
INSPECTION PROCEDURE 88201 APPENDIX A

CONFIGURATION MANAGEMENT

Effective Date: June 20, 2025

PROGRAM APPLICABILITY: IMC 2600, 2694

88201.A-01 INSPECTION OBJECTIVES

- 01.01 To determine if the applicant or licensee has established and is implementing an effective configuration management (CM) program that ensures consistency in the facility design and operational requirements, the physical configuration, and the facility documentation.
- 01.02 To determine if the applicant's or licensee's CM program captures formal documentation governing the design, construction, and continued modification of the site, structures, processes, systems, components, computer programs, personnel activities, and supporting management measures.
- 01.03 To determine if the applicant's or licensee's CM program adequately establishes and is implementing measures associated with design control, document control, change control, and assessments, as applicable, consistent with the licensing basis and integrated safety analysis (ISA).
- 01.04 To determine if the applicant's or licensee's CM program ensures that design changes and plant modifications are evaluated to determine the effect of each change or modification on the performance capabilities of items relied on for safety (IROFS), or other safety controls that are part of the safety design-basis.
- 01.05 To determine if the applicant's or licensee's CM system complies with Title 10 of the *Code of Federal Regulations* (10 CFR) 70.72.
- 01.06 To determine if the applicant's or licensee's CM program is adequately coordinated and integrated with other management measures.
- 01.07 To determine if new facilities or new processes at existing facilities that require a license amendment in accordance with 10 CFR 70.72 comply with the applicable requirements of 10 CFR 70.64.

88201.A-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 Determine if the applicant or licensee has established and is implementing an effective CM program to ensure consistency in the facility design and operational requirements, the physical configuration, and the facility documentation. Review the following areas as applicable:

- a. Design Control: Determine if the applicant or licensee has established and is implementing an effective design control process that ensures that design requirements and associated design bases, for those IROFS to which the CM program applies, are established and maintained through design, construction, and operation.
- b. Document Control: Determine if the applicant or licensee has established and is implementing an adequate process to create and control documents that are relied on for safety or under the CM program.
- c. Change Control: Determine if the applicant or licensee has established and is implementing effective procedures to properly address the following aspects of modifications in accordance with 10 CFR 70.72:
 1. technical basis for the modification;
 2. impact of the change on safety and health or control of licensed material;
 3. revisions to existing operating procedures including any necessary training or retraining before operations;
 4. authorization requirements for the modification;
 5. for temporary changes, the approved duration (e.g., expiration date) of the change; and
 6. impact or revision to existing program documents including the application, safety analysis reports, ISA, or other safety program information developed.
- d. Records of Modifications: Determine if the applicant or licensee has established and is implementing effective procedures to properly maintain records of modifications for specified periods, including the evaluation on which the change was based, as required by 10 CFR 70.72.
- e. Assessments: Determine if the applicant or licensee is periodically performing audits or assessments to check the adequacy of the CM program.
- f. Notification of Changes: Determine if the applicant or licensee has established and is implementing effective procedures to properly inform the NRC of changes made without

NRC prior approval and that the applicant or licensee provides revisions to program documents at specified intervals, as required by 10 CFR 70.72.

88201.A-03 INSPECTION GUIDANCE

General Guidance

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

The applicant's or licensee's CM program should capture formal documentation governing the design and continued modification of the site, structures, processes, systems, components, computer programs, personnel activities, and supporting management measures. The CM program should be adequately coordinated and integrated with other management measures.

The inspector should review the applicant's or licensee's descriptions and commitments for CM, including descriptions of the organizational structure responsible for CM activities; descriptions of the process, procedures, and documentation required by the applicant for modifying the site; and descriptions of the various levels of CM to be applied to IROFS designated in the ISA. The review should focus on the applicant's or licensee's CM measures that provide reasonable assurance of the documentation of engineering, procurement, installation, and modifications; the training and qualification of affected staff; the revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; and the post-modification testing. The review of the overall approach to implementing CM should include the evaluation of the CM program measures associated with design control, document control, change control, and assessments, as described in the following paragraphs.

03.01 Inspection Requirement 02.01

a. Design Control

1. The applicant or licensee should have a well-developed and documented design control process to effectively manage the design process and control design changes.
2. The applicant's or licensee's design control process should include measures for:
 - (a) the identification, approval, and documentation of design inputs;
 - (b) the correct translation of design inputs into design output documents;
 - (c) the identification and control of design interfaces;
 - (d) design review and verification; and
 - (e) control of design changes.
3. Review whether the design documents adequately define the technical requirements of safety significant items (and services) and are consistent with the licensing basis and ISA.
4. When reviewing design documents or design changes, the inspector should be cognizant that for new facilities or new processes at existing facilities licensed under Part 70, the facility and system design and facility layout should be based on

defense-in-depth practices, in accordance with 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities." Facilities licensed under 10 CFR Part 40 may commit to similar practices. Inspectors should review the licensing basis for these facilities.

b. Document Control

1. The applicant or licensee should have a well-developed and documented process to control the preparation and issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which are relied on for safety or within the CM program. These documents may include design requirements, ISAs, as-built drawings, specifications, procedures that are IROFS, procedures involving training, quality assurance, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that the applicant or licensee deems part of the CM program.
2. The records generated and maintained should include ISAs and other safety analyses, facility and process descriptions, IROFS, procedures, training requirements, and internal inspection/audit procedures.
3. Review the CM program to evaluate the extent to which it is formalized and institutionalized, its capabilities, and the extent to which it involves coordination between safety and other plant functions. The CM program is expected to keep design-basis documentation current and maintain associated technical support information.

c. Change Control

The programmatic review of the CM change control process should focus on the effectiveness of the written procedures to accomplish the requirements of the CM system.

1. Determine if the applicant's or licensee's procedures detail how to evaluate the basis for modification so that the licensee's reviewers and evaluators are empowered to properly assess the change.
2. Confirm by observation, discussion, and document review that written procedures exist for safety system/ISA change control. Determine whether the procedures identify the process for carrying out changes. Evaluate whether the procedures include adequate instructions including who has responsibility for preparing process descriptions, IROFS, safety limits and controls, maintenance and surveillance procedures, inspection and verification procedures and records, nuclear criticality safety (NCS) postings, updated inspection and audit requirements, and 10 CFR Part 21 postings, if applicable.
3. Determine whether the procedures identify the process for carrying out procedure changes, maintenance and surveillance procedures, pre- and post-inspection and verification procedures and records, training, postings, and post-change inspection and audit requirements.

4. Determine whether the program requires an appropriate level of supervisory review of procedure development, including, if applicable, a requirement for Operations to approve a change request, who has responsibility for preparing documents for certain process descriptions, and what safety/ISA limits and controls are involved.
5. All safety evaluations/ISAs should be maintained in the configuration management system and should identify the processes, process equipment, accident pathways, IROFS, safety limits on controlled parameters, NCS control systems and postings, and training requirements. The safety evaluations/ISAs should clearly document all assumptions, analysis methods, and staff members who performed them. The CM program should include the engineered control systems in the maintenance program. It should include the required schedules for preventive maintenance, calibrations, and surveillances. It should provide adequate controls to ensure appropriate replacement parts are used in safety control systems.

d. Records of Modifications

1. Applicants or licensees should maintain records of any changes made to their facilities under 10 CFR 70.72 until license termination, including a written evaluation that provides the bases for determining that no prior NRC approval under 10 CFR 70.72(c) or (d) is required.
2. The applicant's or licensee's criteria for making the determinations below should be captured in the licensee's procedures so that the originator, internal reviewers, and inspectors can follow the logic and reach the same conclusion. Types of changes that may warrant more detailed evaluations to demonstrate that prior NRC approval is not required include the following:
 - (a) For changes that require the addition of accident sequences to the ISA summary, the records should document whether the ISA summary already lists accident sequences of the same type.
 - (b) For changes that will remove an IROFS, the records should document either that the IROFS or IROFSs being removed are not needed to meet the performance requirements or that they will be replaced with an IROFS or IROFSs that provide at least an equivalent safety function.
 - (c) For changes to a sole IROFS, the records should document whether the change is an alteration (i.e., whether the change will modify, positively or negatively, any of the attributes associated with the safety function of the IROFS).
 - (d) For changes that include new processes, technologies, or control systems, the records should document whether the licensee has relevant prior experience and whether the license authorizes this activity.

e. Assessments

The applicant or licensee should conduct periodic assessments to determine the CM program's effectiveness and to correct deficiencies. These assessments should be performed by qualified individuals, in accordance with written procedures or checklists and include physical verification that as-built construction meets design requirements.

f. Notification of Changes

Licensees are required to annually provide the NRC with summaries of modifications that affect records required by 10 CFR 70.62(a)(2) and modifications to the ISA.

Note: Regulatory Guide (RG) 3.74, "Guidance for Fuel Cycle Facility Change Processes," describes the types of changes for which licensees are to seek prior approval from the NRC before their implementation. This RG describes how licensees can evaluate potential changes to determine whether NRC approval is required before implementing them. RG 3.74 also identifies an acceptable level of information to be provided by licensees when documenting and reporting changes made without prior NRC approval.

88201.A-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.A-05 PROCEDURE COMPLETION

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

88201.A-06 REFERENCES

American National Standards Institute/American Nuclear Society 8.1-1998, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," American Nuclear Society, La Grange Park, IL, dated 1998

NUREG-1513, "Integrated Safety Analysis Guidance Document," dated May 2001

NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," dated March 2002

RG 3.74, "Guidance for Fuel Cycle Change Processes," dated January 2012

END

List of Attachments:

1. Revision History for IP 88201 Appendix A

Attachment 1: Revision History for IP 88201 Appendix A

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)
	ML25010A398 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