OBJECTIVES

A1.01.01 Verify that the licensee's QA implementing documents for organization are consistent with the NRC-approved QAPD and commitments in the safety analysis report (SAR).

A1.01.02 Verify that the licensee has effectively implemented its QA implementing documents for organization.

69021-A1.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix B, "Inspection of Requirement 2.2 - Quality Assurance Program"

Appendix D, "Inspection of Requirement 2.4 - Procurement Document Control"

Appendix R, "Inspection of Requirement 2.18 - Assessments"

69021-A1.03 SAMPLE SIZE

A1.03.01 The inspector will examine documents and records and will interview personnel to verify implementation of the licensee's organizational structure, responsibilities, and authorities. The licensee may have one overall and several sub tier organizational descriptions. A representative sample would include the overall organizational description and a selection of up to three sub tier organizational descriptions.

The inspector will interview personnel who perform activities that meet quality objectives and perform specific QA functions (see "General Guidance" below) to determine whether they have an adequate understanding of the program and their roles. A representative sample would include at least one member who performs specific QA oversight functions and up to five staff members not assigned to conduct specific QA oversight functions but who implement the licensee's QA program.

69021-A1.04 INSPECTION REQUIREMENTS AND 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 whether 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 whether the licensee has delegated responsibilities through the purchase order and whether 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.

Inspection Requirements.

A1.04.01 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 organization.

b. Review applicable sections of the licensee's QAPD and SAR. Ensure that appropriate implementing documents address QA functions and responsibilities:

A1.04.02 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 organization).

d. Interview a sample of personnel that perform QA oversight functions to determine whether 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 performs activities in support of quality objectives to determine whether 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 whether 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.

Appendix B. Inspection of Requirement 2.2 – Quality Assurance Program

69021-A2.01 INSPECTION OBJECTIVES

A2.01.01 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.

A2.01.02 Verify that the licensee has effectively implemented its QA implementing documents for the QA program.

69021-A2.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix A, "Inspection of Requirement 2.1 – Organization"

Appendix R, "Inspection of Requirement 2.18 – Assessments"

69021-A2.03 SAMPLE SIZE

A2.03.01 It is anticipated that the licensee will have a limited number of implementing documents that provide uniform direction for establishing the QA program, for indoctrination and training of personnel, and for assessing the status and adequacy of the QA program. If there are one or two documents, the inspector will review all implementing documents. If there are more than two, a representative sample of no more than three implementing documents will be reviewed.

A2.03.02 The inspector will examine documents and interview personnel to verify implementation

69021-A2.04 INSPECTION REQUIREMENTS AND 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 that is reviewed as part of the NRC's evaluation of the licensee's SAR.

Inspection Requirements.

A2.04.01 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.

A2.04.02 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 10CFR 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 ascertain whether 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 whether 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 A2.04.02.c above):

(a) 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.

Appendix C. Inspection of Requirement 2.3 – Design Control

69021-A3.01 INSPECTION OBJECTIVES

A3.01.01 Verify that the licensee's QA implementing documents for design control are consistent with the NRC-approved QAPD and commitments in the SAR.

A3.01.02 Verify that the licensee is effectively implementing its design control program.

69021-A3.02 RELATED INSPECTION PROCEDURES AND REFERENCES

None

69021-A3.03 SAMPLE SIZE

A3.03.01 This IP appendix covers both initial design activities and design change activities that are associated with preserving and implementing the completed design during the construction phase after the final system designs have been completed. This can be accomplished by reviewing a sample of up to 3 design documents (samples should be from different disciplines, e.g., Mechanical, Civil, Electrical, etc.) and a sample of two design changes and 2 field changes. In addition, inspectors should assess the implementation of the licensee's documents for controlling the turnover of the design information from the design authority to the licensee or from multiple construction contractors to the licensee. The review of the turnover of design information should be accomplished for three systems on a one-time basis.

69021-A3.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

Inspection of the licensee's implementation of design control can also be reviewed through 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.

Inspection Requirements.

A3.04.01 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.

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.

A3.04.02 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.

d. Ensure that proper verification, validation, and version control of all quality related computer software used in the performance of design work.

e. 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.

f. 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.

Appendix D. Inspection of Requirement 2.4 – Procurement Document Control

69021-A4.01 INSPECTION OBJECTIVES

A4.01.01 Verify that the licensee's QA implementing documents for procurement document control are consistent with the NRC-approved QAPD and commitments in the SAR.

A4.01.02 Verify that the licensee has effectively implemented its QA program implementing documents for procurement document control.

69021-A4.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix G, "Inspection of Requirement 2.7 - Control of Purchased Items and Services"

Appendix M, "Inspection of Requirement 2.13 – Handling, Shipping, and Storage"

Appendix O, "Inspection of Requirement 2.15 - Control of Nonconforming Items and Services"

69021-A4.03 SAMPLE SIZE

A4.03.01 The inspector will examine safety related procurement documents to verify implementation of the procurement process. A representative sample would include up to a total of 3 procurement documents, with a mix of licensee and contractor procurement documents.

The inspector should review the SAR and select some safety related plant equipment. The inspector should then review the purchase specifications for that equipment to confirm that those SAR attributes are included in the specifications.

69021-A4.04 INSPECTION REQUIREMENTS AND 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.

Inspection Requirements.

A4.04.01 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.

A4.04.02 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.

Appendix E. Inspection of Requirement 2.5 – "Procedures, Instructions, and Drawings" – Instructions, Procedures, and Drawings

69021-A5.01 INSPECTION OBJECTIVE

A4.01.01 Verify that the licensee's QA program documents for preparing and revising implementing instructions, procedures and drawings that prescribe activities affecting quality are consistent with the NRC-approved QAPD and commitments in the SAR.

A5.01.02 Verify that the licensee has effectively implemented its QA program implementing instructions, procedures and drawings for revising implementing documents.

A5.01.02 Verify that the licensee personnel are trained to follow safety-related instructions and procedures.

69021-A5.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix F, "Inspection of Requirement 2.6 – Document Control"

Appendix Q, "Inspection of Requirement 2.17 – Quality Records"

69021-A5.03 SAMPLE SIZE

A5.03.01 The licensee typically will have numerous categories of implementing documents. A representative sample of implementing documents that address applicable administrative and technical activities should be selected. Up to 2 administrative and 3 technical implementing documents should be inspected, for a total of no more than 5.

A5.03.02 The inspector will inspect new, revised and modified implementing documents to verify implementation of this appendix. A representative sample of no more than 3 implementing documents that have been changed will be inspected.

69021-A5.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

The inspector should find QA program documents that specifically address preparation and modification of implementing documents that establish requirements for conducting quality-affecting activities that involve 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.

Inspection Requirements.

A5.04.01 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).

A5.04.02 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.

Appendix F. Inspection of Requirement 2.6 – Document Control

69021-A6.01 INSPECTION OBJECTIVE

A6.01.01 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.

A6.01.02 Verify that the licensee has effectively implemented its QA program documents related to document control.

69021-A6.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix E, "Inspection of Requirement 2.5 - Procedures, Instructions, and Drawings"

Appendix Q, "Inspection of Requirement 2.17 – Quality Records"

69021-A6.03 SAMPLE SIZE

A6.03.01 It is anticipated that the licensee will have a limited number of implementing documents for document control. If there are one or two documents, the inspector review all implementing documents. If there are more than two, a representative sample of no more than 3 implementing documents will be reviewed.

A6.03.02 The inspector will examine lists of quality-affecting controlled documents, paper copy and electronic controlled documents, and other documentation to verify implementation of this appendix, e.g.:

a. Lists of currently controlled documents - a representative sample would include no more than two lists.

   NOTE: licensee may have separate systems for controlling instructions, procedures, design drawings, and other controlled implementing documents.

b. Current controlled documents under electronic control - a representative sample of no more than five documents to verify: 1) access to documents and 2) records of review.

c. Current controlled documents under paper copy control (different selection from b. above) - a representative sample of no more than five documents to verify: 1) access to documents, 2) indication as controlled document, and 3) records of review.

d. Current controlled documents that have been revised (different selection from b. and c. above) - a representative sample of no more than five documents.

e. Current controlled documents under paper copy control at work location (different selection from b., c. and d. above) - a representative sample would include a total of six documents to verify: 1) access to documents and 2) indication as controlled document.

f. Most recently cancelled/rescinded and expired documents - a representative sample of no more than four documents.

69021-A6.04 INSPECTION REQUIREMENTS AND GUIDANCE

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 actually have direct access to the correct (e.g., current revision) documents that apply to the activities that are performing.

Inspection Requirements.

A6.04.01 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

A6.04.02 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.

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

69021-A7.01 INSPECTION OBJECTIVE

A7.01.01 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.

A7.01.02 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.

69021-A7.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix D, "Inspection of Requirement 2.4 - Procurement Document Control"

Appendix M, "Inspection of Requirement 2.13 - Handling, Shipping, and Storage"

69021-A7.03 SAMPLE SIZE

A7.03.01 It is anticipated that the licensee will have a limited number of implementing documents for control of purchased items and services. If there are one or two documents, the inspector will review all implementing documents. If there are more than two, a representative sample of no more than three implementing documents will be reviewed.

A7.03.02 The inspector will examine various records and other documentation to verify implementation. A representative sample would include a total of 4 procurements.

69021-A7.04 INSPECTION REQUIREMENTS AND 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) activities performed on behalf of the licensee by those contractors acting as an agent to the licensee.

Inspection Requirements.

A7.04.01 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.

A7.04.02 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.

Appendix H. Inspection of Requirement 2.8 – Identification and Control of Items

69021-A8.01 INSPECTION OBJECTIVES

A8.01.01 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.

A8.01.02 Verify that the licensee has effectively implemented its QA implementing documents for the identification and control of items.

69021-A8.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix O, "Inspection of Requirement 2.15 - Control of Nonconforming Items and Services"

Appendix P, "Inspection of Requirement 2.16 – Corrective Actions"

69021-A8.03 SAMPLE SIZE

A8.03.01 The inspector will examine items to verify implementation of the licensee's process for identification and control of items. A representative sample of no more than 5 individual items and their associated markings, documentation, and records will be selected.

69021-A8.04 INSPECTION REQUIREMENTS AND 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 that items that are procured, installed, and used are traceable. 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 by the use of 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 whether accepted items are controlled adequately to ensure that they are not used if a nonconformance or corrective action is identified.

Inspection Requirements.

A8.04.01 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.

A8.04.02 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.

Appendix I. Inspection of Requirement 2.9 – Control of Special Processes

69021-A9.01 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.

69021-A9.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix K, "Inspection of Requirement 2.11 – Test Control"

Appendix N, "Inspection of Requirement 2.14 – Inspection, Test, and Operating Status"

69021-A9.03 SAMPLE SIZE

It is anticipated that the licensee will have numerous technical implementing documents that provide specific direction for the control of special processes. A maximum of four implementing documents will be reviewed. Samples should be drawn from more than one of the construction disciplines applicable to the licensee, such as structural/civil, piping, and mechanical.

69021-A9.04 INSPECTION REQUIREMENTS AND 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.

Inspection Requirements.

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.

A9.04.02 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.

Appendix J. Inspection of Requirement 2.10 – Inspection

69021-A10.01 INSPECTION OBJECTIVES

A10.01.01 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.

A10.01.02 Verify that the licensee has effectively implemented its QA implementing documents for inspection of items.

69021-A10.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix G, "Inspection of Requirement 2.7 - Control of Purchased Items and Services"

Appendix K, "Inspection of Requirement 2.11 – Test Control"

Appendix N, "Inspection of Requirement 2.14 – Inspection, Test, and Operating Status"

69021-A10.03 SAMPLE SIZE

A10.03.01 It is anticipated that the licensee will have technical implementing documents that provide specific direction for conducting inspections. A maximum of 4 implementing documents will be reviewed Samples should be drawn from more than a single construction discipline applicable to the licensee, such as structural/civil, piping, mechanical, and electrical/instrumentation and control.

A10.03.02 The inspector will examine items and their associated inspection documentation to verify implementation of the licensee's process for conducting inspection. A representative sample of no more than 5 completed inspections and their associated stamps, tags, labels, routing cards, documentation, and records will be inspected. If licensee inspections are expected to be performed during the NRC inspection of the requirements in this appendix, a representative sample would include observing one active inspection being conducted by the licensee.

69021-A10.04 INSPECTION REQUIREMENTS AND GUIDANCE

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.

Inspection Requirements.

A10.04.01 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.

A10.04.02 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.

Appendix K. Inspection of Requirement 2.11 – Test Control

69021-A11.01 INSPECTION OBJECTIVES

A11.01.01 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.

A11.01.02 Verify that the licensee has effectively implemented its QA implementing documents for test control.

69021-A11.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix J, "Inspection of Requirement 2.10 – Inspection"

Appendix N, "Inspection of Requirement 2.14 – Inspection, Test, and Operating Status"

69021-A11.03 SAMPLE SIZE

It is anticipated that the licensee will have numerous technical implementing documents that provide specific direction for conducting tests. A maximum of 4 implementing documents will be reviewed. Samples should be drawn from more than one construction discipline applicable to the licensee, such as structural/civil, piping, mechanical, pre-op, and electrical/instrumentation and control. A maximum of 4 tests should be selected for inspection, the inspection should include observation of the actual test if possible, but reviewing completed test documentation is an acceptable option. Implementation of test control may also be completed during SSC inspections (e.g., reviewing test performance for the specific SSC being inspected).

69021-A11.04 INSPECTION REQUIREMENTS AND 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.

Inspection Requirements.

A11.04.01Inspection 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

A11.04.02 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.

Appendix L. Inspection of Requirement 2.12 – Control of Measuring and Test Equipment

69021-A12.01 INSPECTION OBJECTIVES

A12.01.01 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.

A12.01.02 Verify that the licensee has effectively implemented its QA program implementing documents for control of M&TE.

69021-A12.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix D, "Inspection of Requirement 2.4 – Procurement Document Control"

Appendix G, "Inspection of Requirement 2.7 - Control of Purchased Items and Services"

Appendix 8, "Inspection of Requirement 2.8 - Identification and Control of Items"

Appendix I, "Inspection of Requirement 2.9 – Control of Special Processes"

Appendix J, "Inspection of Requirement 2.10 – Inspection"

Appendix K, "Inspection of Requirement 2.11 – Test Control"

Appendix M, "Inspection of Requirement 2.13 – Handling, Storage, and Shipping"

Appendix N, "Inspection of Requirement 2.14 – Inspection, Test, and Operating Status"

69021-A12.03 SAMPLE SIZE

A12.03.01 It is anticipated that the licensee will have a limited number of implementing documents that provide uniform, general direction for controlling M&TE. If there are one or two documents, the inspector will review all implementing documents. The licensee also may have numerous technical implementing documents that provide specific direction for controlling M&TE. A maximum of three technical implementing documents will be reviewed. Samples should be drawn from more than one construction discipline applicable to the licensee, such as structural/civil, piping, mechanical, and electrical/instrumentation and control.

A12.03.02 The inspector will examine M&TE, records and other documentation, and observe calibration activities (if possible), to verify implementation of this appendix, e.g.:

a. Licensee's M&TE tracking system - a representative sample would include a total of one system.

b. Calibrated M&TE - a representative sample would include a total of three recent pieces of M&TE (M&TE may be selected from the selection of implementing documents in A12.03.01).

c. New calibrated M&TE recently added to the M&TE tracking system – a representative sample would include a total of two pieces of M&TE (may be from sample of A12.03.02.b).

d. M&TE recently taken out of service because of nonconforming condition - a representative sample would include a total of two pieces of M&TE.

e. M&TE recently taken out of service - a representative sample would include a total of two pieces of M&TE (may be from sample of A12.03.02.d).

f. M&TE located at on-site work facilities - a representative sample would include a total of two pieces of M&TE.

69021-A12.04 INSPECTION REQUIREMENTS AND 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 A12.02 above. M&TE may be calibrated by a contractor (appendices 4 and 7). M&TE is identified, handled, stored (appendices 8, 13, and 14). M&TE also is used to conduct inspections, tests, and special processes (appendices 9, 10, and 11). This IP appendix describes inspection activities that address all of the above-mentioned appendices. Therefore, the inspector should use the appendices in 69021-A12.02 above 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.

Inspection Requirements.

A12.04.01 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.

A12.04.02 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).

Appendix M. Inspection of Requirement 2.13 – Handling, Storage and Shipping

69021-A13.01 INSPECTION OBJECTIVES

A13.01.01 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.

A13.01.02 Verify that the licensee has effectively implemented its QA implementing documents for handling, shipping, and receiving.

69021-A13.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix D, "Inspection of Requirement 2.4 - Procurement Document Control"

Appendix G, "Inspection of Requirement 2.7 - Control of Purchased Items and Services"

Appendix O, "Inspection of Requirement 2.15 – Control of Nonconforming Items and Services"

69021-A13.03 SAMPLE SIZE

A13.03.01 It is anticipated that the licensee may have numerous implementing documents for the handling, storage, and shipping of items. If there are up to five implementing documents, the inspector will review two of them. If there are more than five, a representative sample of no more than 3 implementing documents will be reviewed.

A13.03.02 The inspector will examine various types of items for handling, storage, and shipping:

a. At least 3 safety related items that have been received on site. To the extent practical, the samples should include items from at least two of the following categories: mechanical, electrical, instrument/electronic, and consumables (chemicals, reagents, lubricants, filters, etc.). An attempt should be made to choose equipment for which specific storage requirements are required.

b. At least two samples of items that have been handled on site. An attempt should be made to choose equipment for which specific handling requirements are required.

69021-A13.04 INSPECTION REQUIREMENTS AND 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 off-site, as well as on-site, safety related items.

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

Inspection Requirements.

A13.04.01 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.

A13.04.02 Inspection of QA Program Implementation.

a. Inspect a sample of safety related items that have been received on site. Tour the on-site and off-site 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.

Appendix N. Inspection of Requirement 2.14 – Inspection, Test, and Operating Status

69021-A14.01 INSPECTION OBJECTIVES

A14.01.01 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.

A14.01.02 Verify that the licensee has effectively implemented its QA implementing documents for indicating inspection, test, and operating status of items.

69021-A14.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix J, "Inspection of Requirement 2.10 – Inspection"

Appendix K, "Inspection of Requirement 2.11 – Test Control"

Appendix L, "Inspection of Requirement 2.12 - Control of Measuring and Test Equipment"

69021-A14.03 SAMPLE SIZE

A14.03.01 It is anticipated that the licensee will have a limited number of implementing documents that provide uniform direction for indicating inspection, test, and operating status. If there are one or two documents, the inspector will review all implementing documents. However, the licensee may instead have numerous technical implementing documents that provide specific instructions for indicating inspection, test and operating status. If this is the case, then no more than three implementing documents will be reviewed.

A14.03.02 The inspector will examine items to verify implementation of the licensee's process for indicating the inspection, test and operating status of those items. A representative sample of no more than five individual items and their associated stamps, tags, labels, routing cards, documentation, records, or other suitable means.

69021-A14.04 INSPECTION REQUIREMENTS AND GUIDANCE

<u>General Guidance</u>.

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.

Inspection Requirements.

A14.04.01 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

A14.04.02 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.

Appendix O. Inspection of Requirement 2.15 – Control of Nonconforming Items and Services

69021-A15.01 INSPECTION OBJECTIVES

A15.01.01 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.

A15.01.02 Verify that the licensee has effectively implemented its QA implementing documents for the control of nonconforming items.

69021-A15.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix P, "Inspection of Requirement 2.16 – Corrective Actions"

IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance's."

69021-A15.03 SAMPLE SIZE

A15.03.01 The inspector will review the licensee's implementation of its processes for the control of nonconforming items by inspecting no more than five samples of nonconforming items in storage and no more than five samples of nonconformance evaluations for items that have been previously rejected, repaired or reworked.

69021-A15.04 INSPECTION REQUIREMENTS AND 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.

Inspection Requirements.

A15.04.01 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.

A15.04.02 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 requirement.

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.

Appendix P. Inspection of Requirement 2.16 – Corrective Actions

69021-A16.01 INSPECTION OBJECTIVES

A16.01.01 Verify that the licensee's QA implementing documents for the identification, evaluation, and corrective action to conditions adverse to quality are in accordance with the NRC-approved QAPD and commitments in the SAR.

A16.01.02 Verify that the licensee has effectively implemented its corrective action program (CAP).

69021-A16.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix O, "Inspection of Requirement 2.15 – Control of Nonconforming Items and Services"

69021-A16.03 SAMPLE SIZE

A16.03.01 During the first annual team inspection, the inspectors will review up to two CAP implementing documents in accordance with Section A16.04.01 of this appendix. If there are more than two CAP implementing documents, a representative sample of no more than three implementing documents will be reviewed. During subsequent annual inspections, the inspectors will review the licensee's implementation of its CAP by inspecting no more than four significant conditions adverse to quality or 10 CFR 50.55(e) reportable events and four conditions adverse to quality. If the designated number of samples is not available, the inspectors will review all of the available samples. Corrective action implementation should also be inspected during SSC inspections.

69021-A16.04 INSPECTION REQUIREMENTS AND GUIDANCE

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 be mischaracterized and inappropriately handled outside the CAP.

Inspection Requirements.

A16.04.01 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.

A16.04.02 CAP Implementation.

Inspectors will conduct the initial team inspection in accordance with Section 16.04.01. 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 5 significant conditions adverse to quality or 10 CFR 50.55(e) reportable events and 5 conditions adverse to quality. If the designated 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.

Appendix Q. Inspection of Requirement 2.17 – Quality Records

69021-A17.01 INSPECTION OBJECTIVES

A17.01.01 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.

A17.01.02 Verify that the licensee has effectively implemented its QA implementing documents for QA records.

69021-A17.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix E, "Inspection of Requirement 2.5 - Procedures, Instructions, and Drawings"

Appendix F, "Inspection of Requirement 2.6 – Document Control"

69021-A17.03 SAMPLE SIZE

A17.03.01 It is anticipated that the licensee will have a limited number of implementing documents that provide uniform direction for general records creation, maintenance, storage, and disposition. If there are one or two documents, the inspector will review all implementing documents.

In addition, it is anticipated that the licensee will also have numerous other implementing documents that provide specific instructions for the creation of designated records that support the implementation of specific activities. If this is the case, then no more than three implementing documents will be reviewed.

A17.03.02 The inspector will examine records, interview personnel, and visit records storage facilities to verify implementation of this appendix, e.g.:

a. Individual records and records packages - a representative sample would include a total of three documents (may be a mix of records).

b. Temporary records facilities - a representative sample would include no more than one facility.

c. Main records storage facilities - a representative sample would include no more than one facility.

69021-A17.04 INSPECTION REQUIREMENTS AND 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 expected degradation, of the media is identified.

Inspection Requirements.

A17.04.01 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.

A17.04.02 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.

Appendix R. Inspection of Requirement 2.18 – Assessments

69021-A18.01 INSPECTION OBJECTIVES

A18.01.01 Verify that the licensee's QA implementing documents for conducting assessments are consistent with the NRC-approved QAPD and commitments in the SAR.

A18.01.02 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.

69021-A18.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix A, "Inspection of Requirement 2.1 – Organization"

Appendix B, "Inspection of Requirement 2.2 - Quality Assurance Program"

Appendix G, "Inspection of Requirement 2.7 - Control of Purchased Items and Services"

69021-A18.03 SAMPLE SIZE

A18.03.01 It is anticipated that the licensee will have a limited number of implementing documents that provide uniform direction for conducting assessments. If there are one or two documents, the inspector will review all implementing documents. If there are more than two, a representative sample of no more than three implementing documents will be reviewed.

A18.03.02 The inspector will examine assessment schedules, reports, and associated documentation (such as plans and personnel qualifications) to verify implementation of the licensee's process for conducting assessments. A representative sample would include a maximum of one schedule, two internal assessment reports, two external (contractor) assessment reports, two follow-up actions, and associated documentation (e.g., plans, team qualifications).

69021-A18.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

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

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 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.

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.

Inspection Requirements.

A18.04.01 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.

A18.04.02 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 A18.03.02 of this appendix.

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 and Feedback Resolution Accession Number (Pre-Decisional, Non-Public)
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