

QUALITY ASSURANCE PROGRAM IMPLEMENTATION DURING CONSTRUCTION AND PRE-CONSTRUCTION ACTIVITIES

PROGRAM APPLICABILITY: 2502, 2504 App A

35007-01 INSPECTION OBJECTIVES

- 01.01 To verify that the holder of a combined license (COL) or a Limited Work Authorization (LWA) (collectively: licensee) has developed quality assurance (QA) procedures, instructions, and other documents (collectively: implementing documents) that are consistent with the licensee's NRC-approved QA program description (QAPD) that is 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.
- 01.03 To verify that the applicant for a COL has effectively developed and implemented its QA program implementing documents for pre-construction activities¹ that may support future inspections, tests, analyses, and acceptance criteria (ITAAC) closure evaluation activities, including oversight of its contractors.

35007-02 INSPECTION REQUIREMENTS AND GUIDANCE

Exhibits 1 and 2 do not apply to pre-construction inspections. Throughout this procedure, including Appendix 1 through Appendix 18, the term "applicant" should be substituted for "licensee," and the term "pre-construction" should be substituted for "construction," for those inspections related to pre-construction activities.

02.01 Background.

The regulations in 10 CFR Part 52 require that a QA program that meets the requirements of Appendix B to 10 CFR Part 50 be approved by the NRC for LWA and COL quality-related activities. Although not a requirement, it is expected that all 10 CFR Part 52 licensees will have committed to a version of ASME's NQA-1 as a way of meeting, in part, the requirements of Appendix B to 10 CFR Part 50. This commitment is contained in the licensee's NRC reviewed and approved QAPD, which describes the overall approach to meeting the Appendix B requirements. In preparation for inspection, inspectors should review the QAPD and the applicable revision to the NQA-1 guidance

¹ Pre-Construction Activity: Any activity conducted prior to issuance of a COL or LWA by the applicant or contracted suppliers on behalf of the applicant associated with a proposed ITAAC for safety-related components or portions of the proposed facility and occurring at other than the final, in-place location at the facility.

referenced in the QAPD. These documents should be used in conjunction with the specific guidance and inspection requirements contained in this inspection procedure (IP).

Ongoing work that supports the NRC's future closure verification of ITAAC may be performed during pre-construction activities by the applicant and its contractors. The NRC will inspect the applicant's oversight of pre-construction activities that may support the NRC's future closure verification of ITAAC.

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 criteria of Appendix B to 10 CFR Part 50 are contained within Appendix 1 through Appendix 18 of this IP. Contained within each appendix are guidance and requirements for inspecting the applicable portions of the QA program and its implementation. Exhibit 1, "Inspection Frequency Matrix for IP 35007 Appendices," provides a separate periodicity for inspecting both the program documents and the program implementation for each of the 18 appendices.
3. Exhibit 2, Inspection Categories of Associated Criteria of Appendix B to 10 CFR Part 50, provides suggested groupings of the appendices to this IP to be considered when planning inspections of QA program implementation. Inspections may also be planned to coincide with other inspection activities to optimize use of NRC inspectors.
4. The actual planning and scheduling of these inspections should factor in the importance to safety of the ongoing activities. All inspection activities should be coordinated through Region II staff. Sampling recommendations for conducting the inspections are provided in each of the 18 appendices.
5. The inspection sample sizes provided in each of the appendices are to be used as guidance and should not be construed as requirements. For the initial QA program review and implementation, the sampling recommendations found in the 18 appendices should be followed. For subsequent years, Region II will determine the construction QA criteria to be inspected and number of samples required for the following year at the end-of-cycle assessment. Criteria and samples shall be selected based on licensee performance, projected construction activities, programmatic changes, and any other considerations. Continuous assessment will be performed throughout the year (per IMC 2505) and Region II can adjust samples based on emergent issues.
6. The inspection sample sizes in each of the appendices should also include some graded QA program activities for important to safety equipment needed to meet the regulations in 10 CFR 50.48, "Fire Protection," 10 CFR 50.49, "Environmental Qualification of Electrical Equipment Important to Safety for Nuclear Power Plants,"

10 CFR 50.62, "Requirements for Reduction of Risk from Anticipated Transients without Scram Events for Light Water Nuclear Power Plants," 10 CFR 50.63, "Loss of All Alternating Current Power," (i.e., Station Blackout) and 10 CFR 50, Appendix S, Earthquake Engineering Criteria for Nuclear Power Plants." These graded QA programs affect active defense in depth equipment and/or Regulatory Treatment for Non-Safety Systems (RTNSS) found under UFSAR Section 17.4, "Reliability Assurance Program," where non-safety related equipment is classified as important to safety and/or risk significant under the licensee's site specific probabilistic risk assessment (PRA).

b. Requirements for Performance of Inspections.

The inspection will be performed in accordance with the inspection plan. Adjustments to the inspection plan should be communicated to the Region II staff to minimize impact on the licensee or applicant and to assist in revising inspection planning efforts accordingly. 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 Appendix B to 10 CFR Part 50 and the licensee's QAPD. Select the appropriate appendix or appendices to this IP that address the criteria of Appendix B to 10 CFR Part 50 that have been assigned in the inspection plan. Use the sections of the appendix or appendices that address the inspection of the QA program implementing documents. Where the licensee has delegated portions of its 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 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 organizations. 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. Inspectors should exercise judgment 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 0613.

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 criteria for the first year of construction. After the initial team inspection, periodic inspections will be performed of selected criteria of Appendix B to 10 CFR Part 50, at a periodicity as indicated in Exhibit 1.

- b. Gather pertinent information and discuss inspection planning and scheduling issues with the appropriate Region II Branch Chief, or designee, for example:
 1. Importance and prioritization of activities.
 2. Concurrent inspections to be conducted using other IPs.
 3. 10 CFR Part 21 and 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. Using the information gathered in b and c above, determine which activities will be inspected and develop the inspection plan accordingly. Use the appropriate appendices to this IP that address the criteria of Appendix B to 10 CFR Part 50 that are relevant to the activities to be inspected in order to further develop specific inspection tasks.
- e. During 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 9 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 10 CFR Part 50 Appendix B requirements:

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 criteria of Appendix B to 10 CFR Part 50 may apply to each construction activity.
- f. During the routine implementation inspections, the inspector should focus on the review and observation of a variety of safety-related construction activities, 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 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 Appendix B criteria, and sections of this procedure, can be accomplished for almost any safety-related construction activity.

02.04 Pre-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.

Inspections are conducted when the applicant or their contractors are performing pre-construction activities that support the NRC's future ITAAC closure verification. Resident inspectors will communicate with the applicant and its contractors to determine when they will be performing applicable activities. All pre-construction inspection activities should be coordinated through Region II staff.

Region II staff will identify pre-construction activities that are ongoing both in proximity to the construction site, and at remote locations. Inspection of the applicant's oversight of pre-construction activities that are ongoing in proximity to the construction site will primarily be conducted by the construction resident inspector staff. Inspection of pre-construction activities that are ongoing at remote locations will require coordination between Region II staff, [Division of Reactor Oversight \(DRO\)](#) and [the Vogtle 3 & 4 Project Office \(VPO\)](#) prior to initiation of the inspection activities. NRC oversight of most pre-construction activities that occur at remote locations (i.e., vendors) should be

accomplished through vendor inspections. There should be minimal impact to the contractor during the inspection. Unexpected events, such as a delay in contractor activities or revisions to the scope of the contractors activities may result in changes to the proposed inspection activities.

For the purposes of evaluating the applicant's oversight of pre-construction activities, the inspector should primarily focus on appendices of this IP that address procurement of contractor items and services, and oversight of contractor activities. In conjunction with the applicable appendices in this IP, the inspector may be informed by the IP 65001 series of inspection procedures that apply to the contractor activity being inspected (e.g., welding).

- b. Gather pertinent information and discuss inspection planning and scheduling issues with the appropriate Region II Branch Chief, or designee, for example:
 1. How inspection of this activity may support the NRC's future ITAAC closure verification.
 2. Importance/prioritization of pre-construction activities.
- c. Contact the applicant and contractor for information needed to conduct the inspection, for example:
 1. Activity to be performed by the contractor.
 2. Location and estimated time period of performance of activity.
 3. Availability of applicant personnel during the period tentatively scheduled for the inspection. It is not necessary for a representative of the applicant to be present during the inspection.
- d. Using the information gathered in b and c above, determine which activities will be inspected and develop the inspection plan accordingly. Use the appropriate appendix or appendices to this IP that address the criteria of Appendix B to 10 CFR Part 50 that are relevant to the activities to be inspected in order to further develop specific inspection tasks.
- e. During 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 the applicable IP 65001 series document as the primary tools to conduct the inspection.

The inspector would then perform the following in order to verify that the applicant's QA program for procurement and oversight of contractors has been implemented effectively by the responsible organizations for pre-construction activities that may support the NRC's future closure verification of ITAAC:

1. Determine what implementing documents were used by the contractor to conduct the activity.

2. Observe the activity being performed to see that it is conducted in accordance with the applicable implementing document.
3. Conduct interviews with contractors 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 criteria of Appendix B to 10 CFR Part 50 may apply to each pre-construction activity.

35007-03 RESOURCE ESTIMATE

The resource estimate for conducting inspections during the first 12 months of construction is approximately 866 hours of direct inspection effort. This is based upon 180 hours of review of the QA program documents by a five-person team for one week, plus 686 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 may change based on the criteria and samples selected for inspection during the end-of-cycle assessment.

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 COL. Within this limited safety-related work scope, the resource estimate should be reduced to the QA safety-related work activities allowed under the LWA.

The resource estimate for conducting inspections of pre-construction activities depends on the amount of such activities occurring before a COL is issued that may support the NRC's closure verification of ITAAC. However, the resource estimate for conducting pre-construction inspections should not exceed approximately 100 hours of direct inspection.

Licensees may have contractors acting as their agents but using separate QA programs. For this circumstance, additional inspection resources may be necessary to review additional QA programs. The following areas should be evaluated for each contractor to determine if its QA program should be reviewed and the necessary level of review:

- a. The contractor's scope of work;
- b. Applicability of each criteria of 10 CFR Part 50, Appendix B; and
- c. The need for full or partial samples for each applicable criterion.

35007-04 PROCEDURE COMPLETION

For pre-construction activities, implementation of this IP may continue up until the Commission issues a COL.

For construction activities, the initial QA program review and implementation inspection is considered complete when the recommended samples listed in each appendix have been inspected (first year only).

For subsequent years, this IP is considered complete when the samples identified for inspection during the end-of-cycle assessment are complete.

35007-05 REFERENCES

NOTE: Additional references specific to Appendix 1 through Appendix 18 are included in the Reference section of that appendix.

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

10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

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

10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," American Society for Mechanical Engineers.

Inspection Manual Chapter 0613, "Power Reactor Construction Inspection Reports."

Inspection Manual Chapter 2502, "Construction Inspection Program: Pre-Combined License (Pre-COL) Phase."

Inspection Manual Chapter 2503, "Construction Inspection Program: Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) Related Work."

Inspection Manual Chapter 2504, "Construction Inspection Program: Inspections of Construction and Operational Programs."

Inspection Procedure 65001, "Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) Related Work" (NOTE: There are over 25 IPs with two numbering schemes (e.g., 65001.01 and 65001.A) that support IP 65001.)

END

Exhibits:

1. Inspection Frequency Matrix for IP 35007 Appendices.
2. Inspection Categories of Associated Criteria of Appendix B to 10 CFR Part 50.

Appendices:

1. Inspection Guide for Criterion I - Organization
2. Inspection Guide for Criterion II - Quality Assurance Program
3. Inspection Guide for Criterion III - Design Control
4. Inspection Guide for Criterion IV - Procurement Document Control
5. Inspection Guide for Criterion V - Instructions, Procedures and Drawings
6. Inspection Guide for Criterion VI - Document Control
7. Inspection Guide for Criterion VII - Control of Purchased Material, Equipment, and Services

8. Inspection Guide for Criterion VIII - Identification and Control of Materials, Parts and Components
9. Inspection Guide for Criterion IX - Special Processes
10. Inspection Guide for Criterion X - Inspection
11. Inspection Guide for Criterion XI - Test Control
12. Inspection Guide for Criterion XII - Control of Measuring and Test Equipment
13. Inspection Guide for Criterion XIII - Handling, Storage, and Shipping
14. Inspection Guide for Criterion XIV - Inspection, Test, and Operating Status
15. Inspection Guide for Criterion XV - Nonconforming Materials, Parts, or Components
16. Inspection Guide for Criterion XVI - Corrective Action
17. Inspection Guide for Criterion XVII - Quality Assurance Records
18. Inspection Guide for Criterion XVIII - Audits

Attachment:

1. Revision History for IP 35007

Exhibit 1. Inspection Frequency Matrix for IP 35007 Appendices.

IP 35007 Appendix #	10 CFR Part 50 Appendix B Criterion Title and IP 35007 Appendix Title	Year 1: Initial Team Inspection within 6 mo. of initiation of construction activities and other QA Program Implementation Inspections		Subsequent years: QA Program Implementation
		QA Program Review (initial team inspection)	QA Program Implementation (during initial team inspection and throughout Year 1)	As determined during end-of-cycle assessment
1	Organization	x	x	x
2	Quality Assurance Program	x	x	x
3	Design Control	x	x	x
4	Procurement Document Control	x	x	x
5	Instructions, Procedures, and Drawings	x	x	x
6	Document Control	x	x	x
7	Control of Purchased Material, Equipment, and Services	x	x	x
8	Identification and Control of Materials, Parts, and Components	x	x	x
9	Control of Special Processes	x	implementation inspection through other IPs	
10	Inspection	x	x	x
11	Test Control	x	implementation inspection through other IPs	
12	Control of Measuring and Test Equipment	x	x	x
13	Handling, Storage and Shipping	x	x	x
14	Inspection, Test, and Operating Status	x	x (if activities exist in this area)	x
15	Nonconforming Materials, Parts, or Components	x	x	x
16	Corrective Action	x	x	x
17	Quality Assurance Records	x	x	x
18	Audits	x	x	x

NOTE: This matrix shows the recommended periodicity for implementing each of the 18 appendices. After the first year, each appendix is considered complete when the minimum number of samples is completed within the time period as determined during end-of-cycle assessment. The actual inspection may be completed at any time within the given time period.

Exhibit 2. Inspection Categories of Associated Criteria of Appendix B to 10 CFR Part 50.

Inspection Category	IP 35007 Appendix	Appendix B to 10 CFR 50 – Criterion and Title
Management Controls	1	I Organization
	2	II Quality Assurance Program
	18	XVIII Audits
Design Control	3	III Design Control
Procurement and Control of Items and Services, and Nonconformance's	4	IV Procurement Document Control
	7	VII Control of Purchased Material, Equipment, and Services
	13	XIII Handling, Storage and Shipping
	15	XV Nonconforming Materials, Parts or Components
Work Controlling Documents and Records	5	V Instructions, Procedures, and Drawings
	6	VI Document Control
	17	XVII Quality Assurance Records
Control of Material and Equipment	8	VIII Identification and Control of Materials, Parts, and Components
Inspection and Test Control	10	X Inspection
	11	XI Test Control
	14	XIV Inspection, Test, and Operating Status
Corrective Action	16	XVI Corrective Action
Measuring and Test Equipment	12	XII Control of Measuring and Test Equipment
Control of Special Processes	9	IX Control of Special Processes

Appendix 1. Inspection of Criterion I – Organization

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

A1.01.02 Verify that the licensee has effectively implemented its QA implementing documents for organization, including delegation of authority.

35007-A1.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 2, “Inspection of Criterion II – Quality Assurance Program”

Appendix 4, “Inspection of Criterion IV – Procurement Document Control”

Appendix 18, “Inspection of Criterion XVIII – Audits”

35007-1-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 subtier organizational descriptions. A representative sample would include the overall organizational description and a selection of up to three subtier organizational descriptions. In addition, a representative sample of delegations of authority would include five documented delegations.

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 five QA staff who perform specific QA functions and five staff not assigned to conduct specific QA functions but who implement the licensee’s QA program.

35007-A1.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

The inspector should find implementing documents that specifically address the licensee’s organizational structure, responsibilities, authorities, and delegation of authority. The licensee’s entire staff, including contractors (e.g., subcontractors, agents, suppliers, vendors), is responsible for performing activities that meet quality objectives that affect safety-related functions of structures, systems, and components (SSCs).

In addition, the licensee should have specific staff members who have been designated to perform specific QA functions that are independent of the work being performed. These functions include: establishing the QA program (including the QAPD and implementing documents), determining whether the QA program is effectively being implemented (conducting

oversight activities), and verifying that safety related and important to safety activities have been performed correctly (may be recognized as the quality control (QC) function).

Inspection of the licensee's organization may require more in-depth interviews of staff and management than other criteria of Appendix B to 10 CFR Part 50. The inspection of implementation in this area should be directed at verifying that the overall QA program is established and clear, that the staff performing the specific QA functions is 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 understands 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 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 audit process, where applicable.

Inspection Requirements.

A1.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for organization. As a minimum, the implementing documents should provide for the following:
 1. Organizational description, including:
 - (a) Organizational structure (e.g., managers, supervisors, QA/QC staff, technical staff)
 - (b) Functional responsibilities and duties of staff
 - (c) Levels of authority
 2. Delegation of specific responsibility and authority for planning, establishing, and implementing the QA program; however, the licensee retains overall responsibility for the QA program.
 3. Delegation of work and authority within or outside the licensee's organization (may also be described in the licensee's procurement documents to its contractors).
 4. Management controls and lines of communication between licensee and delegated organization (may also be described in the licensee's procurement documents to its contractors or agents).

5. Direct access and lines of communication with levels of management for all licensee staff.
- b. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents address the following specific QA functions and responsibilities of the QA staff:
 1. Reports to management level sufficiently high to ensure independence of cost and schedule considerations (when opposed to safety considerations).
 2. Has authority and organizational freedom to implement assigned responsibilities.
 3. Assures that an appropriate QA program is established and maintained.
 4. Evaluates the overall effectiveness of the QA program (audits).
 5. Verifies that activities affecting safety related and important to safety functions are performed by independently checking, auditing and inspecting the activity (QC function).
 6. Identifies quality problems; initiates, recommends, or provides solutions to those problems, and verifies implementation of solutions.

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 the QA 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 subtier organizations, such as engineering, field QC, and procurement.
- b. Examine the organizational description and, if available, the organizational chart to determine if the staff that performs specific QA functions is 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 staff that performs specific QA 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 2 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 2 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.

- 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.

35007-A1.05 RESOURCE ESTIMATE

A1.05.01 The review of the QA program implementing documents will require approximately 6 direct inspection hours.

A1.05.02 The verification of the implementation of the QA program documents will require approximately 12 direct inspection hours during the initial team inspection.

Appendix 2. Inspection of Criterion II – Quality Assurance Program

35007-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 SSCs are consistent with the NRC-approved QAPD and commitments in the FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A2.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 1, "Inspection of Criterion I – Organization"

Appendix 18, "Inspection of Criterion XVIII – Audits"

10 CFR 50.54, "Conditions of Licenses"

35007-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 five implementing documents will be reviewed.

A2.03.02 The inspector will examine documents and interview personnel to verify implementation, e.g.:

- a. Licensee's overall QA program structure.
- b. Current revision of the QAPD including any recent QAPD changes to determine if there were any reductions in commitments that should have been submitted to the NRC for review and approval.
- c. Training and indoctrination records – a representative sample would include records representing 10 people.
- d. Work plans – a representative sample would include five current planning documents.
- e. Management evaluations (e.g., assessment) – a representative sample would include three recent assessments.
- f. Stop-work documentation – a representative sample would include two document packages.

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, evaluation of the status and adequacy of the QA program, and stopping of work when necessary. 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 FSAR. This IP appendix provides guidance regarding inspection of the revision of the QAPD. Access to licensee qualification and training records may require special permission because of records classification designation. Planning is included in this IP appendix, although it is not specifically addressed in Criterion II of Appendix B to 10 CFR Part 50, but is in the introduction of Appendix B.

Management-directed evaluations of the status and adequacy of the QA program are conducted by the licensee. These evaluations are different from audits performed by the licensee in accordance with Criterion XVIII of Appendix B to 10 CFR Part 50. Assessments should be conducted at an appropriate frequency, at sufficient depth, and in a comprehensive, objective, and self-critical manner. They may focus on identification of areas for improvement and effectiveness of selected organizational groups.

Inspection Requirements.A2.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that policies and appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for revising and modifying the QAPD and for notifying the NRC in a timely manner of proposed and completed changes to the QAPD. As a minimum, the policies and implementing documents should provide for the following:
 1. Preparation and approval of updates to the QAPD.
 2. Changes to the QAPD (reduction in commitments to previous revision of QAPD as accepted by NRC) are submitted to the NRC and receive NRC approval, prior to implementation [10 CFR 50.54(a)(4)].
 3. Changes to the QAPD (no reduction in commitments to previous revision of QAPD as accepted by NRC) are submitted to the NRC (NRC approval not required) [10 CFR 50.54(a)(3)].
- b. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for establishing the QA program, ensuring indoctrinated and trained personnel conduct quality-affecting activities, and periodically assessing the QA program. As a minimum, the policies and implementing documents should provide for the following:

1. Established licensee QA program includes:
 - (a) Policies, procedures, instructions, and other implementing documents are used during construction for activities affecting the quality of SSCs.
 - (b) Major organizations participating in QA program are identified.
 - (c) Designated functions of these major organizations are specified.
2. Personnel qualifications (e.g., education, experience, position description) are established for selected positions, as determined by management or industry standards.
3. Personnel are indoctrinated and trained prior to quality-affecting work being conducted:
 - (a) QA indoctrination is provided to all personnel conducting quality-affecting activities.
 - (b) Training assessment is performed for staff member or specific position to assure suitable proficiency is achieved and maintained, and staff receives appropriate training.
 - (c) QA personnel (e.g., auditors and quality control (QC) inspectors) are trained to specific activities performed.
 - (d) Periodic reevaluation of qualifications/certifications (including recognized industry requirements) for inspectors and test control personnel is conducted.
 - (e) Auditor is qualified and/or certified in:
 - (1) Overall company policies and QA implementing documents that establish its QA program.
 - (2) Implementing documents that address the QA program related to specific job-related activities.
4. Planning documents for quality-affecting activities are prepared and approved prior to the commencement of work.
5. Status and adequacy of the QA program is regularly reviewed by management of that part of QA program that they are executing (this activity may be specified in a procurement document to an organization performing the QA functions on behalf of the licensee):
 - (a) Programmatic, organizational, and management assessments are scheduled, performed, and reported.
 - (b) Assessment results are reviewed by management having responsibility for the area evaluated.
 - (c) Corrective actions are initiated with appropriate documentation.

6. Work is stopped by designated on-site individual or organizational position if evaluated work or situation is unsatisfactory. Similar unsatisfactory work is stopped to prevent continued work. Cost and schedule considerations are not to override safety considerations of stop work. Stop work associated with quality affected activities is entered into corrective action program.

A2.04.02 Inspection of QA Program Implementation.

- a. Examine the structure of the licensee's QA program (QAPD, policies, implementing documents). Verify that major organizations participating in the QA program, along with their designated functions, are described.
- b. Examine the most recent revision of the QAPD. Verify that the changes were documented and submitted by the licensee to the NRC. If there was a reduction in commitments to previous revision of QAPD as accepted by NRC, then verify that written approval by the NRC was received.

NOTE: The QAPD will have already been reviewed by the NRC to verify that the identification of activities affecting SSCs is specified. Designated functions may be described in more detail in the licensee's implementing documents for Criterion I – 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 SSCs 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:
 - (a) Examine, e.g., position descriptions, education, and experience requirements for those personnel, and verify that qualification requirements have been met for the following positions:
 - (1) QA auditors
 - (2) supervisory positions in the on-site and off-site QA organizations
 - (3) QA surveillance and inspection personnel
 - (4) special process, inspection and testing personnel
 - (5) others as designated (e.g., calibration, repair personnel, electricians, construction craft)

Review of records should relate to the activity that is being observed (e.g., engineering, special processes), if possible. Give emphasis to verifying that replacement QA personnel or those newly assigned to the on-site organization meet position requirements.

- (b) Review all changes of key positions within the past 12 months 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 all staff performing quality-affecting activities received indoctrination and training. Examine training requirements for those positions, and verify that orientation and training were completed within the specified time frame.
 - (b) Verify that QA auditors and QA inspection and test personnel have undergone training that included company policies, and specific QA implementing documents. Examine training requirements for those positions, and verify that orientation and training were completed within the specified time frame.
- d. Select a sample of work plans, and verify that they were approved by the appropriate personnel responsible for the work. Interview personnel to verify that they can identify the work plans that address the activities they are performing.
- e. Obtain the current schedule for management evaluations (e.g., assessments). It should include recently completed assessments and planned assessments. Select a sample of assessments indicated as completed:
 - 1. Verify that the assessments were performed on schedule and were documented.
 - 2. Verify that assessment results and recommendations are reviewed by management having responsibility for the area evaluated. Examine the organizational structure to determine that the appropriate managers reviewed the assessments.
 - 3. If conditions adverse to quality were identified as a result of the assessment, verify that they were promptly brought to the attention of the appropriate level of management for action and entered into the corrective action program. Examine the corrective actions to evaluate whether they effectively address the issue documented in the assessment report.
- f. Determine whether any work has been stopped because of unsatisfactory conditions. Obtain from designated QA personnel a sample of documentation that addresses work that has been stopped:
 - 1. Verify that work was stopped by designated on-site QA personnel.
 - 2. Potentially affected management personnel and organizations were notified of stop work condition in a timely manner (e.g., written or electronic notification, documented telephone call).

35007-A2.05 RESOURCE ESTIMATE

A2.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A2.05.02 The verification of the implementation of the QA program documents will require approximately 24 direct inspection hours during the initial team inspection.

Appendix 3. Inspection of Criterion III – Design Control

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A3.02 RELATED INSPECTION PROCEDURES AND REFERENCES

10 CFR 50.59, "Changes, tests, and experiments"

COL-ISG-025, "Interim Staff Guidance on Changes during Construction under 10 CFR Part 52"

IN 2012-07, "Inappropriate use of Certified Material Test Report Yield Stress and Age-Hardening Concrete Compressive Strength in Design Calculations"

IP 37805, "Engineering Design Verification Inspections" (conducted under IMC 2507)

IP 65001.14, "Inspection of ITAAC-Related Installation of Complex Systems with Multiple Components"

IP 65001.16, "Inspection of ITAAC-Related Engineering"

IP 65001.F, "Inspection of the ITAAC-Related Design and Fabrication Requirements"

IP 71111.21, "Component Design Basis Inspections" (ADAMS Accession Number ML13331B444)

NEI 97-07, Revision 1. "Guidelines for 10 CFR 50.59 Evaluations," (ADAMS Accession Number ML003771157)

35007-A3.03 SAMPLE SIZE

A3.03.01 This IP appendix is focused on the design 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 periodically reviewing a sample of two design changes, four field changes, and six material substitutions. 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.

General Guidance.

Inspection of the licensee's implementation of design control will be reviewed primarily through the associated IPs, as indicated in paragraph 35007-A3.02 above. For example, IP 37805 will assess the processes being used by the design authority to translate the higher level design into detailed design drawings, construction drawings, and procurement specifications. Included within IP 37805 is inspection of the design change/design modification process.

This IP appendix is focused on the design activities that are associated with preserving and implementing the completed design during the construction phase after the final system designs have been completed and inspected in accordance with IP 37805 and prior to the final turnover of systems to the licensee. These activities may be performed by the design authority, licensee staff, or by outside contracted organizations. Among the activities covered by this IP appendix are the development of design changes, development of field changes, and engineering evaluations for substitution of materials.

Inspection Requirements.A3.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR 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 FSAR. For design work being performed by the design authority or other outside contracted organization, ensure that the licensee has invoked applicable portions of its QAPD and has performed audits and surveillances to ensure conformance with quality requirements.
- 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 govern the control of design interfaces between plant systems and among participating design organizations. Implementing documents should ensure that processes are established to confirm that changes made to one system do not adversely affect other safety systems or invalidate design assumptions.
- e. Review implementing documents that govern the control of material substitutions. Verify that proper controls have been established to ensure that all material substitutions are documented and receive the appropriate level of engineering review.
- f. 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 changes (changes to set point calculations, accident analyses, flow calculations, electrical voltage drop calculations, etc.). To the extent practical, the samples chosen for review should involve multiple systems and organizations (e.g., operations, maintenance, engineering, 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 for the control of design changes to ensure that the modified design continues to conform to the NRC-approved licensing basis. The design change process conducted under 10 CFR 50.59 will contain an evaluation or "screening" process to conclude whether each design change will require prior NRC approval before implementation. Inspectors should review that process to ensure it is rigorous. The process should evaluate each design change to ensure that changes that affect Tier 1 or Tier 2* information of the certified DCD or the technical specifications require an NRC license amendment to the plant COL prior to implementation.

10 CFR Part 52, Appendix D, Paragraph VIII contains the requirements for changes and departures from DCD information. It specifies that the licensee may only depart from Tier 2 information without prior NRC approval if the departure does not involve a change to or departure from Tier 1 information, Tier 2* information or technical specifications. It also specifies the conditions under which a departure from Tier 2 information would require a prior license amendment. Guidance on evaluation for those conditions should also be included in the licensee design change procedures.

- b. Select a sample of design changes that appear to potentially require prior license amendments. Review the documentation of the licensee's screening process to determine if the licensee followed their documented process and reached a correct decision on whether a prior NRC approval via a license amendment was required for the design changes. The inspection sample should include at least one that is a change affecting Tier 1 information, several that affect Tier 2*, and several that affect Tier 2 information. Where license amendments are required, inspectors should verify that the action to submit the license amendment either has been completed or is in a tracking system to be completed.

Also review a sample of design changes that the licensee concluded involve Tier 2 information and do not require a prior license amendment, confirm that those design changes contain documentation of an accident evaluation required by 10 CFR 52 Appendices, Paragraphs VIII.B.5.b and B.5.c. Those paragraphs contain accident evaluation requirements similar to the 10 CFR 50.59 like screening process with the difference being that 10 CFR Part 52 Appendices, paragraph B.5.c added two additional safety evaluation requirements for 10 CFR Part 52 licensed plants. Specifically, paragraph B.5.c, states:

A proposed departure from Tier 2 affecting resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

- (1) There is a substantial increase in the probability of an ex-vessel severe accident such that a particular ex-vessel severe accident previously reviewed and determined to be not credible could become credible; or

- (2) There is a substantial increase in the consequences to the public of a particular ex-vessel severe accident previously reviewed.
- c. If a departure or design change requires a license amendment as noted by the inspection guidance above, then the COL should follow the guidance in COL-ISG-025, "Interim Staff Guidance on Changes during Construction under 10 CFR Part 52." The COL should follow the license amendment request (LAR) or preliminary amendment request (PAR) process, as described in COL-ISG-025. For design changes which may also include test changes that require a license amendment, see Section 35007-A11-04 for additional details.
 - d. Select a sample of field changes (changes to approved drawings 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.
 - e. Identify which affected parameters listed below are to be inspected. Emphasis should be placed on those parameters not verified by testing. Ensure that the resulting engineering work products are in accordance with the design requirements as specified in the FSAR. Review the adequacy of the design work by performing the inspection activities for the selected parameters. Ensure that the relevant program implementing documents have been effectively implemented, including those for the review and approval of design documents.

Affected Parameter	Inspection Activity
Energy Needs: <ul style="list-style-type: none"> • electricity • steam • fuel + air • air 	Verify energy requirements can be supplied by supporting systems when required under accident/event conditions. Verify energy requirements of modified SSCs will not deprive other SSCs of required energy under accident/event conditions.

Affected Parameter	Inspection Activity
<p>Materials/Replacement Components:</p> <ul style="list-style-type: none"> • material compatibility • functional properties • environmental qualification • seismic qualification classification 	<p>Verify QA attributes for Components using IP 71111.12, Appendix 1, Component Review Attributes</p> <p>Verify materials/replacement components are compatible with physical interfaces.</p> <p>Verify that galvanic corrosion considerations have been appropriately addressed.</p> <p>Verify material/replacement component properties serve functional requirements under accident/event conditions. This includes potential post LOCA debris sources and blockage mitigation.</p> <p>Verify materials/replacement components are environmentally qualified for application.</p> <p>Verify replacement components are seismically qualified for the application and that seismic two over one design requirements have been appropriately considered.</p> <p>Verify Code and safety classification of replacement SSCs is consistent with design bases.</p> <p>Verify replacement schedule consistent with inservice/equipment qualification life.</p>
<p>Timing:</p> <ul style="list-style-type: none"> • sequence • response time • duration 	<p>Verify that any sequence changes are bounded by accident analyses and loading on support systems are acceptable.</p> <p>Verify SSC response time is sufficient to serve accident/event functional requirements assumed by design analyses.</p> <p>Verify modified SSC response time does not cause an unintended interaction with other SSCs.</p> <p>Verify equipment will be able to function for the duration required under accident/event conditions.</p>
<p>Heat Removal</p>	<p>Verify that heat removal requirements can be addressed by support systems under accident/event conditions.</p>

Affected Parameter	Inspection Activity
Control Signals: <ul style="list-style-type: none"> • initiation • shutdown • control 	Verify that control signals will be appropriate under accident/event conditions.
Equipment Protection: <ul style="list-style-type: none"> • fire • flood • missile • high energy line break • freeze 	Verify that equipment protection barriers and systems have not been compromised. Verify that floor drains are adequately sized and protected. Verify that fire protection and suppression requirements have been appropriately considered.
Operations	Verify that affected operation procedures and training have been identified and necessary changes are in process. Verify that changes to the plant simulator have been identified as required.
Flow paths	Verify that revised flow paths serve functional requirements under accident/event conditions.
Pressure Boundary	Verify pressure boundary integrity is not compromised.
Ventilation Boundary	Verify that changes to ventilation boundaries do not increase risk of spreading contamination. Verify that changes to ventilation boundaries do not adversely affect functionality of ventilation system under accident/event conditions.

Affected Parameter	Inspection Activity
Structural	<p>Verify modified SSCs' structural integrity is acceptable for accident/event conditions.</p> <p>Verify modified SSCs' structural effects upon attachment points are acceptable.</p> <p>Verify modified SSCs' effects on seismic evaluations are acceptable and that seismic two over one requirement has been considered.</p> <p>Verify modified SSCs demonstrate compliance with acceptance criteria defined in the FSAR.</p> <p>Verify modified SSCs are designed for loading conditions defined in the FSAR.</p>
Process Medium: <ul style="list-style-type: none"> • fluid pressures • fluid flow rates • voltages • currents 	Verify that affected process medium properties will be acceptable for both modified SSCs and unmodified SSCs under accident/event conditions.
Licensing Basis: <ul style="list-style-type: none"> • 10 CFR 50.59 	<p>Verify that necessary technical specification changes have been identified.</p> <p>Verify that the changes do not involve Tier 1 material included as part of the FSAR (if so a design certification amendment or license amendment may be required to address the departure).</p> <p>Verify acceptability of licensee's conclusions for those modifications where evaluations in accordance with 10 CFR 50.59 were not performed.</p>
Failure Modes	Verify those failure modes introduced by the modification are bounded by existing analyses.

- f. Ensure that proper verification, validation, and version control of all quality-related computer software used in the performance of design work.
- g. As applicable, verify that post-modification testing is performed to:
 1. Verify that unintended system interactions will not occur.
 2. Verify SSC performance characteristics that could have been affected by the design change, have been maintained in accordance with the design bases.

3. Validate the appropriateness of design assumptions.
4. Demonstrate that the design change test acceptance criteria have been met.

NOTE: Licensees often use existing implementing documents, such as surveillance procedures, for post-modification testing. Although performance of existing implementing documents may have been reviewed by inspectors for other applications, inspectors still need to verify the appropriateness of using the existing implementing documents for validating the modification.

- h. 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: FSAR, Technical Specifications, drawings, supporting calculations and analyses, plant equipment lists, maintenance instructions, and vendor manuals.
 1. Verify that significant plant implementing documents, such as normal, abnormal, and emergency operating procedures, testing and surveillance procedures, and licensed operator training manuals are updated to reflect the effects of the design change.
 2. Verify that the plant's probabilistic risk assessment (PRA) is updated as necessary to account for changes to equipment, system configurations, assumed operator actions, etc. resulting from implementation of the design change.
- i. Select a sample of material substitutions. In general, it is expected that all safety related component and material substitutions are documented and evaluated in accordance with applicable procedures. Verify that all critical characteristics of the subject material have been evaluated, including related environmental and seismic qualification requirements.
- j. 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 only need to be completed one time toward the end of the construction cycle.

35007-A3.05 RESOURCE ESTIMATE

A3.05.01 The review of the QA program implementing documents will require approximately 24 direct inspection hours.

A3.05.02 The verification of the implementation of the QA program documents will require approximately 80 direct inspection hours.

A3.05.03 The verification of the turnover of the design from the design authority to the licensee will require approximately 24 direct inspection hours.

Appendix 4. Inspection of Criterion IV – Procurement Document Control

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A4.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 7, “Inspection of Criterion VII – Control of Purchased Materials, Items, and Services”

Appendix 13, “Inspection of Criterion XIII – Handling, Shipping, and Storage”

Appendix 15, “Inspection of Criterion XV – Nonconforming Materials, Parts, or Components”

IP 36100.01, “Inspection of 10 CFR 50.55© Programs for Reporting Defects and Noncompliance During Construction”

IP 43004, “Inspection of Commercial Grade Dedication Programs” (conducted under IMC 2507)

35007-A4.03 SAMPLE SIZE

A4.03.01 The inspector will examine procurement documents to verify implementation of its procurement process. A representative sample would include a total of 30 procurement documents, with a mix of licensee and contractor procurement documents.

The inspector should review the licensee’s procurement procedures for plant equipment “important to safety” to see if the process includes a “screening process” to evaluate if the equipment being purchased is equipment whose existence and performance capabilities are included in the DCD. If the equipment is included in the DCD, then the attributes and performance capabilities should be included in the purchasing specifications. For example if the DCD specifies the minimum internal flow area for a valve or the minimum electrical capacity of a safety related battery bank, then that attribute should be included in the purchase specifications for the equipment.

The inspector should review the DCD and select some plant equipment important to safety where performance attributes are included in the DCD. Then review the purchase specifications for that equipment to confirm that those DCD attributes are included in the specifications.

35007-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.

The licensee may have established defined channels for developing and approving procurement documents for major items but may also allow for direct procurement by on-site supervision or other personnel. For example, on-site personnel may, in some cases, be assigned the responsibility or be permitted to directly purchase expendable items, such as chemicals, boron, lubricants, solvents, bar and plate stock, and welding rod. If this practice is permitted, the licensee’s procedures should also define how these procurement activities will be controlled.

Procurement documents may contain some of or all of the requirements identified in Section A4.04.01, depending upon the item or service procured.

Criterion IV of Appendix B to 10 CFR 50 requires, in part, that “To the extent necessary, procurement documents shall require contractors or subcontractors to provide a QA program.” In some cases, judgment related to the above phrase “To the extent necessary” is required. For example, specific tests or packaging requirements may not be included in the procurement document if none are required for the item in question.

Inspection Requirements.

A4.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee’s QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for procurement document control for purchases of safety related and risk significant items and services. At a minimum, the implementing documents should provide for the following:
 1. Scope of work (specific identification of items or services purchased).
 2. Technical, regulatory, administrative, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21 and 10 CFR 50.55©) necessary for items and services.
 3. Specific identification or traceability of equipment, supplies, consumables (chemicals, welding rods, etc.) or services purchased.
 4. Hold points and acceptance requirements.
 5. Special instructions for fabrication, packaging, shipping or storage.
 6. Access to the contractor’s location and records for purposes of inspection or audit.
 7. Identification of the documentation, and date of submission, required to be provided for information, review, or approval (e.g., certificate of conformance, calibration certificate, source verification documents).

When documentation in the form of certification is used at the site in lieu of original records establishing quality of items important to safety, the following guidelines should be used:

- (a) Typical certifications are manufacturer's certifications that a product (usually consumables, such as weld rod and chemicals), if tested, would exhibit the product characteristics shown on the certification document. Typical certifications are acceptable only if the user can demonstrate that the product was manufactured under a process control system that provides for product control and process records that establish the product was manufactured within the characteristic limits identified on the certification.
 - (b) Certification should specifically identify the purchased item, such as by the purchase document number.
 - (c) Certification should identify the specific procurement requirements met by the purchased item, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing on site a copy of the purchase document and procurement specifications or drawings, together with a suitable conformance statement. The procurement requirements identified should include any approved changes, waivers, or deviations applicable to the subject item.
 - (d) Certification should identify any procurement requirements that have not been met, together with an explanation and the means used to resolve the condition adverse to quality or nonconformance.
 - (e) Certification should be attested to by a person who is responsible for this QA function and whose function and position are described in the purchaser's or contractor's QA program.
 - (f) Certification system, including the implementing documents to be followed for completing a certificate and for review and approval of the certificate, should be described in the purchaser's or contractor's QA program.
 - (g) Means should be provided by the licensee to verify the validity of certificates and to determine the effectiveness of the certification system when desired, such as during the performance of audits.
- 8. Requirement for the licensee's contractor to provide a QA program consistent with Appendix B to 10 CFR Part 50 (a contractor may also work in accordance with the licensee's QA program or have a process for dedicating commercial grade items).
 - 9. Requirements for reporting and approving disposition of nonconformances.
 - 10. Review and approval of changes to procurement documents by the same individual/organization that approved the original document unless another qualified organization is formally designated.
- b. Review applicable section(s) of the QAPD and associated lower tier implementing documents, and verify that administrative controls provide measures and assign responsibilities in writing for:

1. Initiation of procurement documents.
2. Review and approval of specifications differing from original design documents.
3. Review and approval of procurement documents.
4. Making changes to procurement documents subject to the same degree of control, review, and approval as those used in the preparation of the original documents.
5. Basis for designation of quality classification of procured items.

A4.04.02 Inspection of QA Program Implementation.

Review a sample of recently issued purchase documents for safety related and risk significant non-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 following for procured items and services:

- a. Procurement documents were prepared in accordance with licensee's implementing documents.
- b. Items/services were purchased from qualified contractors (i.e., contractor on the nuclear quality approved suppliers list (ASL)).
- c. Procurement document contained requirements for the contractor to provide appropriate documentation of quality, including component traceability.
- d. Procurement document was maintained in the licensee's document control program.
- e. If delivery date of procurement document was extended by a modification to the purchase document (i.e., contractor conducted work after original delivery date), then contractor was still on the ASL.
- f. Specifications differing from the original design documents were reviewed and approved by qualified technical personnel.

35007-A4.05 RESOURCE ESTIMATE

A4.05.01 The review of the QA program implementing documents will require approximately 6 direct inspection hours.

A4.05.02 The verification of the implementation of the QA program documents will require approximately 48 direct inspection hours.

Appendix 5. Inspection of Criterion V – Instructions, Procedures, and Drawings

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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. Verify that instructions and procedures with drawings accurately display safety-related SSCs design information with no errors.

NOTE: Verification by the NRC of the licensee's preparation of implementing instructions, procedures and drawings will be conducted in accordance with other IPs.

35007-A5.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 6, "Inspection of Criterion VI – Document Control"

Appendix 17, "Inspection of Criterion XVII – Quality Assurance Records"

35007-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 each of the applicable administrative criteria (i.e., I, II, IV, V, VI, VII, XVII, XV, XVI, and XVIII) of Appendix B to 10 CFR Part 50 should be selected. No more than one implementing document from each administrative Appendix B criteria will be inspected, for a total of no more than 10.

In addition, other implementing documents address technical-type processes. A representative sample of implementing documents that address each of the applicable technical criteria (i.e., III, VIII, IX, X, XI, XII, XIII, and XIV) of Appendix B to 10 CFR Part 50 should be selected. No more than one implementing document from each technical Appendix B criteria will be inspected, for a total of no more than eight.

A5.03.02 The inspector will inspect revised and modified implementing documents to verify implementation of this criterion. A representative sample of no more than five implementing documents that have been changed will be inspected. Additionally, the inspector will select a representative sample of five individuals.

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 and important to safety SSCs. 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 the 18 criteria of Appendix B to 10 CFR Part 50. 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. Other documents, such as ASTM International specifications and contractor manuals, may be included or referenced in implementing documents when they include specific instructions or acceptance criteria.

The inspector should select for review those implementing documents that are representative of the 18 criteria of Appendix B to 10 CFR Part 50. 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. Emphasis during NRC's inspection of implementation should be placed on verifying that changes (e.g., revisions and modifications) to implementing documents are prepared and available to personnel in a timely manner and do not alter or reduce established program requirements. This is particularly important for design changes during construction. Often times an activity cannot be readily repeated or corrected if a mistake is made because the current design drawing was not available. Verification of the implementation of quality-affecting documents by the licensee will be conducted during inspections of the other Appendix B criteria and activities. An examination of the licensee's audit reports, corrective action reports, and nonconformance reports may provide indications of weak areas in the preparation of effective implementing documents.

Temporary changes may be prepared in cases where an activity must proceed, but the approved implementing document does not provide adequate or accurate instruction. In these cases, an activity may proceed only if a temporary change is documented, tracked, and has an expiration period. These temporary changes are documented in various ways, such as expedited modifications and emergency changes. The content of the temporary change may then, if necessary, be incorporated into a modification or a revision of the controlled document.

Inspection Requirements.

A5.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate QA program documents have been developed to address the QAPD requirements and FSAR commitments for preparation of implementing documents (e.g., preparation of administrative procedures or work instructions). As a minimum, the QA program documents should provide for the following:

1. Adequate information that allows another person with similar training and qualification to recreate the specific activity without recourse to the individual who originally conducted the activity.
 2. If other method is used instead of preparing an implementing document, then information is incorporated by reference in, or as attachment to, the implementing document (referenced method must be available for review with implementing document).
 3. Identification of appropriate equipment to use.
 4. Prerequisites.
 5. Quantitative and qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.
 6. Person or position responsible for implementing activities described in implementing document.
 7. Identification of records (e.g., individual records and record packages) generated by implementing document and records retention requirements.
- b. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate QA program documents have been developed to address the QAPD requirements and FSAR commitments for preparing changes (e.g., revisions, modifications) to implementing documents. As a minimum, the QA program documents should provide for the following:
1. Inclusion of the reason for the change in the implementing document (may be in separate document).
 2. Review and update of implementing documents on a periodic basis.
 3. Implementing document is revised/modified as a result of, e.g.:
 - (a) anticipated changes, e.g., equipment, personnel responsibilities
 - (b) determination during implementation that it does not reflect work process
 - (c) required periodic reviews
 - (d) corrective action
 4. Provisions for making temporary or immediate changes, when necessary, including expiration date.

A5.04.02 Inspection of QA Program Implementation.

Select a sample of revised or modified controlled implementing documents from the list(s) of controlled documents. Select a mixed sample of implementing documents, such as procedures, design drawings, and engineering specifications, and:

- a. Verify that a reason for the change was described (may be included in the change or in the records for the review of the change).
- b. Obtain the names of personnel or locations that received controlled copies of the change. Select a sample of personnel/locations, and verify that the change is at the location where work is being performed.

35007-A5.05 RESOURCE ESTIMATE

A5.05.01 The review of the QA program implementing documents will require approximately 16 direct inspection hours.

A5.05.02 The verification of the implementation of the QA program documents will require approximately 16 direct inspection hours.

Appendix 6. Inspection of Criterion VI – Document Control

35007-A6.01 INSPECTION OBJECTIVE

A6.01.01 Verify that the licensee's QA program documents for the review, issuance, and distribution of implementing documents that prescribe activities affecting quality are consistent with the NRC-approved QAPD and commitments in the FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A6.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 5, "Inspection of Criterion V – Instructions, Procedures, and Drawings"

Appendix 17, "Inspection of Criterion XVII – Quality Assurance Records"

35007-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 will review all implementing documents. If there are more than two, a representative sample of no more than five 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 criterion, 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. Current temporary controlled documents – a representative sample of no more than three documents.
- g. Most recently cancelled/rescinded and expired temporary documents – a representative sample of no more than four documents.

35007-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 risk 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. Lessons learned have identified that incomplete or inaccurate document control processes have resulted in extensive construction rework and necessitated the replacement of SSCs. An examination of the licensee's audit reports, corrective action reports and nonconformance reports may provide indications of weak areas in document control on which the inspector can focus the inspection.

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 controlled documents and are implementing the prescribed activities in the documents. This is particularly important when conducting technical activities, because often times an activity cannot be readily repeated or corrected if a mistake is made because a procedure or drawing was not followed.

Temporary controlled documents that document changes may be implemented in cases where an activity must proceed, but the approved controlled document does not provide complete or accurate instruction. In these cases, an activity may proceed only if a temporary change is documented and has an expiration period. These temporary changes are documented in various ways, such as expedited modifications and emergency changes. The content of the temporary change may then, if necessary, be incorporated into a modification or a revision of the controlled document.

Inspection Requirements.

A6.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for review, approval and issuance of controlled documents. As a minimum, the implementing documents should provide for the following:
 - 1. Document is reviewed for adequacy, completeness, and correctness by designated personnel (e.g., design engineering) other than the preparer of the document.

2. Document is approved by designated personnel other than the preparer of the document.
 3. Document is approved for release by authorized personnel.
 4. Document is issued with a unique identification and revision status and placed under document control by designated personnel.
 5. Current revision of document is made available where the prescribed activity is being performed to ensure staff uses the most recent controlled document.
- b. Review applicable sections of the licensee's QAPD and FSAR. Ensure that implementing documents have been developed to address the QAPD requirements and FSAR commitments for revision, modification, and/or supersession/cancellation of controlled documents. As a minimum, the implementing documents should provide for the following:
1. The revised controlled document is reviewed and approved by the same organization that originally reviewed and approved the document, or is reviewed and approved by another designated responsible organization.
 2. The revised controlled document is issued and made available for use in same manner as the original controlled document.
 3. A temporary controlled document includes an expiration date, or another method is used to ensure that it is not used beyond a set time frame.

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 reviewed and approved by independent, authorized personnel. Examine the records of reviews of implementing documents, including procurement documents, to verify that the reviews required by the implementing document were conducted.
- c. Select a sample of revised controlled documents. Verify that the documents were reviewed and approved by the same organization that reviewed and approved the original document, unless another responsible organization is designated by the licensee. This is particularly important for technical controlled implementing documents, e.g., design drawings and testing procedures, to ensure consistency and technical adequacy.

- 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. Compare a sample of their paper copy controlled documents (if applicable) to the master list of controlled documents to ensure that personnel have the most current revisions.
- e. Select a sample of temporary controlled documents from the master-controlled document list(s). Verify that they are still available for use, i.e., the expiration date has not passed.
- f. Obtain a list of the most recently cancelled/rescinded implementing documents and expired temporary 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.

35007-A6.05 RESOURCE ESTIMATE

A6.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A6.05.02 The verification of the implementation of the QA program documents will require approximately 24 direct inspection hours.

Appendix 7. Inspection of Criterion VII –
Control of Purchased Material, Equipment, and Services

35007-A7.01 INSPECTION OBJECTIVE

A7.01.01 Verify that the licensee’s QA implementing documents for control of purchased material and equipment (collectively referred to as “items”), and services are consistent with the NRC-approved QAPD and commitments in the FSAR, including the appropriate version of NQA-1, as applicable. This appendix addresses:

- a. Evaluation, selection, and placement of contractor on the nuclear quality ASL
- b. Acceptance of items and services (receipt inspection)

A7.01.02 Verify that the licensee has effectively implemented its QA implementing documents for control of purchased items and services, including contractor evaluation, selection, and placement on the ASL; and acceptance of items and services.

35007-A7.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 4, “Inspection of Criterion IV – Procurement Document Control”

Appendix 13, “Inspection of Criterion XIII – Handling, Shipping, and Storage”

NRC SER, “Callaway Plant, Unit 1 – Operating Quality Assurance Manual Revision 31, Change Notice 15-002” (ADAMS Accession No. ML16089A167)

NRC SER, “Nuclear Energy Institute Technical Report 14-05A, “Guidelines for the use of Accreditation in lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1” (ADAMS Accession No. ML20322A019)

35007-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 five implementing documents will be reviewed.

A7.03.02 The inspector will examine various records and other documentation to verify implementation, e.g.:

- a. Licensee’s current nuclear quality ASL.
- b. Records of licensee’s evaluation of contractors, such as audits and surveillances – a representative sample would include a total of five of the most recent audits and surveillances.
- c. Records of licensee’s decision to add or remove a contractor from the nuclear quality ASL – a representative sample would include a total of a mix of five of the most recent additions or removals of contractors from the nuclear quality ASL.

- d. Records of receipt inspection documentation – a representative sample would include a total of receipt inspections completed for five procurements.

35007-A7.04

INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

The inspector should find implementing documents that specifically address qualification of contractors and acceptance of safety related and risk significant non-safety related procured items and services. It is important to verify that implementing documents provide controls that assure that only procured items or services are procured from qualified contractors (i.e., on nuclear quality ASL), and that items or services meet the procurement requirements and are accepted prior to its use.

Examples of contractors that are on the licensee's nuclear quality ASL may provide the following services: non-destructive examination, testing, calibration, computer software codes/programs, heat treatment, third-party inspections, engineering and consulting services, installation, repair, or maintenance work.

Various methods may be used to accept items and services, such as certificate of conformance, source verification, audit, surveillance, receiving inspection, dedication of commercial grade item, or a combination thereof. Typical certifications are manufacturer's certifications that an item, if tested, would exhibit characteristics shown on certification. Certifications are acceptable only if they can demonstrate that the item was manufactured under process control system that provides for item control and process records that can establish that item was manufactured within the characteristic limits identified on the typical certification.

The activities related to contractor qualification activities and acceptance of items and services may occur at various locations. For example, the process for receipt inspection should accommodate off-site and on-site deliveries of items. It is possible that the licensee maintains records and documents related to contractor qualification on site or at the licensee's corporate office.

For a sample of safety-related activities delegated by the licensee to contractors acting as an agent to the licensee, the inspector should evaluate the licensee's oversight of those contractor's activities. This might be through the review of a sample of licensee performed surveillances (different than audits which are covered by attachment 18).

The inspector should also review a sample of 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 FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for evaluation, selection, and placement of contractors on the nuclear quality ASL. As a minimum, the implementing documents should provide for the following:

1. Audit/surveillance of potential contractor for placement on the nuclear quality ASL is conducted that consists of (all, or in combination) an on-site visit to contractor facility, an evaluation of past performance, a records review, and interviews with contractor personnel. The licensee may use one or more of the following methods to conduct the evaluation and selection:
 - (a) Contractor's history and current capability of providing identical or similar item or service.
 - (b) Contractor's QA records and supporting information can be evaluated objectively.
 - (c) Contractor's technical and quality capability, such as evaluation of facilities and personnel, and evidence for implementation of the QA program.
 2. Documentation of audit/surveillance is prepared to support addition of contractor to the nuclear quality ASL.
 3. The nuclear quality ASL is to reflect the current information of contractor, such as company name; contractor's location that is approved to supply items or services; scope of procured item or service; and due date of next audit, surveillance, or evaluation.
 4. Periodic audit, surveillance, or evaluation of contractor on the nuclear quality ASL is performed to assess the contractor for effective control of quality and to evaluate the contractor for continued use. The licensee should assess the contractor at intervals consistent with the importance, complexity, and quantity of the items or services.
 5. Objective evidence related to removal of contractor from the nuclear quality ASL is to reflect circumstances (e.g., inadequate performance, lack of use, company dissolution).
- b. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for acceptance of items and services. As a minimum, the implementing documents should provide for the following:
1. Authorized/qualified licensee personnel conduct and document receiving inspection.
 2. A general receipt inspection is performed (e.g., shipping damage, cleanliness, presence of contractor documentation).
 3. Items and services (and associated documentation) are examined for conformance with requirements specified in the procurement document. Receiving inspections of items should verify, as a minimum, item configuration, dimensions, physical characteristics, and identification and traceability of the item, including status of inspection or tests performed, as required.
 4. Receipt inspection, including determination of acceptability, is conducted and documented prior to use of item or service.
 5. Certification documentation (e.g., calibration certificate) of item or service includes, e.g.:

- (a) Identification of contractor and contractor location
 - (b) Reference to licensee purchase document identification
 - (c) Identification of item or service
 - (d) Data or information required by purchase document
 - (e) Identification of specific requirements met, e.g., codes, standards, specifications
 - (f) Identification of implementing documents used to produce item, conduct service, complete certification documentation, etc.
 - (g) Identification of procurement requirements that were not met, with explanation and means used to resolve nonconformance
 - (h) Attestation of certification by authorized contractor personnel
6. If critical in-process test was performed to verify attributes that cannot be verified after subsequent assembly, then prescribed tests were performed on item to confirm conformance with procurement document requirements.
 7. If source verification is specified for acceptance of an item in addition to certification, then the appropriate receiving inspection organization is made aware of the source verification results.

A7.04.02 Inspection of QA Program Implementation.

- a. Inspect the current nuclear quality ASL and associated documentation that supports the inclusion of contractors on the nuclear quality ASL. Select a sample of contractors, and examine the associated documentation that supports their inclusion on the nuclear quality ASL:
 1. Review the overall contractor audit program for the previous year. Determine how many scheduled contractor audits were conducted. Determine how many scheduled contractor audits were deferred or cancelled and the reasons for deferral or cancellation. Review the means to compensate for cancellation.
 2. Verify that an audit, surveillance or other method was conducted and documented and that it supports the placement or retention of the contractor on the nuclear quality ASL. Verify that it was conducted on schedule, if applicable. Verify that the person who conducted the audit, surveillance or evaluation was qualified.
 3. Verify that any identified substantive deficiencies relating to implementation of the contractor's QA program were included in the licensee's or the contractor's corrective action program. Ensure that the licensee has considered these deficiencies in its decision to retain the contractor on the nuclear quality ASL.
- b. Verify that contractors are removed from the nuclear quality ASL when warranted. Request from the licensee's procurement personnel a list of the most recently removed contractors from the nuclear quality ASL. Select a sample, and examine documentation to verify that:

1. Nuclear quality ASL and associated documentation reflect removal of the contractor from the nuclear quality ASL.
 2. Notification was sent to affected licensee personnel that contractor was removed from nuclear quality ASL.
 3. Contractor was not removed from the nuclear quality ASL until all items/services described in procurement document were received and/or an agreement between the licensee and contractor was documented.
- c. Examine related documentation on a contractor (e.g., audit, evaluation report) that provides justification for reinstating the contractor on the nuclear quality ASL. Verify that, if a contractor was removed from the nuclear quality ASL and was subsequently reinstated, the licensee obtains objective evidence that fully supports the reinstatement.
- d. Inspect a sample of safety related and risk significant non-safety items and services that were procured from contractors. Select a representative sample from the following categories: mechanical, electrical, and instrument/electronic items; consumables (e.g., reagents, lubricants, filters); and services that require only documentation as the deliverable (i.e., no tangible item was procured):
1. Verify that the contractor of safety related and risk significant non-safety related item or service was on the nuclear quality ASL at the time the item or service was procured. Examine the licensee's current nuclear quality ASL and/or licensee's documentation on the contractor.
 2. Verify that documentation of item and service was examined for conformance with requirements specified in procurement document (including approved changes) by authorized/qualified licensee personnel. These personnel may include receiving department staff, QA staff, and/or technical personnel. The technical personnel should have the documented experience, education, or training that demonstrates that they are capable of performing the technical acceptance. Verify that a documented determination of acceptability was made.
 3. Examine accepted item to verify that it was tagged/marked as acceptable for use, as acceptable with condition, or unacceptable. If the item was accepted for conditional use, then this status was indicated, such as on a tag or in documentation. The justification for conditional use should be provided, and the authority for conditional release of item should be specified. If the item was determined to be unacceptable, then the item was segregated or marked as unavailable for use and a nonconformance report or corrective action report was initiated.
 4. Where source inspection is used by the licensee as the means to accept an item for construction, the inspector should review a sample of those source inspection records along with the applicable on-site receipt inspection records to determine whether adequate objective evidence was provided to ensure that the acceptance criteria have been met.
 5. For the item inspected above, the inspector should review the applicable source / receipt inspection plans to determine whether the acceptance process established adequate acceptance criteria to provide reasonable assurance that the item meets the established technical and quality procurement requirements.

- e. Ascertain how the licensee determines that all items and services are received prior to closing out the procurement. Select a sample of procurement documents, and verify that all items and services stated in the procurement document were received.
- f. Examine the licensee's files of audits, surveillances, and evaluations of contractors that are, or have been, on the nuclear quality ASL.
- g. For vendors purchasing commercial-grade calibration and testing services from domestic and international calibration and testing laboratories accredited by a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process, refer to the Safety Evaluation Report (SER) of NEI 14-05A, **Revision 1**, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," (ADAMS No. ML20322A019) to verify that the conditions listed are being adequately implemented.
- h. **SER to Callaway Unit 1 (ADAMS Accession No. ML16089A167), incorporates the QA alternative of using the ILAC MRA accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA. SER to NEI approves the use of NEI 14-05A, Revision 1, which recognizes the 2017 edition of ISO/IEC-17025 as the basis for the ILAC accreditation process in lieu of performing commercial-grade survey (ADAMS Accession No. ML20322A019). For vendors who use the ISO/IEC-17025 as the basis for the ILAC accreditation process in lieu of performing commercial-grade survey, ensure that the vendors are using the most up to date 2017 edition.**

35007-A7.05 RESOURCE ESTIMATE

A7.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A7.05.02 The verification of the implementation of the QA program documents will require approximately 48 direct inspection hours.

Appendix 8. Inspection of Criterion VIII –
Identification and Control of Materials, Parts and Components

35007-A8.01 INSPECTION OBJECTIVES

A8.01.01 Verify that the licensee’s QA implementing documents for the identification and control of materials, parts, and components, including partially fabricated assemblies and spare parts (collectively referred to as “items”), are consistent with the NRC-approved QAPD and commitments in the FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A8.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 15, “Inspection of Criterion XV – Nonconforming Materials, Parts, or Components”

Appendix 16, “Inspection of Criterion XVI – Corrective Action”

35007-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 these items. A representative sample of no more than 20 individual items and their associated markings, documentation, and records.

35007-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. Examples of items include cable/wire, pipe, valves, cast parts, resistors, concrete and components.

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. 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 FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for the identification and control of safety related and risk significant items. As a minimum, implementing documents should provide for the following:

- a. Markings maintained on items are to be traceable to item throughout fabrication, erection, installation, and use of item. Examples of markings include heat number, part number, and serial number.
- b. Markings to be applied using materials and methods that provide a clear and legible identification, and do not adversely affect the function or service life of the item.
- c. Where physical identification on the item is impractical or insufficient, physical separation, procedural control, documentation, or other appropriate means may be used to ensure traceability of the item throughout fabrication, erection, installation, and use of the item.
- d. Identification and traceability of the item includes status of inspection or tests performed, as required.
- e. Markings or other means of identification ensure that only specified and accepted items are used to prevent use of incorrect or defective items.

A8.04.02 Inspection of QA Program Implementation.

- a. Inspect a sample of safety related and/or risk significant non-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. Verify that traceability of the item is consistent and accurate from identification of the item through the resultant documentation and use of the item, including fabrication, erection, and installation.
- b. Verify that item identification methods make use of physical markings to the maximum extent possible.
- c. 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.
- d. 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.
- e. Examine items that are indicated as incorrect or defective (e.g., nonconformance, corrective action). Methods used to indicate nonconforming items may include tags and segregation. Verify that the associated documentation and records are in agreement with the indicated item.

35007-A8.05 RESOURCE ESTIMATE

A8.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A8.05.02 The verification of the implementation of the QA program documents will require approximately 16 direct inspection hours.

Appendix 9. Inspection of Criterion IX – Control of Special Processes

35007-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 FSAR, including the appropriate version of NQA-1, as applicable. Special processes include welding, nondestructive testing (NDT), heat treatment, and coatings.

NOTE: The NRC's verification of the licensee's implementation of this criterion of Appendix B to 10 CFR Part 50 is conducted in accordance with other IPs.

35007-A9.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 11, "Inspection of Criterion XI – Test Control"

Appendix 14, "Inspection of Criterion XIV – Inspection, Test, and Operating Status"

35007-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 five implementing documents will be reviewed that includes a sample from each construction discipline applicable to the licensee, such as structural/civil, piping, and mechanical.

35007-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 SSCs 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 in accordance with specified applicable codes, standards, specifications, criteria, 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 FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for control of special processes. As a minimum, the implementing documents should provide for the following:

- a. Type of special process to be performed.
- b. Purpose of the special process.
- c. When performance of the special process is required.
- d. Prerequisites, e.g.:
 1. Identification of special materials to be used (e.g., coatings, shielding gas).
 2. Calibrated measuring and test equipment (M&TE) to be used, including type, range, accuracy, and tolerance.
 3. Suitably controlled environmental conditions, such as isolation or protection of the item during performance of special process.
- e. Qualification and re-qualification requirements (e.g., education, experience, and certification) of personnel conducting the special process, e.g.:
 1. Demonstration of skills by performing specific performance qualification tests prescribed by the applicable code; performance qualification may expire within a specified timeframe if the person has not conducted the special process during that time period.
 2. Performance qualification tests are fully documented.
 3. Personnel conducting special process may need to re-qualify if an essential variable for the process is changed beyond the limits specified in the applicable code.
 4. Personnel conducting NDT may be qualified to different levels of capability.
- f. Use of qualified and controlled computer software, if applicable.
- g. Mandatory hold points, such as documented, independent verification/witness by QA staff or Authorized Nuclear Inspector.
- h. Other testing to be performed to verify that special process was performed properly.
- i. Specified acceptance criteria to be met at checkpoints of fabrication and installation.
- j. Specific provisions for objective evidence or collection of data that supports the special process:
 1. Acceptance criteria have been met.

2. Repeat of the special process, if necessary.
- k. Identification of potential sources of uncertainty and error.
- l. Special process records include, e.g.:
 1. Type of method used to perform special process.
 2. Item upon which the special process was performed.
 3. Date of performance of special process.
 4. Person performing special process.
 5. M&TE used during special process (e.g., identification number, most recent calibration date).
 6. Special process control documents, e.g., travelers, process sheets, checklists.
 7. Criteria or reference documents used to determine acceptance.
 8. Description of activity performed and results.
 9. Evaluation of acceptability.
 10. Name of independent evaluator.
 11. Identification of qualified computer software.
 12. Corrective actions for noted nonconformance or deficiency.

35007-A9.05 RESOURCE ESTIMATE

The review of the QA program implementing documents will require approximately 8 direct inspection hours.

Appendix 10. Inspection of Criterion X – Inspection

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A10.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 7, “Inspection of Criterion VII – Control of Purchased Material, Equipment, and Services”

Appendix 11, “Inspection of Criterion XI – Test Control”

Appendix 14, “Inspection of Criterion XIV – Inspection, Test, and Operating Status”

35007-A10.03 SAMPLE SIZE

A10.03.01 It is anticipated that the licensee will have numerous technical implementing documents that provide specific direction for conducting inspections. A maximum of six implementing documents will be reviewed that includes a representative sample from each 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 10 completed inspections and their associated stamps, tags, labels, routing cards, documentation, and records. If licensee inspections are expected to be performed during the NRC inspection of this criterion of Appendix B to 10 CFR Part 50, a representative sample would include observing two active inspections being conducted by the licensee.

35007-A10.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

The inspector should find implementing document that specifically address inspection of items during construction to demonstrate that SSCs 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 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. Examples of inspections include: examinations and measurements of items; source and receipt inspection of procured

items as defined by procurement documents; in-process and final inspections; and modification inspections.

Inspection Requirements.

A10.04.01 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 FSAR commitments for conducting inspections to ensure quality. As a minimum, the implementing documents should provide for, or identify, the following:

- a. Examinations and measurements for each work operation, where necessary.
- b. Methods/documents used to perform inspections and document results.
- c. Frequency or point of inspections.
- d. M&TE, including type, range, accuracy, and tolerance.
- e. Sampling requirements.
- f. Hold points (witness or inspection by designated representative, beyond which work cannot proceed without consent of designated representative).
- g. Acceptance criteria, such as markings, adjustments, protection from damage.
- h. Qualified inspection personnel are other than those who perform or directly supervise the work being inspected.
- i. Use of qualified and controlled computer software.
- j. If inspection of processed items is impractical, then indirect control is provided by monitoring of processing methods, equipment, and personnel. Both inspection and process monitoring are conducted when control is inadequate with only one method.
- k. Final inspection of item or work operation to verify conformance with acceptance criteria.
- l. Re-inspection is performed, if applicable, when deficiency or nonconformance is identified subsequent to final inspection.
- m. Inspection documentation includes, e.g.:
 1. item inspected
 2. date of inspection
 3. identification of data recorder
 4. type of observation or method of inspection
 5. results indicating acceptability of characteristics inspected
 6. identification of person who determined acceptability

- a. Evaluate a sample of inspection documentation for safety related and risk significant non-safety related items that require inspection. In addition, the inspector should visit work areas and select the samples based upon physical markings (e.g., inspection tags) on items. 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, as described in the implementing document. Inspection may include verification of completeness, markings, installation, adjustments, protection from damage, or other characteristics.
 3. Examine inspection documentation and confirm that mandatory hold points were complied with and witnessed by the licensee's designated representative. Verify that work did not proceed without written authorization of designated personnel by examining the dates of completion of work and subsequent inspection. If hold points were waived, then verify that consent was documented and approved before work continued beyond the designated hold point.
 4. If modifications, repairs, or replacements of items were performed subsequent to final inspection, then verify that appropriate re-inspections were performed.
- b. Inspect a sample of inspection documentation of safety related and risk significant non-safety items where inspection was impractical. Select a sample of inspected items to verify that:
 1. Documented process monitoring methods, equipment, and qualified personnel (if required) were used to as an alternative to direct inspection.
 2. Results were documented and complete (see A10.04.02.d. below).
 3. Both inspection and process monitoring were provided when control was inadequate without both.
- c. 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. During the performance of the licensee inspection, verify that:
 1. Item (e.g., bolts, nuts, and other fasteners of proper type, size, and material with required identification markings) or system was installed or erected as described by drawings and construction specifications. The NRC inspector shall make physical measurements, where appropriate.
 2. Item was marked accurately to reflect its inspection status.

3. Results were documented and complete (see A10.04.02.d. below).
 4. If an inspected item was installed differently from the drawings or specifications, such changes were approved and controlled.
 5. Where potential discrepancies are suspected, the NRC inspector shall ask the licensee to confirm measurements in order to verify compliance with the applicable requirements. The NRC inspector may arrange for independent measurements by others, should he/she feel this is necessary to verify compliance with requirements.
- d. Inspection documentation (travelers, process sheets, instructions, checklists, etc.) includes, e.g.:
1. Observation or type of method used to perform inspection.
 2. Item inspected and date of inspection.
 3. Identification of person conducting inspection (e.g., Authorized Nuclear Inspector).
 4. M&TE used during inspection (e.g., identification number, most recent calibration date).
 5. Identification (or reference to) inspection criteria, sampling plan, or reference documents used to determine acceptance.
 6. Results or description of inspection performed.
 7. Evaluation of acceptability and identification of person determining acceptability.
 8. Results indicating acceptability of characteristics inspected.
 9. Identification of qualified computer software.
 10. Resolution of corrective actions for noted nonconformance or deficiency.

35007-A10.05 RESOURCE ESTIMATE

A10.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A10.05.02 The verification of the implementation of the QA program documents will require approximately 16 direct inspection hours.

Appendix 11. Inspection of Criterion XI – Test Control

35007-A11.01 INSPECTION OBJECTIVES

Verify that the licensee's QA implementing documents for the control of testing are consistent with the NRC-approved QAPD and commitments in the FSAR, including the appropriate version of NQA-1, as applicable.

NOTE: The NRC's verification of the licensee's implementation of this criterion of Appendix B to 10 CFR Part 50 will be conducted in accordance with other IPs.

35007-A11.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 10, "Inspection of Criterion X – Inspection"

Appendix 14, "Inspection of Criterion XIV – Inspection, Test, and Operating Status"

35007-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 six implementing documents will be reviewed that includes a representative sample from each construction discipline applicable to the licensee, such as structural/civil, piping, mechanical, and electrical/instrumentation and control.

35007-A11.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

The inspector should find implementing documents that specifically address testing during construction to demonstrate that SSCs 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.

Construction testing includes provisions for pre- or post-installation operational tests and generally verifies that certain components pass specific test parameters. However, this type of testing does not necessarily demonstrate system capability, especially for systems that include non-electrical equipment. 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. Evaluation of the licensee's implementing documents for pre-operational testing programs is addressed in other IPs.

Inspection Requirements.

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 FSAR commitments for testing. As a minimum, the implementing documents should provide for the following:

- a. Type of test to be performed, including proof tests performed prior to installation.
- b. Purpose of the test.
- c. When testing is required and sequencing of tests within an activity.
- d. Testing prerequisites, e.g.:
 1. Identification of calibrated M&TE to be used, including type, range, accuracy, and tolerance.
 2. Qualification of test personnel.
 3. Suitably controlled environmental conditions, including isolation of item during testing.
 4. Use of qualified and controlled computer software.
- e. Mandatory hold points, such as independent verification/witness by QC or QA staff or Authorized Nuclear Inspector.
- f. Acceptance limits (as provided in design documents).
- g. Specified acceptance criteria.
- h. Specific provisions for collection and documentation of testing results.
- i. Evaluation of test results by assigned independent personnel to ensure that:
 1. Testing requirements have been satisfied.
 2. Acceptance criteria have been met.
 3. Retesting is conducted (if required).
- j. Identification of potential sources of uncertainty and error.
- k. Evaluation of test changes by independent personnel to ensure that:
 1. The test change is minor requiring no safety evaluation or license amendment.
 2. If the test change or departure is to a Tier 1 ITAAC or Tier 2* first of a kind (FOAK) test change, then the COL holder must submit a license amendment to the NRC for NRC prior approval before the test change can be made. For additional details on license amendments requests (LARs) or preliminary amendment requests (PARs)

during the construction phase process, see COL-ISG-025, "Interim Staff Guidance on Changes during Construction under 10 CFR Part 52."

3. If the test change is a Tier 2 change, then the COL holder must initiate the 10 CFR 50.59 like safety evaluation process to determine if the test change can be made without prior NRC approval. If the test change evaluation requirements in 10 CFR Part 52 Appendices, Sections B.5.b and B.5.c are met, then the COL holder must submit a licensee amendment to the NRC for NRC prior approval before the test change can be made. For additional details on license amendments requests (LARs) or preliminary amendment requests (PARs) during the construction phase process, see COL-ISG-025, "Interim Staff Guidance on Changes during Construction under 10 CFR Part 52."
- I. Test records include, e.g.:
1. Type of test and/or method
 2. Item tested
 3. Date of test
 4. Tester (or data recorder)
 5. M&TE used during test (e.g., identification number, most recent calibration date)
 6. Test criteria or reference documents used to determine acceptance
 7. Results
 8. Evaluation of acceptability
 9. Name of independent evaluator
 10. Identification of qualified computer software
 11. Corrective actions for noted nonconformance or deficiency
- m. Item is properly restored upon test completion.

35007-A11.05 RESOURCE ESTIMATE

The review of the QA program implementing documents will require approximately 8 direct inspection hours.

Appendix 12. Inspection of Criterion XII – Control of Measuring and Test Equipment

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A12.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 4, “Inspection of Criterion IV – Procurement Document Control”

Appendix 7, “Inspection of Criterion VII – Control of Purchased Material Equipment, and Services”

Appendix 8, “Inspection of Criterion VIII – Identification and Control of Materials, Parts, and Components”

Appendix 9, “Inspection of Criterion IX – Control of Special Processes”

Appendix 10, “Inspection of Criterion X – Inspection”

Appendix 11, “Inspection of Criterion XI – Test Control”

Appendix 13, “Inspection of Criterion XIII – Handling, Storage, and Shipping”

Appendix 14, “Inspection of Criterion XIV – Inspection, Test, and Operating Status”

35007-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 six technical implementing documents will be reviewed that includes a representative sample from each 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 criterion, e.g.:

- a. Licensee’s M&TE tracking system – a representative sample would include a total of two separate systems.

- b. Calibrated M&TE – a representative sample would include a total of six 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 five pieces of M&TE.
- g. M&TE being calibrated (this inspection activity does not apply to observing contractors performing calibrations) – a representative sample would include a total of two pieces of M&TE.
- h. M&TE being prepared for shipment – a representative sample would include a total of two pieces of M&TE.

35007-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 SSCs 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 criterion of Appendix B to 10 CFR Part 50 is closely related to inspections of several other Appendix B criteria, 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 35007-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 FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for control of M&TE. As a minimum, the implementing documents should provide for the following:

- a. Only calibrated M&TE will be used, when the use of such M&TE has been determined (technical implementing documents describe when calibrated M&TE is to be used).
- b. Calibration is performed at prescribed intervals, or before use. If M&TE is used in a one-time-only application, then calibration is performed both before and after use. Calibration also is to be performed when the accuracy of calibrated M&TE is suspect.
- c. M&TE is calibrated, adjusted, and maintained against reference calibration standards having traceability to nationally recognized standards (e.g., National Institute of Standards and Technology standards). If no nationally recognized standards or physical constants exist, a basis for calibration is documented. Calibration standards must have greater accuracy than the required accuracy of the M&TE being calibrated.
- d. Calibrated M&TE is labeled/tagged/suitably marked or documented, e.g.:
 1. Unique identification to provide traceability to its calibration data.
 2. Date of calibration.
 3. Due date or interval of next calibration.
 4. Limitations on use (e.g., use within a specified range).
- e. Out-of-calibration M&TE (i.e., nonconforming) is tagged, segregated, etc. to ensure that it is not used.
- f. Calibrated M&TE, including standards used for calibrating M&TE, is handled and stored to maintain accuracy.
- g. Documentation of calibration includes, e.g.:
 1. Unique identification of the M&TE calibrated.

2. Method used to perform the calibration.
3. Identification of the calibration standard (including traceability to the primary standard) used for calibration.
4. Identification of the qualified computer software used to perform the calibration.
5. Calibration data including results of the calibration and “as found” and “as left” data or measurements about the M&TE.
6. Statement of acceptability of the calibration; the purchaser of the calibration service may also provide this statement upon satisfactory receipt inspection of the calibrated M&TE.
7. Date of calibration and recalibration due date or interval.
8. Identification of the individual performing the calibration.
9. Purchase document number (if a contractor calibrated the M&TE).

A12.04.02 Inspection of QA Program Implementation.

- a. Select a sample of tracking systems for calibrated M&TE (may be multiple systems to control M&TE). Verify that a log-out/log-in system is in place to control the use of M&TE and is maintained by authorized personnel. Interview the instrument and control supervisory personnel to verify that the M&TE program aspects are understood. If it is not apparent that the supervisory personnel have a clear understanding, then the inspector should examine documents to determine if requirements for training or qualification are sufficient (reference Appendix 2 for additional information on training and qualification).
- b. Select a sample of calibrated M&TE from the tracking system(s) of active M&TE used to conduct an activity (e.g., test and inspection procedures). Verify that the M&TE met requirements by conducting the following:
 1. Obtain the implementing documents that contain requirements for the calibration of the specific M&TE. Some of the requirements also may be included in a general M&TE implementing document.
 2. Locate the calibrated M&TE to verify that it meets the requirements of the implementing document(s), including:
 - (a) Identified by a unique number.
 - (b) Tagged/labeled/etc. to indicated current calibration status.
 - (c) Properly stored.

NOTE: For calibrations performed by a contractor, the inspector should be able to obtain the QA and technical requirements of the applicable procurement document from the contractor.

3. Examine the related calibration documentation to verify that it meets the requirements of the implementing document(s), including, e.g.:
 - (a) M&TE was calibrated within specified calibration interval.
 - (b) Accuracy was within specified limits.
 - (c) Documentation and test/inspection results are traceable to M&TE being verified.
- c. Select a sample of new M&TE that was recently added to the tracking system. Examine the associated M&TE and its documentation (inspection/test results) to determine when the M&TE was first used and to verify that it was calibrated prior to being placed into service.
- d. Select a sample of M&TE from the tracking system(s) that has recently been taken out of service because of nonconforming condition, including being out of calibration, loss or damage. In addition, nonconforming conditions may be identified for calibration standards. Determine if the M&TE met requirements by conducting the following:
 1. Verify that the M&TE has been properly tagged/indicated as out of service.
 2. Verify that a nonconformance report (NCR) was initiated to evaluate previous use of the M&TE.
 3. Verify that a documented evaluation of the validity of previous inspections, tests, and status determinations was conducted since the last calibration, in conjunction with the corrective actions for the NRC.
 4. Verify that M&TE found consistently out of calibration during recalibration process was repaired, replaced, or the calibration interval shortened.
- e. Verify that M&TE deleted from the list(s) of M&TE has been permanently removed from service and is no longer available for use. Select a sample of M&TE from the list, and verify that the M&TE was stored in a segregated area, transferred, or disposed.
- f. Inspect M&TE that is located at on-site work facilities and is being used to conduct inspections, tests, and other activities. Tour the area, and select a sample of M&TE. Verify that the items are tagged/labeled to indicate the current calibration status. Examine the associated calibration implementing document, records and M&TE tracking system, and verify that the tags/labels are in agreement with the calibration documentation and M&TE tracking system.
- g. Observe M&TE being calibrated (this inspection activity does not apply to observing contractors performing calibrations). Verify that the implementing document used to conduct calibration of the M&TE is available at the work site. Verify that the M&TE is calibrated in accordance with implementing document, that the records produced were accurate and complete, and the M&TE was correctly tagged to indicate its status.
- h. Observe the licensee's shipping of M&TE to the contractor responsible for calibrating the M&TE. Select a sample of M&TE that is being readied for shipment. Verify that the licensee is properly implementing its implementing documents for shipping M&TE.

Special shipping is sometimes required for M&TE because of the sensitive nature of the M&TE, such as susceptibility to shock damage.

35007-A12.05 RESOURCE ESTIMATE

A12.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A12.05.02 The verification of the implementation of the QA program documents will require approximately 24 direct inspection hours.

Appendix 13. Inspection of Criterion XIII – Handling, Storage and Shipping

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A13.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 4, “Inspection of Criterion IV - Procurement Document Control”

Appendix 7, “Inspection of Criterion VII - Control of Purchased Materials, Items, and Services”

Appendix 15, “Inspection of Criterion XV - Nonconforming Materials, Parts, or Components”

35007-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 all of them. If there are more than five, a representative sample of no more than 10 implementing documents will be reviewed.

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

- a. At least 10 safety related and risk significant non-safety related items that have been received on site. To the extent practical, the samples should include items from 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 four samples of items that have been handled on site. An attempt should be made to choose equipment for which specific handling requirements are required.
- c. At least two samples of items that have been shipped off site. An attempt should be made to choose equipment which has specific or unique shipping requirements.

35007-A13.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

It should be noted that all safety related and risk significant non-safety related items are not necessarily stored on site. Rather, they may be stored in a warehouse, etc., near the site. 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 and risk significant non-safety related items, e.g., the reactor coolant pressure boundary.

Inspection Requirements.

A13.04.01 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 FSAR commitments for the handling, storage, and shipping of safety related and risk significant items. As a minimum, the implementing documents should provide for the following:

- a. Controls for the designation of graded storage levels and the establishment of appropriate environmental conditions.
- b. Controls for access, identification of items, coverings, and preservatives.
- c. Conducting periodic inspections of the storage area to ensure that controlled conditions will be maintained in special environments.
- d. Maintenance and care of items in storage, including shelf life.
- e. Assigning responsibilities associated with the implementation of handling and storage controls.
- f. Establishment of routine and special handling measures.
- g. Control of rigging, lifting, hoisting equipment, and transporting equipment.
- h. Cleanliness and environmental controls, e.g., inert gas atmosphere, specific moisture content levels, temperature levels.
- i. Cleaning, including the use of distilled water or solvents, as appropriate. For additional inspection guidance, the inspector should refer to the guidance the licensee commits to in its licensing basis on QA requirements for cleaning fluid systems and components in nuclear power plants. For steam generator water chemistry control many licensees commit to EPRI "PWR Primary Water Chemistry Guidelines" or "PWR Secondary Water Chemistry Guidelines." During preoperational testing, the EPRI guidance for steam generators has more restrictive water chemistry limits than NQA-1 guidance to maintain steam generator tube integrity. If the relevant chemistry parameter concentrations are above the guideline limits, the licensee would take the appropriate actions to restore chemistry to within the guideline values.

A13.04.02 Inspection of QA Program Implementation.

- a. Inspect a sample of safety related and/or risk significant non-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.
- c. Observe the licensee's shipping of items off site. Verify that the licensee is properly implementing its controlling documents for shipping. Special shipping is sometimes required for certain items because of sensitive nature of the materials (e.g., temperature), susceptibility to shock damage, etc.

35007-A13.05 RESOURCE ESTIMATE

A13.05.01 The review of the QA program implementing documents will require approximately 12 direct inspection hours.

A13.05.02 The verification of the implementation of the QA program documents will require approximately 16 direct inspection hours.

Appendix 14. Inspection of Criterion XIV – Inspection, Test, and Operating Status

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A14.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 10, “Inspection of Criterion X – Inspection”

Appendix 11, “Inspection of Criterion XI – Test Control”

Appendix 12, “Inspection of Criterion XII - Control of Measuring and Test Equipment”

35007-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 five 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 20 individual items and their associated stamps, tags, labels, routing cards, documentation, records, or other suitable means.

35007-A14.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

The inspector should find implementing documents and instructions that specifically address the inspection, test, and operating status of items. Examples of items requiring 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, operation 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 FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for indicating the inspection, test and operating status of safety-related and risk significant items. As a minimum, the implementing documents should provide for the following:

- a. Status of inspection and test performed on individual item is indicated either on the item or on documentation traceable to item, e.g.:
 1. stamps, tags, labels
 2. routing cards, travelers, logs
 3. inspection or test records
- b. Inspected/tested item is identified to indicate that it passed required inspection(s) and/or test(s).
- c. Inspected/tested item is identified to indicate that, if it failed the required inspection(s) and/or test(s), a nonconformance or corrective action was initiated.
- d. Inspected/tested item is identified to preclude inadvertent bypassing of required inspection(s) and/or test(s).
- e. Item is properly designated to prevent inadvertent operation, e.g.:
 1. tagging valves and switches
 2. keyed entry/use
- f. Authority for application and removal of tags, markings, labels, and stamps that indicated test, inspection, or operating status is specified.

A14.04.02 Inspection of QA Program Implementation.

- a. Evaluate a sample of safety related and risk significant non-safety 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).
- b. Observe the licensee's testing or inspection of an item:

1. Verify that personnel conducting the inspection or test are authorized to change/update markings (e.g., tags) or documentation subsequent to the inspection or test.
 2. Verify that the item is then properly marked and/or that the associated documentation regarding its test, inspection or operating status is accurately completed.
 3. Verify that associated documents are updated to reflect this test or inspection and are traceable.
- c. Determine how the licensee ensures that inspections and tests are conducted in proper sequence. Methods to track the progress of these activities may include, for example, paper logs, electronic inventory (e.g., database, spreadsheet), and posted checklists. Select items from the licensee's schedule, and verify that the inspection or test was completed as required and that the markings and associated documentation are accurate and consistent.
- d. 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 marked and/or 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.
- e. Select items marked/documented as being placed back into full service from the lists of NCRs or CARs. The appropriate sample of items might be selected by examining the actions described in open or closed NCRs or CARs. Examine the selected items to verify that each item was marked and/or documented as in service.

35007-A14.05 RESOURCE ESTIMATE

A14.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A14.05.02 The verification of the implementation of the QA program documents will require approximately 16 direct inspection hours.

Appendix 15. Inspection of Criterion XV –Nonconforming Materials, Parts, or Components

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A15.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 16, “Inspection of Criterion XVI – Corrective Action”

IP 36100.01, “Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance During Construction.”

35007-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.

35007-A15.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

During the review of the requirements established for the disposition of safety related and risk significant non-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; and (4) the responsibility and authority for the disposition of nonconforming items will be clearly defined in writing. It is extremely important that nonconforming safety related and risk significant non-safety related items are properly controlled to prevent their inadvertent use or installation.

Nonconforming conditions may need to be evaluated for potential reporting to the NRC. Inspection of reporting requirements is done in accordance with IP 36100.01, “Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance During Construction.”

Inspection Requirements.

A15.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for the control of nonconforming items. As a minimum, the implementing documents should provide for the following:
 1. Marking and segregating nonconforming items to prohibit the use or installation of the item, e.g.:
 - (a) Placed in clearly identified and designated area.
 - (b) Tagged, marked, labeled (action does not adversely affect end use).
 2. Review of nonconformance to determine disposition of nonconforming items, e.g., accepted, rejected, repaired, reworked, and use-as-is.
 3. Notification to affected organizations of nonconforming items.
 4. Documentation of nonconforming items.

A15.04.02 Inspection of QA Program Implementation.

- a. Tour the on-site and off-site warehouse facilities to confirm that the licensee has established areas for segregating and controlling nonconforming items.
- b. Select a representative sample of safety related and/or risk significant non-safety related items currently in storage that have been identified to be in nonconformance with specified requirements. Ensure that the items are segregated or marked to preclude inadvertent use, further processing, delivery, or installation. For each selected item, review the associated documentation of the nonconformance to verify that it contains a technically adequate description of the problems with the item.
- c. Select a representative sample of licensee nonconformance evaluations of items that have been previously rejected, repaired or reworked. Verify that they contain technically adequate explanations for the resulting dispositions of the nonconforming items.
- d. Nonconformance was reported to NRC IAW 10 CFR 21.21(d)(1) and 10 CFR 50.55(e), if applicable.

35007-A15.05 RESOURCE ESTIMATE

A15.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A15.05.02 The verification of the implementation of the QA program documents will require approximately 8 direct inspection hours.

Appendix 16. Inspection of Criterion XVI – Corrective Action

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A16.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 15, "Inspection of Criterion XV – Nonconforming Materials, Parts, and Components"

Inspection Manual Chapter 2503, "Construction Inspection Program: Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)"

Inspection Manual Chapter 2504, "Construction Inspection Program: Inspection of Construction and Operational Programs"

NRC OEDO Procedure 0220, "Coordination with the Institute of Nuclear Power Operations" (ML062000752)

35007-A16.03 SAMPLE SIZE

A16.03.01 The inspectors will conduct an annual team inspection in accordance with Section A16.04.01 and/or Section A16.04.02.03 of this appendix. 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 five implementing documents will be reviewed. During subsequent annual team inspections, the inspectors will review the licensee's implementation of its CAP by inspecting at least 10 significant conditions adverse to quality or 10 CFR 50.55(e) reportable events, 15 conditions adverse to quality, and five construction operating experience (ConE) entries. If the designated number of samples is not available, the inspectors will review all of the available samples.

A16.03.02 The inspectors will conduct routine screening of CAP entries in accordance with A16.04.02.01 of this appendix.

A16.03.03 The inspectors will conduct a focused inspection of four to six issues entered into the licensee's CAP annually in accordance with A16.04.02.02 of this appendix.

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 promptly identified, fully evaluated, tracked, trended, and corrected in a timely manner commensurate with their safety significance and complexity. If multiple CAPs exist, ensure that interfaces are defined so that the potential impact of identified problems is appropriately evaluated across organizational boundaries.

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.

Conditions adverse to quality should be identified completely, accurately, and in a timely manner commensurate with their safety significance. Problems, such as design errors, personnel errors, procedure deficiencies, noncompliance with regulatory requirements, inadequate procurement requirements, equipment deficiencies, inadequate implementation of work controls, QA record deficiencies, inadequate training, inadequate storage conditions, equipment functional and pre-operational testing problems, problems meeting ITAAC, and NRC identified issues should all be considered by the licensee's program for entrance into the CAP. Licensee inspections may result in the rejection and repair of identified deficient conditions and or materials within that process being inspected, rather than being separately entered into the corrective action process. These items should, however, be documented and considered by the licensee's program for trending.

When assessing the significance of an item, the licensee should, to the extent practical, consider the risk/safety significance of the problem. Some additional factors that should be considered when assigning graded levels of treatment within the CAP include: 1) consequence of malfunction or failure of the item, 2) design and fabrication complexity or uniqueness of the item, 3) the need for special controls and surveillance over processes and equipment, 4) the degree to which functional compliance can be demonstrated by inspection or test, 5) the quality history and degree of standardization of the item, and 6) the difficulty of repair or replacement.

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 FSAR, including the appropriate version of NQA-1. The team should accomplish the following steps during its inspection:

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for the identification, evaluation, and resolution of conditions adverse to quality. As a minimum, the implementing documents should provide for the following performance attributes:
1. Classification, prioritization, and evaluation for report ability (i.e., 10 CFR 50.55(e)) of conditions adverse to quality.
 2. Complete and accurate identification of the problem in a timely manner commensurate with its significance and ease of discovery.
 3. Screening of items entered into the CAP, as necessary to determine the proper level of evaluation.
 4. Identification and correction of: procurement document errors; deviations from procurement document requirements; defective items; poor workmanship; incorrect vendor instructions; significant recurring deficiencies at both vendor shops and on site; and generic procurement related deficiencies.
 5. Identification and correction of design deficiencies (errors). For significant deficiencies, it includes determining the cause and instituting fixes to the design process and QA program to prevent recurrence of similar deficiencies.
 6. Consideration of extent of condition, generic implications, common cause, and previous occurrences.
 7. Classification and prioritization of the resolution of the problem commensurate with its safety significance.
 8. Identification of root and contributing causes, as well as actions to preclude recurrence for significant conditions adverse to quality.
 9. Identification of corrective actions that are appropriately focused to correct the problem.
 10. Completion of corrective actions in a timely manner commensurate with the safety significance of the issue. If permanent corrective actions require significant time to implement, then interim corrective actions and/or compensatory actions are identified and implemented to minimize the problem and/or mitigate its effects, until the permanent action can be implemented.
 11. Provisions for escalating to higher management those corrective actions that is not adequate or not timely.
 12. Overview of trends in conditions adverse to quality. The licensee should periodically trend and assess information from the CAP in the aggregate to identify programmatic and common cause problems and then communicate the results of the trending to the applicable personnel.

- b. Ensure that the licensee has extended the CAP coverage to include non-safety related SSCs, such as Seismic II and Regulatory Treatment of Non-Safety Systems (RTNSS) that perform safety significant functions, as required by the QAPD. These non-safety related risk significant SSCs are also included in UFSAR Section 17.4, Reliability Assurance Program.
- c. Ensure that the licensee has put into place a process to evaluate OE information, including vendor recommendations and internally generated lessons learned. Specifically (as applicable) relevant internal and external OE should be systematically collected, evaluated, and communicated to affected internal stakeholders. OE that is determined to be applicable to the facility should be entered into the CAP.
- d. If any of the above steps cannot be verified during the initial team inspection, they should be completed during a subsequent annual team inspection.

A16.04.02 CAP Implementation.

Implementation of the licensee's CAP will be assessed in three different ways: (1) through routine screening of CAP entries, (2) through a focused review of four to six samples per year, and (3) through an annual team inspection.

02.01 Routine Review.

- a. Resident inspectors should screen each item entered into the CAP to select the best samples for follow-up. This review can be accomplished by attending daily CAP review board meetings; reviewing computerized CAP entries, or reading hard copies of CAP documents. The intent of this review is for inspectors to be alert to conditions such as repetitive or long-term issues or cross-cutting components that might warrant additional follow-up through the annual follow-up of selected issues, annual team inspections, or other baseline inspections. Inspectors should also be alert for adverse performance trends.
- b. Inspectors should verify that corrective actions commensurate with the significance of the issue have been identified and implemented by the licensee. An in-depth review of selected issues may be conducted in accordance with Section 02.02 of this appendix.
- c. Inspectors should verify that equipment, human performance, and program issues are being identified by the licensee at an appropriate threshold and entered into the CAP.
- d. Inspectors should review a sample of issues to verify that the licensee has appropriately classified the issue and has taken appropriate short-term corrective actions.
- e. Additionally, inspectors are expected to conduct reviews of corrective action activities during the conduct of other baseline inspection procedures.

02.02 Annual Follow-up of Selected Issues.

- a. The annual follow-up of selected issues ensures that the licensee has planned and/or implemented corrective actions commensurate with the significance of identified issues. The resident inspectors should select an annual sample of four to six items for a more in-depth focused review. These samples can be reviewed throughout the annual assessment cycle. The selected samples should be reviewed against the performance attributes contained in A16.04.01.a of this IP appendix.
- b. To the extent available, the sample selected should include:
 - (1) Conditions and significant conditions adverse to quality, which are in the licensee's CAP;
 - (2) Cited or non-cited violations of regulatory requirements and other documented findings;
 - (3) Issues identified through NRC ConE;
 - (4) Issues identified through industry ConE, which have been placed in the licensee's CAP; and
 - (5) Licensee audits and assessments.

Refer to Section 3.3 of OEDO Procedure 0220, "Coordination with the Institute of Nuclear Power Operations," (INPO) for guidance prior to reviewing any INPO documents. INPO findings, recommendations, corrective actions, and OE that are placed in the licensee's CAP can be considered appropriate for inspection.

02.03 Annual Team Inspection

Inspectors shall perform an annual team inspection of CAP activities as described below. While performing these inspections, the inspectors should be aware of any contribution that cross-cutting components make to performance deficiencies and consider insights that these issues may provide into the licensee's progress in addressing any developing or existing cross-cutting themes.

Inspectors will conduct the first annual team inspection in accordance with Section 16.04.01. If there is enough CAP activity at the time of the first annual team inspection, the inspectors can also review CAP implementation.

Once the CAP has been verified to be in accordance with the QAPD and other requirements listed in Section 16.04.01, the annual inspection team will conduct the following steps:

- a. On an annual basis, select a representative sample of 10 significant conditions adverse to quality or 10 CFR 50.55(e) reportable events, 15 conditions adverse to quality, and five operating experience (OE) entries. If the designated number of samples is not available, the inspectors will review all of the available samples. To the extent available, the sample selected should include:
 - (1) Conditions and significant conditions adverse to quality, which are in the licensee's CAP;

- (2) Cited or non-cited violations of regulatory requirements and other documented findings;
- (3) Issues identified through NRC OE;
- (4) Issues identified through industry OE, which have been placed in the licensee's CAP; and
- (5) Licensee audits and assessments.

Refer to Section 3.3 of OEDO Procedure 0220, "Coordination with the Institute of Nuclear Power Operations," (INPO) for guidance prior to reviewing any INPO documents. INPO findings, recommendations, corrective actions, and OE that are placed in the licensee's CAP can be considered appropriate for inspection.

- b. For each condition/problem selected for review, ensure that the licensee has appropriately followed its implementing documents and has addressed the applicable CAP performance attributes contained in A16.04.01.a of this appendix.
- c. Assess whether the licensee is using alternative processes to handle issues that do not constitute conditions adverse to quality. Sample entries into these alternative processes to ensure that conditions adverse to quality have not be mischaracterized and inappropriately handled outside the CAP.
- d. Review the results of recent audits and/or assessments of the licensee's CAP, and compare and contrast the results of those audits and/or assessments with the results developed through this inspection.
- e. Identify any issues that might hinder the willingness of individuals to identify issues within the CAP or allow for effective resolution.

Upon conclusion of the annual team inspection, complete the following items:

- a. Perform an assessment of the licensee's ability to identify, evaluate, and correct problems.
- b. Perform an assessment of the licensee's use of ConE information. Externally identified problems include, but are not limited to: 10 CFR 21 notifications; NRC generic communications; reports issued by the Nuclear Steam Supply System vendor (and the applicant for applicable design certification), other facilities under licensee's control, similarly designed facilities under construction, the Architect/Engineer corporate office, major contractor corporate offices, and equipment suppliers and manufacturers; information from the Electric Power Research Institute; Licensee Event Reports; and general ConE. Refer to Section 3.3 of OEDO Procedure 0220, "Coordination with the Institute of Nuclear Power Operations," for guidance prior to reviewing any INPO documents. INPO findings, recommendations, corrective actions, and ConE that are placed in the licensee's CAP can be considered appropriate for inspection.
- c. When performing an assessment of actions taken by the licensee in the identification and correction of issues, the inspector should look for indications that licensee maintains a positive safety culture as encouraged by the NRC safety culture policy. In conducting interviews or observing other activities involving licensee personnel during the

inspection, the inspector should be sensitive to areas and issues that may be indicative of a decline in safety culture as captured by the 10 aspects of a positive safety culture in IMC 0613, Appendix F. Although the licensee may be implementing an employee concerns or similar program regarding the identification of safety issues, the possibility of existing underlying factors that would produce a "chilling" effect or reluctance to report such issues could exist, and inspectors should be alert for such indications. Such factors could go beyond direct retaliation and could include issues such as inadequate staffing that results in excessive overtime and an unwillingness to raise issues that might result in further increases to an already high workload, or cases where repeat issue identification have not resulted in adequate corrective action causing personnel to be reluctant to identifying additional related issues.

At the end of this IP appendix is a list of questions that can be used when discussing CAP issues with licensee individuals to help assess whether there are impediments to the establishment of a positive safety culture. It is not intended that inspectors conduct formal interviews solely for the purpose of assessing the safety culture of the construction site, but rather, that inspectors make use of the questions during discussions with licensee individuals concerning other attributes of the inspection. It is expected that during this inspection, discussions and interviews will be held with both licensee management and staff.

If, as a result of the interviews or observations, inspectors become aware of specific examples of employees being discouraged from raising safety or regulatory issues within the licensee's or contractor's organization or to the NRC, inspectors should inform regional management prior to further follow up. If inspectors becomes aware of a "chilling" effect or other general reluctance of employees to raise safety or regulatory issues unrelated to a specific event or incident, regional management should be informed prior to further follow up.

- d. Perform an assessment of the licensee's evaluation of its CAP. Determine whether licensee reviews are consistent with the NRC review of CAP issues by comparing the result of the team's review of CAP issues with licensee performance reviews, including specific licensee reviews of the CAP.
- e. Problem Identification and Resolution. The inspector should confirm that problems identified during the inspection are entered into the licensee/constructor corrective action program in accordance with program requirements. The inspector may review licensee actions to address similar or related problems that were previously identified, in order to check the extent of condition and confirm the effectiveness of the licensee's corrective measures. Inspection activities under this procedure include independent verification that the licensee is identifying problems related to this inspection area and entering them in the corrective action program. For a sample of selected problems documented in the corrective action program, verify that the corrective actions and resolutions are appropriate and adequate."

35007-A16.05 RESOURCE ESTIMATE

A16.05.01 The verification of the implementation of the QA program documents during the annual team inspection will require approximately 200 direct inspection hours.

A16.05.02 Inspectors will select an adequate number of samples to gain reasonable assurance that the licensee and its contractors/subcontractors are implementing their respective CAPs effectively and in accordance with their procedures and 10 CFR Part 50, Appendix B, and Criterion XVI. These samples should include significant conditions adverse to quality or 10 CFR 50.55(e) reportable events, conditions adverse to quality, and construction/operating experience.”

Suggested Questions for Use in Discussing Corrective Action Program Issues

The following are suggested questions that may be used when discussing CAP issues with licensee individuals. It is not intended that these questions are asked verbatim, but rather, that they form the basis for gathering insights regarding whether there are indications of a decline in safety culture. In cases where a potential problem with the employee’s willingness to raise concerns or other safety culture aspect issues are identified in response to these questions, the inspector should consult with regional management for directed course of action.

1. Raising a safety concern
 - a. Are you willing to raise a safety concern?
 - b. Are there any conditions under which you would be hesitant to raise a safety concern?
 - c. If yes, does that condition exist here at (Insert Plant Name)? Please elaborate.
2. Awareness of situations
 - a. Are you aware of situations where any employee or contractor may be hesitant to raise concerns, internally or externally?
 - b. If yes, please explain. (If an NRC inspector is aware of a specific incident that may have caused such hesitation, then ask about it. Focus on whether or not the interviewee or others may be less likely to report concerns since that incident).
3. Avenues for raising safety issues
 - a. Where would you go to raise a safety issue? (The NRC inspector should be aware of the following avenues for raising concerns, but not prompt the interviewee: supervisor, CAP, alternative program (Employee Concerns Program (ECP)/Ombudsman), NRC, or other avenue.)
 - b. Why would you pick this avenue? Have you or others had any experiences, or know of any situations, that have influenced your decision to pick this avenue? If so, please describe.
4. Would you say that your management is supportive of the ECP/Ombudsman program?
 - a. If yes, how is such support demonstrated?
 - b. If no, please describe what has led you to believe that they are not supportive.
5. Are there other avenues available to you for raising safety issues? Ask each of the questions listed in the following table for each avenue available:

Question	Supervisor	Corrective Action Program	ECP/ Ombudsman	NRC	Other
Have you ever submitted a safety issue to <i>(insert method)</i> ? If not, why not?					
If yes, was the issue adequately addressed? Why or why not?					
If not adequately addressed, did you further pursue the issue? If not, why not?					
Given the nuclear safety importance of the issue, did you receive timely feedback?					
Describe any instances in which you know of another employee who submitted an issue to <i>(insert method)</i> and you considered the response unacceptable?					

6. Are you aware of any actions taken by your management to prevent and detect retaliation and/or chilling effect?
 - a. Are their actions effective?
 - b. Has management's handling of any chilling effect issues been consistent?
7. Are you aware of any instances in which another individual experienced a negative reaction for raising a safety issue? If yes, please describe the incident, including any information conveyed by management concerning the incident.
8. Would you say that your management is supportive of the NRC's safety culture policy?
 - a. If yes, how is such support demonstrated?
 - b. If no, please describe what has led you to believe they are not supportive.

9. Have events or circumstances occurred in the past six months that have reduced:
 - a. Your willingness to identify or raise safety issues?
 - b. Your confidence in the CAP?
 - c. Your willingness to challenge actions or decisions you believe is unsafe?

Appendix 17. Inspection of Criterion XVII – Quality Assurance Records

35007-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 FSAR, including the appropriate version of NQA-1, as applicable.

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

35007-A17.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 5, “Inspection of Criterion V – Instructions, Procedures, and Drawings”

Appendix 6, “Inspection of Criterion VI – Document Control”

35007-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 six 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 criterion, e.g.:

- a. Individual records and records packages - a representative sample would include a total of 10 documents (may be a mix of records).
- b. Temporary records facilities - a representative sample would include three facilities.
- c. Main records storage facilities - a representative sample would include no more than two facilities.
- d. Records transferred from leaving/transferring personnel to designee - a representative sample would include documents for a total of two persons.

35007-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 and important to safety SSCs. Records furnish evidence

of activities affecting quality during construction. Implementation of the 18 criteria of Appendix B to 10 CFR Part 50 will result in the creation of numerous QA records during the construction phase. These records are created to support objective evidence that the plant has been constructed to design specifications and in accordance with regulations and implementing documents. These records must be traceable to the activities that they support. The establishment of adequate procedural controls includes the turnover/retention of contractor quality records. Inspections within this Appendix B criterion will verify that adequate procedural controls have been established to maintain quality-affecting records and assure proper identification and retrievability of these records.

Records will be created by the licensee and its contractors on the ASL. 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. Inadequacies in records and records retention programs for quality-affecting activities may result in significant challenges to licensees during construction, including extensive rework of safety related SSCs as a result of inadequate or indeterminate QA records. The need to maintain accurate and retrievable QA records is a significant consideration during the construction phase.

Records may be designated as individual records that provide sufficient evidence that an activity was conducted and documented. The inspector should keep in mind that each individual record must be fully traceable on its own. The licensee may choose to maintain a group of records together to provide a more thorough description and history of particular activity. These related records may be maintained as records packages.

Records are maintained in print or 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 FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for creation, maintenance and disposition of QA records. As a minimum, the implementing documents should provide for the following:

- a. Select a sample of implementing documents that describes the processes for general records creation, maintenance, storage, and disposition. Select this sample from a master list of controlled implementing documents. Verify that the implementing document addresses:
 1. Methods to ensuring that records are legible, complete, and traceable to the activity or item; authenticated by authorized personnel; and classified in accordance with regulatory requirements (e.g., permanent, non-permanent, confidential/privileged).
 2. Provisions for corrections to records.
 3. Records (including electronic records) are maintained and stored in designated facilities:

- (a) To prevent deterioration, damage, and loss (e.g., duplicate storage, migrating and preserving electronic media if degradation is identified).
 - (b) To be accessible to designated organization.
 - (c) For a specified duration.
 - (d) To be retrievable within a reasonable time frame, e.g., use of filing system.
4. Disposal of records is performed by authorized personnel.
- b. Select a sample of implementing documents (e.g., administrative QA procedures, technical instructions, and engineering specifications) that provide specific instructions for the creation of designated records that support the implementation of the specific activity. Select this sample from a master list of controlled implementing documents. Verify that the implementing document includes:
- 1. Specific records to be created to provide evidence that the activity was completed, i.e.:
 - (a) Operating logs.
 - (b) Results of reviews, audits, inspections, tests.
 - (c) Monitoring of work performance.
 - (d) Materials analysis.
 - (e) Closely-related information, e.g., personnel qualification, procedures, drawings, procurement documents, calibration results, corrective actions, nonconformance's.
 - (f) Other records determined to be necessary.
 - (g) Calculations, analysis, drawings and NDE reports (i.e., safety related special lifting devices).
 - 2. Organizations or personnel responsible for creating and transmitting records to the storage facility.

A17.04.02 Inspection of QA Program Implementation.

- a. Obtain a sample of completed individual records or records packages from the implementing documents selected in A17.04.01.b. These may be maintained at the main records facility. Verify that:
 - 1. Records were authenticated (initials or signature, date).
 - 2. Corrections to the records did not obscure original information on record.

3. Records were transmitted from temporary storage to main storage within designated time frame.
- 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:
 1. Accessible to designated organization or personnel.
 2. Protected from damage (e.g., water, fire) and theft.
- c. Determine if in-process records and records stored temporarily were transferred to designated personnel if a person left employment or transferred to another unrelated position within the organization. Interview human resources personnel to obtain a list of affected personnel, and select a sample of personnel from the list. Verify that records were transferred to designated personnel.
- d. 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 the following:
 1. Facility is accessible to designated organization or personnel.
 2. Access to the facility by visitors is controlled.
 3. Records are readily retrievable, e.g., use of filing system.
 4. Records are protected from damage (e.g., water, fire) and theft.
 5. Records temporarily removed from the storage facility are controlled.
 6. Electronic media that include QA records (e.g., electronic recordings, vary large sets of data) are stored in accordance with designated requirements, such as humidity, light, temperature.
- e. Verify that construction-phase QA records (e.g., design, procurement), stored by contractors that were assigned those major responsibilities, were transferred to the licensee. Interview contractor QA records personnel to obtain information regarding transferred records, and select a sample of those records. Verify that the records were transferred within the established schedule and that the licensee received the records.

NOTE: This inspection activity does not include transfer of records by the majority of contractors to the licensee in accordance with most procurement activities of Criterion IV and VII of Appendix B to 10 CFR Part 50.

35007-A17.05 RESOURCE ESTIMATE

A17.05.01 The review of the QA program implementing documents will require approximately 12 direct inspection hours.

A17.05.02 The verification of the implementation of the QA program documents will require approximately 24 direct inspection hours.

Appendix 18. Inspection of Criterion XVIII – Audits

35007-A18.01 INSPECTION OBJECTIVES

A18.01.01 Verify that the licensee's QA implementing documents for conducting audits are consistent with the NRC-approved QAPD and commitments in the FSAR, including the appropriate version of NQA-1, as applicable.

A18.01.02 Verify that the licensee has effectively implemented its QA implementing documents for conducting audits.

35007-A18.02 RELATED INSPECTION PROCEDURES AND REFERENCES

Appendix 1, "Inspection of Criterion I – Organization"

Appendix 2, "Inspection of Criterion II - Quality Assurance Program"

Appendix 7, "Inspection of Criterion VII – Control of Purchased Material, Equipment and Services"

35007-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 audits. 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 five implementing documents will be reviewed.

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

35007-A18.04 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

The inspector should find implementing documents that specifically address the conduct of audits by the licensee. Personnel conducting audits evaluate programmatic compliance and effectiveness of the implementation of the QA program. Licensee audits are independent, planned and documented evaluations performed by trained QA personnel. Two categories of audits are generally performed by the licensee: 1) internal audits of the activities performed by the licensee and its contractors, and 2) external audits of contractors that provide safety related items and services and are placed on an ASL or provide commercial grade items for dedication in accordance with 10 CFR Part 21. Internal audits conducted by the licensee focus on activities performed by the licensee and by contractors that work to the licensee's QA program. External audits (evaluation required by Criterion VII of Appendix B to 10 CFR Part 50) 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.

The NRC inspector must keep in mind that these inspections are focused on the licensee, not on the licensee's contractor that is on the ASL or provides commercial grade items for dedication. The primary purpose of the NRC inspections is to examine the implementation of the licensee's QA program, including its oversight activities of its contractors on the ASL or those contractors providing commercial grade items that are dedicated.

Audits may be performed to assist licensee management in making overall evaluations of the implementation of the QA program, may be focused on specific areas because of the safety significance of the area, or may address contractors for which repetitive deficiencies or nonconformance's have been identified. The licensee may have two or more separate audit programs to cover these categories. The licensee may have a contractor that performs these audits in accordance with the licensee's QA program or its own QA program (the contractor would then be on the ASL).

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

Inspection Requirements.

A18.04.01 Inspection of QA Implementing Documents.

- a. Review applicable sections of the licensee's QAPD and FSAR. Ensure that appropriate implementing documents have been developed to address the QAPD requirements and FSAR commitments for conducting internal audits. The licensee may have more than one process for conducting internal and external audits. As a minimum, the implementing documents shall provide for the following:
 1. Audit Planning and Scheduling:
 - (a) Schedule of proposed audits is maintained and provides coverage of applicable aspects of quality-affecting activities (i.e., criteria of Appendix B to 10 CFR Part 50).
 - (b) Audit plan is developed, including developing audit checklists (if used).
 - (c) Purpose of the audit is to verify compliance with the specified aspects of the QA program and to determine effectiveness of the QA program.
 - (d) Auditors must meet and maintain auditor qualification requirements (e.g., training, experience, conduct of audits; knowledge of overall policies, procedures and instructions that establish the QA program; procedures or Instructions that implement QA program related to specific job-related activities).
 - (e) Auditor is independent of direct responsibility for activity to be audited.
 - (f) Specialists (i.e., not qualified auditors) participating on the audit team, receives audit briefing (e.g., purpose of audit, scope of auditing to be conducted by the specialist, and expected input from specialist).
 2. Documentation of Audit Results:

- (a) Results of audit are documented (e.g., report, checklists, forms).
- (b) Documented audit results are reviewed by management having responsibility for the area(s) that are audited.
- (c) Identification and summary of deficiencies and nonconformance's were documented.
- (d) Documented audit results include a determination of:
 - (1) compliance with all aspects of QA program.
 - (2) effectiveness of the auditee's QA program.
- 3. Follow-up audit of areas of deficiency, nonconformance or weakness are conducted when determined to be necessary; criteria for making determination (e.g., management decision, repetitive deficiencies or nonconformance's) are established.

A18.04.02 Inspection of QA Program Implementation.

- a. The following inspection activities will be performed for both internal and external audits that are performed by the licensee:
 - 1. Examine the current long-range, internal audit schedule. Verify that areas to be audited and audit frequencies identified are consistent with commitments. If a scheduled audit is indicated as deferred or cancelled, verify that a justification was documented.
 - 2. Select a sample of the most recently completed audit reports, and verify the following for each:
 - (a) Audit was included in the audit schedule.
 - (b) Audit was performed within the scheduled time frame.
 - (c) Audit plan was prepared and issued.
 - (d) Audit report included a determination of effectiveness of implementation and compliance with the QA program.
 - (e) Audit report was reviewed by management responsible for audited area.
 - (f) Audit report was distributed to designated organizations.
 - (g) Audit report included summary of identified deficiencies and nonconformance's, and a response due date.
 - (h) Audit findings corrected during audit were documented and verified during audit process.
 - 3. Determine which organization (licensee or its contractor) performed the audit (the sample may be from same sample of audit reports as A18.04.02 a.2. above). If a contractor performed the audit, verify that the procurement document between the

licensee and the contracting company or individual included the responsibility to conduct audits.

4. Select a sample of auditors and specialists who conducted audits (the sample may be from same sample of audit reports as b. above). Verify that:
 - (a) Auditors were trained, i.e., auditor training was maintained in accordance with schedule.
 - (b) Auditors did not have direct responsibility in the areas that were audited, nor did they perform the work being audited.
 - (c) Specialists who participated on the audit team received an audit briefing prior to the start of the audit.
 5. Select a sample of qualified auditors and specialists who have recently conducted audits (the sample may be from same sample of audit reports as A18.04.02 a.2. above). Conduct interviews with these personnel, and verify that they had direct access to the levels of management of the activities being audited.
 6. Review a sample of deficiencies identified during previous QA audits (the sample may be from same sample of audit reports as A18.04.02 a.2. above). Verify that deficiencies and nonconformances identified during the audit have been resolved or they are currently being carried as "open items" with a defined schedule for resolution.
 7. Determine how follow-up activities (e.g., re-audit, surveillance, evaluation) to audits are tracked so that the actions are completed. Interview QA staff to obtain a sample of follow-up actions. Verify that the actions were taken or are scheduled to be completed.
- b. The following additional inspection activities will be performed for external audits that are performed by the licensee (the sample may be from same sample of audit reports as A18.04.02 a.2. above):
1. Select a sample of audit reports completed by the licensee. Determine if the results of audit activities were sufficient to ascertain the general status of the contractor's implemented QA activities for the requirements in specific procurement documents.
 2. Select a sample of audit reports that documented follow-up activities to previously performed audits. Verify that the follow-up activity fully addressed expressed concerns and that previously identified concerns were appropriately resolved.

35007-A18.05 RESOURCE ESTIMATE

A18.05.01 The review of the QA program implementing documents will require approximately 8 direct inspection hours.

A18.05.02 The verification of the implementation of the QA program documents will require approximately 24 direct inspection hours.

Attachment 1 - Revision History for IP 35007

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 Information)
NA	10/15/09 CN 09-024	Initial issue to support inspection of construction programs described in IMC 2504. In addition, contrary to IMC 0040, the Appendices are numbered, rather than lettered, to align with the numbered criteria of 10 CFR Part 50, Appendix B. Completed 4 year search of Historical Change Notices, and no commitments were found.	N/A	ML092580581
N/A	12/13/10 CN 10-026	Revised to: expand scope to include inspection of pre-COL activities; update NQA-1 version; refine when construction inspections of QA implementing documents begins	N/A	ML103010486
N/A	ML12355A330 01/15/13 CN 13-002	Appendix 16 is being revised to incorporate lessons learned from ConE IFR 2012-13 concerning the corrective action program (CAP) assessments. This revision removes the requirement that the inspection team perform an overall CAP assessment. This assessment requirement is being moved to IMC 2505P. Also, the inspection instructions are being revised to be more user-friendly.	N/A	ML12355A328

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 Information)
N/A	ML13239A133 02/26/14 CN 14-006	Revised to remove the use of IP 43004, Inspection of Commercial-Grade Dedication Programs, as part of IMC 2504. Inserts guidance on design change control and sample of design changes in Appendix 3 and test change control in Appendix 11 based on 10 CFR Part 52, Appendices for Changes and Departures. Adds guidance on sample size for procurement document control in Appendix 4 and adds guidance regarding safety culture in Appendix 16, replacing guidance in IP 40504 which has been deleted. Also mentions Regulatory Guide 1.28 endorsement of NQA-1 in Appendix 13. Removes references to Center for Construction Inspection. Modifies the Approved Supplier List (ASL) nuclear quality ASL. Makes additional minor editorial changes.	N/A	ML13239A129

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 Information)
N/A	ML16285A443 12/08/16 CN 16-032	Revised to include refinements developed from implementation of this IP. Specifically provides guidance on initial program and implementation inspection samples; for subsequent years, provides guidance on the selection of QA criteria and sample recommendations; and clarifies estimated resources may vary based on end-of-cycle recommendations. Includes guidance regarding vendors purchasing commercial-grade calibration and testing services from domestic and international calibration and testing laboratories accredited by a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in lieu of performing a commercial-grade survey. Furthermore, deletes requirements for team to conduct one-week in-office and one-week onsite inspection and that NRC vendor inspection branches should participate in QA inspection.	N/A	ML16286A675
N/A	ML21344A205 02/09/22 CN 22-003	Revised to include the NRC SER to incorporate the QA alternative of using the ILAC accreditation process in lieu of performing commercial-grade survey. Also included the SER to NEI that approves the use of NEI 14-05A, Rev. 1, which recognizes the 2017 edition of ISO/IEC-17025 as the basis for the ILAC accreditation process in lieu of performing commercial-grade survey. Also included editorial changes to reflect the updated Divisions and Branches.	N/A	N/A ML22033A546 (35007-2307)