
INSPECTION PROCEDURE 88201 APPENDIX H

OTHER QUALITY ASSURANCE (QA) ELEMENTS

Effective Date: June 20, 2025

PROGRAM APPLICABILITY: IMC 2600, 2694

88201.H-01 INSPECTION OBJECTIVE(S)

- 01.01 To determine if the applicant or licensee has adequately established and is implementing appropriate quality assurance (QA) elements to items relied on for safety (IROFS) as described in the integrated safety analysis (ISA).
- 01.02 To determine if the applicant's or licensee's QA elements are adequately coordinated and integrated with other management measures, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR), Section 70.4.

88201.H-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) is intended to provide inspection requirements and guidance applicable to a wide variety of potential construction projects at both existing and new fuel cycle facilities. These projects may vary greatly in scope, complexity, and risk to public health and safety. As a result, not all sections, or subsections, of this appendix may be applicable or implemented at a specific facility. Recommended inspection scope and hours for a specific new fuel cycle facility will be documented in the principal inspection plan (PIP) for that facility developed in accordance with Inspection Manual Chapter (IMC) 2694, "Fuel Cycle Facility Construction and Pre-Operational Readiness Review Inspection Program." Additionally, this appendix can be used to provide additional management measures inspection guidance for plant modification inspections at existing facilities but is not required to be implemented for these projects. Use of this appendix or sections of this appendix for modifications at existing fuel cycle facilities, would be done on a case-by-case basis, in accordance with IMC 2600, Appendix B, "NRC Core Inspection Requirements."

02.01 Organization

a. Inspection of QA Implementing Documents

- 1. Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address the commitments for organization.
- 2. Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents address QA functions and responsibilities.

b. Inspection of QA Program Implementation

1. Determine if changes to the organizational structure have occurred, including changes to the relationship between the applicant or licensee upper management and the organization(s) responsible for QA oversight functions. Review changes to the organizational structure and verify that these changes do not adversely impact the ability of the applicant or licensee to effectively implement the QA program. Discuss the changes with project and QA management. The QA functions may be performed by various sub tier organizations, such as engineering, field quality control and procurement.
2. Examine the organizational description and, if available, the organizational chart to determine if the personnel that perform QA oversight functions are sufficiently independent from the work being performed.
3. Determine if changes in personnel authorities, responsibilities and functions have occurred. Discuss the changes with the applicant's or licensee's management to determine why the changes were made (e.g., reassignment of staff, departure of staff from organization).
4. Interview a sample of personnel that perform QA oversight functions to determine whether they have an adequate understanding of the QA program, focusing on roles and responsibilities. If it is not apparent that a staff member has a clear understanding, then the inspector should examine documents to determine if requirements for training or qualification are sufficient (reference Section 02.02 of this appendix 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.
5. 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, if applicable, 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 C of this IP for additional information on training and qualification). Determine whether staff members are aware of the levels of management to which the staff would elevate awareness of a quality issue. Verify that personnel responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed have sufficient authority, access to work, and freedom to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation.
6. Evaluate how delegation of authority is documented. Examine a sample of documentation of the most recent delegations.

02.02 Quality Assurance Program

a. Inspection of QA Implementing Documents

1. Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that policies and appropriate implementing documents have

been developed to address the requirements and commitments for revising and modifying the QA plan.

2. Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for establishing the QA program, ensuring indoctrinated and trained personnel conduct quality-affecting activities.

b. Inspection of QA Program Implementation

1. Examine the structure of the applicant's or licensee's QA program (QA plan, policies, implementing documents). Verify that items and activities subject to the QA program are identified.
2. Examine the most recent revision of the QA plan. Verify that revisions to the QA plan were reviewed and approved in accordance with established requirements.
3. Select a sample of staff from various disciplines (e.g., administrative, QA, engineering, training, and craft, from both the applicant or licensee and contractors):
 - (a) Conduct interviews to ascertain whether staff members understand which items (and services) are covered by the QA program they support. If it is not apparent that a staff member has a clear understanding, then the inspector should examine documents to determine if requirements for training or qualification are sufficient.
 - (b) Verify that personnel performing quality-affecting activities are qualified in accordance with standards established by the applicant or licensee. Review changes of key positions to determine whether the minimum qualifications have been met. Compare the qualification requirements with the associated qualification verification documentation for the personnel.
 - (c) Select the names of a sample of staff from various disciplines (may be from same sample as Section 02.02b.3 above):
 - (1) Verify that staff performing quality-affecting activities received required qualification and training. Examine training requirements for those positions and verify that orientation and training were completed within the specified time frame.

02.03 Design Control

a. Inspection of QA Implementing Documents

1. Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for design control. Ensure that the applicant's or licensee's implementing documents provide a sufficient level of detail to allow staff to perform design/engineering work and maintain control of the plant design in accordance with any requirements and or/commitments documented in the ISA. For design work being performed by the design authority or other outside

contracted organization, ensure that the applicant or licensee has invoked any relevant portions of its' QA program, if applicable.

2. 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.
3. Review implementing documents that govern the review, approval, and process for controlling changes to design documents.
4. Review implementing documents that cover the turnover of the design information from the design authority to the applicant or licensee. Ensure that adequate implementing documents are in place to maintain the design basis.

b. Inspection of QA Program Implementation

1. Select a sample of design documents and design changes. To the extent practical, the samples chosen for review should involve multiple systems and organizations (e.g., electrical, mechanical, maintenance, etc.). These samples may include work performed directly by the applicant or licensee, the construction design authority, or through contracted design organizations.
2. Obtain and review the licensee's procedure(s) for design control to ensure that the design conforms to the proposed or approved licensing basis. Verify that applicable procedures for design control, (including design changes, design verification, and commercial grade items) were followed.
3. If available, the sample should include changes requested by field installation personnel. Such changes might involve requested changes to piping or cabling runs, requested deviations from construction drawings, etc. Ensure that the field changes receive the proper level of engineering review in accordance with applicant or 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.
4. Ensure that proper verification, validation, and version control of all quality-related computer software used in the performance of design work.
5. 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 as follows: ISA, design and/or construction specifications, drawings, supporting calculations and analyses, plant equipment lists, maintenance instructions, and vendor manuals.
6. Ensure that the applicant or licensee is appropriately implementing its documents that govern the turnover and control of design information from the design authority.

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

02.04 Procurement Document Control

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for procurement document control for purchases of safety significant items and services.

b. Inspection of QA Program Implementation

Review a sample of recently issued purchase documents for safety-significant items and services. Select a representative sample from the following categories: mechanical, electrical, instrument/electronic, and consumables (e.g., chemicals, reagents, lubricants, filters). Verify the procurement documents were prepared and processed in accordance with licensee's implementing documents. Verify that procurement documents for IROFS address 10 CFR Part 21 requirements, if applicable.

02.05 Instructions, Procedures, and Drawings

a. Inspection of QA Implementing Documents

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

b. Inspection of QA Program Implementation

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

02.06 Document Control

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for review, approval and issuance of controlled documents.

b. Inspection of QA Program Implementation

1. 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.

2. Select a sample from the list(s) of controlled documents. Verify that the controlled documents were developed in compliance with ISA commitments and implementing document requirements.
3. Select a sample of revised controlled documents. Verify that the controlled documents were developed in compliance with ISA commitments and implementing document requirements.
4. 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.
5. Obtain a list of the most recently cancelled/rescinded implementing documents. Select a mixed sample of documents, such as procedures, design drawings, and engineering specifications. Verify that the documents are no longer available at the work site.

02.07 Control of Purchased Material, Equipment, and Services

a. Inspection of QA Implementing Documents

1. Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for evaluation and selection of contractors.
2. Review relevant sections of the applicant's or licensee's ISA and QA plan, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for acceptance of items and services.

b. Inspection of QA Program Implementation

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

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

02.08 Identification and Control of Materials, Parts, and Components

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for the identification and control of safety-related items.

b. Inspection of QA Program Implementation

1. Inspect a sample of safety-related items that are installed, in use, or stored. Examine associated records and other documentation (e.g., tracking systems) that identify these items. Verify that the items are properly identified and controlled in accordance with implementing documents.
2. Observe the applicant's or 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.
3. 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.
4. Examine items that are indicated as incorrect or defective (e.g., nonconformance, corrective action). Verify that the associated documentation and records are in agreement with the indicated item.
5. Examine items with a limited operating or calendar life. Verify that controls are in place to preclude the use of expired items.

02.09 Control of Special Processes

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for control of special processes.

b. Inspection of QA Program Implementation

Implementation of control of special processes should be verified as a part of safety significant items and services (SSIS) inspections conducted in accordance with IP 88200, "Inspections of Safety Significant Items (and Services) During Construction of Fuel Cycle Facilities." For example, inspections of SSIS that involve welding should include verification that any requirements and/or commitments for nondestructive testing (NDT) have been met for the specific SSIS being inspected.

02.10 Inspection

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for conducting inspections to ensure quality.

b. Inspection of QA Program Implementation

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

02.11 Test Control

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for testing.

b. Inspection of QA Program Implementation

Evaluate a sample of documentation for SSIS that require testing. Select a representative sample from the following categories: mechanical, electrical, instrument/electronic, and pre-op. Either directly observe tests (or portions of tests), or review completed test documentation to verify that QA program implementing documents for testing have been correctly implemented. If applicable, also verify that computer programs used for operational control are tested in accordance with an

approved verification and validation plan, and that they demonstrate required performance over the range of operation of the controlled function or process.

02.12 Control of Measuring and Test Equipment

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for control of measuring and test equipment (M&TE).

b. Inspection of QA Program Implementation

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

02.13 Handling, Storage, and Shipping

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for the handling, storage, and shipping of safety significant items.

b. Inspection of QA Program Implementation

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

02.14 Inspection, Test, and Operating Status

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for indicating the inspection, test and operating status of safety significant items.

b. Inspection of QA Program Implementation

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

02.15 Nonconforming Materials, Parts, or Components

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for the control of nonconforming items.

b. Inspection of QA Program Implementation

Select a representative sample of safety significant items that have been identified to be in nonconformance with specified requirements. Ensure that the items are being processed and controlled in accordance with implementing document requirements.

1. Nonconformance was reported to NRC (IAW 10 CFR 21.21(d)(1), if applicable).

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

02.16 Corrective Action

a. Inspection of QA Implementing Documents

The initial corrective action program (CAP) inspection will be conducted either shortly before or just after construction begins. During that inspection, the team shall verify that the applicant's or licensee's QA implementing documents for the identification, evaluation, and correction of conditions adverse to quality are in accordance with the ISA and QA plan or manual, if applicable. The team should review relevant sections of

the applicant's or licensee's ISA and QA plan, if applicable, and ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for the identification, evaluation, and resolution of conditions adverse to quality.

b. Review of Corrective Actions

Inspectors will conduct the initial team inspection in accordance with Section 02.16a of this appendix. If there is enough CAP activity at the time of the first team inspection, the inspectors can also review CAP implementation. CAP implementation will also be inspected on a recurring basis. For the initial inspection, select a representative sample of between four and six significant conditions adverse to quality. If the minimum number of samples is not available, the inspectors will review all of the available samples. For each condition/problem selected for review, ensure that the applicant or licensee has appropriately followed its implementing documents.

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

02.17 Quality Assurance Records

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for creation, maintenance and disposition of QA records.

b. Inspection of QA Program Implementation

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

02.18 Audits

a. Inspection of QA Implementing Documents

Review relevant sections of the applicant's or licensee's ISA and QA plan or manual, if applicable. Ensure that appropriate implementing documents have been developed to address any requirements and/or commitments for conducting assessments.

b. Inspection of QA Program Implementation

Select a sample of the recently completed assessment reports and verify that they have been scheduled and performed in accordance with implementing document requirements. Verify that the qualifications of personnel performing the assessments were in accordance with implementing document requirements, and that follow-up to assessment findings were performed in accordance with implementing requirements. Verify that assessment results were documented and reviewed by management personnel who have responsibility for the area assessed. Verify that conditions requiring prompt corrective action are reported immediately to the appropriate management of the assessed organizations. Inspection of the implementation of the assessment program should also be performed on annual basis, with the same sample size as established in Section 03.18 of this appendix.

88201.H-03 INSPECTION GUIDANCE

03.01 Organization (Inspection Requirement 02.01)

General Guidance

- a. The inspector should examine documents and records and interview personnel to verify implementation of the applicant's or licensee's organizational structure, responsibilities, and authorities. The applicant or licensee may have one overall and several sub tier organizational descriptions. A representative sample would include the overall organizational description and a selection of up to three sub tier organizational descriptions.
- b. The inspector should interview personnel who perform activities that meet quality objectives and perform specific QA functions (see "General Guidance" below) to determine whether they have an adequate understanding of the program and their roles. A representative sample would include at least one member who performs specific QA oversight functions and up to five staff members not assigned to conduct specific QA oversight functions but who implement the licensee's QA program.
- c. The inspector should find implementing documents that specifically address the applicant's or licensee's organizational structure, responsibilities, and authorities. The applicant's or licensee's staff, including contractors (e.g., subcontractors, agents, suppliers, vendors), is responsible for performing activities that meet quality objectives that affect safety significant items (and services). In addition, the applicant or licensee should have specific staff members who have been designated to perform QA oversight functions that are independent of the work being performed. These personnel need sufficient authority, access to work, and freedom to: (a) identify problems; (b) initiate,

recommend, or provide corrective action; and (c) ensure corrective action implementation.

- d. Inspection of the applicant's or licensee's organization may require more in-depth interviews of staff and management than other QA elements. The inspection of implementation in this area should be directed at verifying that the overall QA program is established and clear, that personnel responsible for performing QA oversight functions are truly independent, that delegation of work to others (including internal to the applicant or licensee and to contractors) is at the appropriate reporting level within the organization, and that staff understand their responsibilities and the lines of authority. At the conclusion of the inspection of the QA program implementation portion of this IP appendix, the inspector should be able to conclude whether the applicant's or licensee's staff members understand their roles and responsibilities, including the importance of their compliance with the applicant's or licensee's QA program in the effective implementation of the QA program.
- e. The inspector should also perform a detailed review of the applicant's or 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 applicant or licensee has delegated responsibilities through the purchase order and whether the contractor QA program would be followed or if the contractor has committed to implementing the applicant's or licensee's QA plan. The applicant or licensee should verify that the contractor follows the applicant's or licensee's QA plan or manual, if applicable, or the contractor's QA plan or manual, if applicable, through the applicant's or licensee's external assessment process, where applicable.

03.02 Quality Assurance Program (Inspection Requirement 02.02)

General Guidance

- a. It is anticipated that the applicant or licensee will have a limited number of implementing documents that provide uniform direction for establishing the QA program, for indoctrination and training of personnel, and for assessing the status and adequacy of the QA program. If there are one or two documents, the inspector will review all implementing documents. If there are more than two, a representative sample of no more than three implementing documents will be reviewed.
- b. The inspector should find policies and implementing documents that specifically address the establishment of the QA program, including personnel training and indoctrination, planning work, and evaluation of the status and adequacy of the QA program. Effective implementation of the QA program ensures that activities affecting quality are accomplished under controlled conditions, including use of appropriate equipment, conduct of work under suitable environmental conditions, and fulfillment of prerequisites. The QA plan or manual, if applicable, is the applicant's or licensee's documented basis for its' QA program. It may be reviewed as part of the NRC's evaluation of the applicant's or licensee's ISA.

03.03 Design Control (Inspection Requirement 02.03)

General Guidance

- a. This appendix section applies to both initial design activities and design change activities that are associated with preserving and implementing the completed design during the construction phase after the final system designs have been completed. This can be accomplished by reviewing a sample of up to three design documents (samples should be from different disciplines, e.g., Mechanical, Civil, Electrical, etc.) and a sample of two design changes and two field changes. In addition, inspectors should assess the implementation of the applicant's or licensee's documents for controlling the turnover of the design information from the design authority to the applicant or licensee or from multiple construction contractors to the applicant or licensee. The review of the turnover of design information should be accomplished for three systems on a one-time basis.
- b. Inspection of the applicant's or licensee's implementation of design control can also be reviewed through SSIS inspections conducted in accordance with IP 88200, "Inspections of Safety Significant Items (and Services) During Construction of Fuel Cycle Facilities." For example, SSIS inspections could assess the processes being used by the design authority to translate the higher-level design into detailed design drawings, construction drawings, and procurement specifications for the SSIS being inspected.

03.04 Procurement Document Control (Inspection Requirement 02.04)

General Guidance

- a. The inspector should examine procurement documents associated with SSIS to verify implementation of the procurement process. A representative sample would include up to a total of three procurement documents, with a mix of licensee and contractor procurement documents.
- b. The inspector should review the ISA and select some safety significant plant equipment. The inspector should then review the purchase specifications for that equipment to confirm that those ISA attributes are included in the specifications.
- c. 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 applicant's or licensee's documented controls. The applicant or licensee may define two types of procurement controls: one for purchase of non-safety significant items and services and one for safety significant 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 SSIS.

03.05 Instructions, Procedures, and Drawings (Inspection Requirement 02.05)

General Guidance

- a. The applicant or licensee typically will have numerous categories of implementing documents. A representative sample of implementing documents that address applicable administrative and technical activities should be selected. Up to two

administrative and three technical implementing documents should be inspected, for a total of no more than five.

- b. The inspector will inspect new, revised and modified implementing documents to verify implementation of this appendix. A representative sample of no more than three implementing documents that have been changed will be inspected.
- c. The inspector should find QA program documents that specifically address preparation and modification of implementing documents that establish requirements for conducting quality-affecting activities that involve safety related items (and services). For example, the licensee may have a QA program document (e.g., administrative level procedure) that describes how an administrative type implementing document (e.g., training) is to be prepared. Additionally, the licensee may have a separate QA program document that addresses preparation of technical type implementing documents, such as work instructions.
- d. The applicant or licensee should have implementing documents that describe activities affecting safety. 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 facility has been constructed to design specifications and in accordance with regulations and implementing documents.
- e. The inspector should select for review those implementing documents that are representative of the QA plan or manual, if applicable. As a result of this inspection, the inspector should develop an overall assessment of the applicant's or licensee's implementing documents that control the performance of quality-affecting activities during construction.

03.06 Document Control (Inspection Requirement 02.06)

General Guidance

- a. It is anticipated that the applicant or licensee will have a limited number of implementing documents for document control. If there are one or two documents, the inspector review all implementing documents. If there are more than two, a representative sample of no more than three implementing documents will be reviewed.
- b. The inspector will examine lists of quality-affecting controlled documents, paper copy and electronic controlled documents, and other documentation to verify implementation of this appendix, e.g.:
 - 1. Lists of currently controlled documents - a representative sample would include no more than two lists.
 - 2. Note: The applicant or licensee may have separate systems for controlling instructions, procedures, design drawings, and other controlled implementing documents.
 - 3. 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.

4. 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.
 5. Current controlled documents that have been revised (different selection from b. and c. above) - a representative sample of no more than five documents.
 6. 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.
 7. Most recently cancelled/rescinded and expired documents - a representative sample of no more than four documents.
- c. 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 applicant or licensee. The inspector should select for review those controlled documents associated with activities that have high safety significance.
 - d. Inspections of document control should focus on ensuring that current work controlling documents are made available promptly to applicant or licensee staff and that all quality-affecting work is being conducted in accordance with current revisions of approved documents.
 - e. Inspection of implementation will include an examination of the actual controlled documents and the document review records. Although this aspect of the inspection is important, more significant is the verification that the personnel actually have direct access to the correct (e.g., current revision) documents that apply to the activities that are performing.

03.07 Control of Purchased Material, Equipment, and Services (Inspection Requirement 02.07)

General Guidance

- a. It is anticipated that the applicant or licensee will have a limited number of implementing documents for control of purchased items and services. If there are one or two documents, the inspector will review all implementing documents. If there are more than two, a representative sample of no more than three implementing documents will be reviewed.
- b. The inspector will examine various records and other documentation to verify implementation. A representative sample would include a total of four procurements.
- c. The inspector should find implementing documents that specifically address acceptance of safety significant procured items and services. It is important to verify that implementing documents provide controls that assure that items or services meet the procurement requirements and are accepted prior to its use.

- d. Various methods may be used to accept items and services, such as certificate of conformance, source verification, surveillance, receiving inspection, dedication of commercial grade item, or a combination thereof.
- e. The inspector should also review a sample of item acceptance activities (e.g., receipt/source inspection) activities performed on behalf of the applicant or licensee by those contractors acting as an agent to the licensee.

03.08 Identification and Control of Material, Parts, and Components (Inspection Requirement 02.08)

General Guidance

- a. The inspector will examine items to verify implementation of the applicant's or licensee's process for identification and control of items. A representative sample of no more than five individual items and their associated markings, documentation, and records will be selected.
- b. The inspector should find implementing documents that specifically address the identification and control of items that are manufactured, procured, installed, and/or used.
- c. The inspection of implementation in this area should be directed at assuring that items that are procured, installed, and used are traceable. Establishing traceability of an item is key to ensuring that the proper item is used, and its pedigree can be verified; that the final assembled component is comprised of the appropriate parts; and that correct spare parts can be acquired and installed, as necessary. Traceability can be established and maintained by the use of physical markings and by associated documentation. When physical marking is impractical or insufficient, other appropriate means (e.g., physical separation, procedural control) must be used. Only items that have undergone required inspection and testing should be used. It is also important to determine whether accepted items are controlled adequately to ensure that they are not used if a nonconformance or corrective action is identified.

03.09 Control of Special Processes (Inspection Requirement 02.09)

General Guidance

- a. It is anticipated that the applicant or licensee will have numerous technical implementing documents that provide specific direction for the control of special processes. A maximum of four implementing documents will be reviewed. Samples should be drawn from more than one of the construction disciplines applicable to the applicant or licensee, such as structural/civil, piping, and mechanical.
- b. The inspector should find implementing documents that specifically address the control of special processes during construction to demonstrate that safety significant items will perform satisfactorily in service. It is important to verify that implementing documents provide controls that assure that special processes are conducted by qualified personnel using qualified procedures and tools, and that the special processes are performed in accordance with specified applicable codes, standards, specifications, and other special requirements.

- c. 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.

03.10 Inspection (Inspection Requirement 02.10)

General Guidance

- a. It is anticipated that the applicant or licensee will have technical implementing documents that provide specific direction for conducting inspections. A maximum of four implementing documents will be reviewed. Samples should be drawn from more than a single construction discipline applicable to the applicant or licensee, such as structural/civil, piping, mechanical, and electrical/instrumentation and control.
- b. The inspector will examine items and their associated inspection documentation to verify implementation of the applicant's or licensee's process for conducting inspection. A representative sample of no more than five completed inspections and their associated stamps, tags, labels, routing cards, documentation, and records will be inspected. If applicant or licensee inspections are expected to be performed during the NRC inspection of the requirements in this appendix, a representative sample would include observing one active inspection being conducted by the applicant or licensee.
- c. The inspector should find implementing documents that specifically address inspection of safety significant items during construction to demonstrate the conformance of an item or activity to requirements. It is important to verify that implementing documents provide controls that assure that only items that have undergone required inspections, and have passed or been determined to be acceptable, are installed and used. Items may undergo inspection on a one-time-only basis, or periodic inspections may be required.

03.11 Test Control (Inspection Requirement 02.11)

General Guidance

- a. It is anticipated that the applicant or licensee will have numerous technical implementing documents that provide specific direction for conducting tests. A maximum of four implementing documents will be reviewed. Samples should be drawn from more than one construction discipline applicable to the licensee, such as structural/civil, piping, mechanical, pre-op, and electrical/instrumentation and control. A maximum of four tests should be selected for inspection, the inspection should include observation of the actual test, if possible, but reviewing completed test documentation is an acceptable option. Implementation of test control may also be completed during SSIS inspections conducted in accordance with IP 88200, "Inspections of Safety Significant Items (and Services) During Construction of Fuel Cycle Facilities." (e.g., reviewing test performance for the specific SSIS being inspected).
- b. The inspector should find implementing documents that specifically address testing during construction to demonstrate that safety significant items will perform satisfactorily in service. These implementing documents should include the requirements and acceptance limits contained in applicable design documents.

- c. It is important to verify that implementing documents provide controls that assure that only items that have undergone required testing, and have passed or been determined to be acceptable, are used. The acceptability of items prior to use is addressed in Section 02.14 of this appendix. Inspectors should consider including applicable portions of Section 02.14 during inspections of Appendix H, Section 02.11.

03.12 Control of Measuring and Test Equipment (Inspection Requirement 02.12)

General Guidance

- a. It is anticipated that the applicant or 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 applicant or licensee also may have numerous technical implementing documents that provide specific direction for controlling M&TE. A maximum of three technical implementing documents will be reviewed. Samples should be drawn from more than one construction discipline applicable to the applicant or licensee, such as structural/civil, piping, mechanical, and electrical/instrumentation and control.
- b. The inspector will examine M&TE, records and other documentation, and observe calibration activities (if possible), to verify implementation of this appendix, e.g.:
 - 1. Applicant's or licensee's M&TE tracking system: a representative sample would include a total of one system.
 - 2. Calibrated M&TE: a representative sample would include a total of three recent pieces of M&TE (M&TE may be selected from the selection of implementing documents in Section 03.12a.).
 - 3. 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 Section 03.12b.2).
 - 4. M&TE recently taken out of service because of nonconforming condition: a representative sample would include a total of two pieces of M&TE.
 - 5. 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 Section 03.12b.4).
 - 6. M&TE located at onsite work facilities: a representative sample would include a total of two pieces of M&TE.
- c. The inspector should find implementing documents that specifically address the control of M&TE that helps to demonstrate that safety significant items will perform satisfactorily in service. These implementing documents should include the requirements and acceptance limits contained in applicable design documents.
- d. 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 applicant's or licensee's identification system should note this situation, and the program shall provide sufficient control to prevent use outside the calibrated ranges.

- e. Calibration and control are not required for rulers, tape measures, levels, and other normal commercial equipment that provide adequate accuracy. The inspection of the implementation of this appendix section is closely related to inspections of several other appendix sections. M&TE may be calibrated by a contractor (appendix Sections 02.04 and 02.07). M&TE is identified, handled, stored (appendix Sections 02.08, 02.13, and 02.14). M&TE also is used to conduct inspections, tests, and special processes (appendix Sections 02.09, 02.10, and 02.11). This IP appendix describes inspection activities that address all of the above-mentioned appendices. Therefore, the inspector should use the above appendix sections for additional guidance and requirements within this area. Coordinated use of the appendices minimizes the duplication of inspection requirements in this IP appendix section.
- f. 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.
- g. 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.
- h. Construction testing includes provisions for pre- or post-installation operational and other construction tests and generally verifies that certain components pass specific test parameters. Examples of tests that may be performed include quality acceptance tests (e.g., concrete testing), baseline data checks (e.g., preservice inspections), 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.

03.13 Handling, Storage, and Shipping (Inspection Requirement 02.13)

General Guidance

- a. It is anticipated that the applicant or licensee may have numerous implementing documents for the handling, storage, and shipping of items. If there are up to five implementing documents, the inspector will review two of them. If there are more than five, a representative sample of no more than three implementing documents will be reviewed.
- b. The inspector will examine various types of items for handling, storage, and shipping:
 - 1. At least three safety-related items that have been received on site. To the extent practical, the samples should include items from at least two of the following categories: mechanical, electrical, instrument/electronic, and consumables

(chemicals, reagents, lubricants, filters, etc.). An attempt should be made to choose equipment for which specific storage requirements are required.

2. At least two samples of items that have been handled on site. An attempt should be made to choose equipment for which specific handling requirements are required.
- c. It should be noted that all safety-significant items are not necessarily stored on site. Rather, they may be in storage areas near the site. Items may also be stored in temporary staging areas. The inspector should therefore verify that the applicant's or licensee's program for handling, storage, and shipping covers off site, as well as on site, safety significant items.
- d. The inspector should find written storage, handling, and shipping requirements that specifically address those items associated with safety significant items.

03.14 Inspection, Test, and Operating Status (Inspection Requirement 02.14)

General Guidance

- a. It is anticipated that the applicant or 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 applicant or licensee may instead have numerous technical implementing documents that provide specific instructions for indicating inspection, test and operating status. If this is the case, then no more than three implementing documents will be reviewed.
- b. The inspector will examine items to verify implementation of the applicant's or licensee's process for indicating the inspection, test and operating status of those items. A representative sample of no more than five individual items and their associated stamps, tags, labels, routing cards, documentation, records, or other suitable means.
- c. The inspector should find implementing documents and instructions that specifically address the inspection, test, and operating status of items. Examples of items that might require inspection and testing and the resultant operating status include pumps, pipes, circuit breakers, valves, safeguards instrumentation, and balances. It is important to verify that implementing documents provide controls that assure that only items that have undergone required inspection and testing, and have passed or been determined to be acceptable, are used. Items may undergo an inspection or test on a one-time-only basis, or periodic inspections and tests may be required.
- d. The inspection of implementation in this area should be directed at assuring that items have been appropriately marked and/or documented to indicate their current status for present or future use. Use of items that are not suitable may result in an installation that does not meet specifications, installation of a component that does not meet design requirements, or measurements that are inaccurate.

03.15 Nonconforming Materials, Parts, or Components (Inspection Requirement 02.15)

General Guidance

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

03.16 Corrective Action (Inspection Requirement 02.16)

General Guidance

- a. During the first annual team inspection (i.e., the implementing document inspection), the inspectors will review CAP implementing documents in accordance with Section 02.16 of this appendix. During subsequent annual inspections, the inspectors will review the applicant's or licensee's implementation of its CAP by inspecting between four and six significant conditions adverse to quality or, 10 CFR Part 21, 10 CFR 70.50, or 10 CFR 70.74 reportable events, as applicable, and between four and ten conditions adverse to quality. If the minimum number of samples is not available, the inspectors will review all of the available samples. Corrective action implementation should also be inspected during SSIS inspections. Both the implementing document inspection and the first CAP implementation inspection may be performed in the same calendar year if sufficient CAP activity has occurred to perform a CAP effectiveness assessment per IMC 2694.
- b. Reviews under this IP appendix section will apply to both the applicant or licensee and its contractors that implement their own QA programs. This IP appendix section should be implemented for contractors participating in the construction phase, regardless of geographic location.
- c. The applicant or licensee may use multiple processes to accomplish its CAP, or it may employ a single process. The processes should ensure that all conditions adverse to

quality are processed in accordance with implementing document requirements, and that significant conditions adverse to quality receive investigations for cause and are provided actions to preclude recurrence.

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

03.17 Quality Assurance Records (Inspection Requirement 02.17)

General Guidance

- a. It is anticipated that the applicant or 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.
- b. In addition, it is anticipated that the applicant or licensee will also have numerous other implementing documents that provide specific instructions for the creation of designated records that support the implementation of specific activities. If this is the case, then no more than three implementing documents will be reviewed.
- c. The inspector will examine records, interview personnel, and visit records storage facilities to verify implementation of this appendix, e.g.:
 - 1. Individual records and records packages - a representative sample would include a total of three documents (may be a mix of records).
 - 2. Temporary records facilities - a representative sample would include no more than one facility.
 - 3. Main records storage facilities - a representative sample would include no more than one facility.
- d. The inspector should find implementing documents that specifically address creation and control of QA records related to safety significant items (and services). Records furnish evidence of activities affecting quality during construction. Implementation of the QA plan will result in the creation of numerous QA records during the construction phase. These records are created to support objective evidence that the facility has been constructed to design specifications and in accordance with regulations and implementing documents. Inspections within this appendix section will verify that adequate procedural controls have been established to maintain quality-affecting records and assure proper identification and retrievability of these records.
- e. Emphasis during inspection should be placed on confirming the adequacy of records related to safety significant items and design control activities during the construction phase. Permanent records and short-term records need to be identified and stored in location(s) that protect them from damage from moisture, temperature, and pestilence. Additional provisions need to be made for special processed records (e.g., radiographs, photographs, negatives, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

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

03.18 Audits (Inspection Requirement 02.18)

General Guidance

- a. It is anticipated that the applicant or licensee will have a limited number of implementing documents that provide uniform direction for conducting assessments. If there are one or two documents, the inspector will review all implementing documents. If there are more than two, a representative sample of no more than three implementing documents will be reviewed.
- b. The inspector will examine assessment schedules, reports, and associated documentation (such as plans and personnel qualifications) to verify implementation of the applicant's or licensee's process for conducting assessments. A representative sample would include a maximum of one schedule, two internal assessment reports, two external (contractor) assessment reports, two follow-up actions, and associated documentation (e.g., plans, team qualifications).
- c. The inspector should find implementing documents that specifically address the conduct of assessments by the applicant or licensee. Personnel conducting assessment evaluate programmatic compliance and effectiveness of the implementation of the QA program. Applicant or licensee assessments are planned and documented evaluations performed by trained personnel.
- d. Internal assessments conducted by the applicant or licensee focus on activities performed by the applicant or licensee and by contractors that work to the applicant's or licensee's QA program. External assessments conducted by the applicant or licensee focus on safety significant and quality related activities performed by contractors that work to their own QA programs or that provide commercial grade items for dedication.
- e. Assessment teams consist of personnel who have undergone training to be recognized as qualified. The assessment team may include specialists in specific areas, in addition to the qualified assessment personnel. This is common when the area to be assessed is of a more technical or complex nature.

88201.H-04 RESOURCE ESTIMATE

The resource estimate for completing this appendix is dependent on the specific facility and will be as determined in the PIP for the facility. Details on the resource estimates are identified in IP 88201, Section 04, "Resource Estimate."

88201.H-05 PROCEDURE COMPLETION

Procedure completion is dependent on the specific facility and will be as determined in the PIP for the facility.

88201.H-06 REFERENCES

NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications," Rev. 2

END

List of Attachments

Attachment 1: Revision History for IP 88201 Appendix H

Attachment 1: Revision History for IP 88201 Appendix H

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional Non-Public Information)
	ML25010A405 06/20/25 CN 25-018	Initial issuance. Initial Issue to provide guidance for the Management Measures inspections of Fuel Facilities licensed under Part 70.	N/A	N/A