

CONFIGURATION MANAGEMENT PROGRAM

88071-01 INSPECTION OBJECTIVES

The objectives of this procedure are to provide the requirements and guidance for evaluating the licensee's or certificate holder's configuration management and change control program. Specifically the evaluation is to determine whether the following aspects of the licensee's or certificate holder's configuration management and change control program meet U.S. Nuclear Regulatory Commission (NRC) issued license or certificate requirements:

01.01 The licensee or certificate holder has established an effective configuration management system to evaluate, implement, and track plant modifications which could affect safety.

01.02 The licensee's or certificate holder's configuration management system ensures that plant modifications are evaluated to determine the effect of each modification on the performance capabilities of items relied on for safety (IROFS), or other safety controls that are part of the safety design basis.

NOTE: As the safety and safeguards inspection program is applied to facilities certified under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 76, "license" shall read as "certificate," and "licensee" shall read as "certificate holder" for such facilities.

88071-02 INSPECTION REQUIREMENTS AND GUIDANCE

02.01 The requirements and guidelines for evaluating the facility Configuration Management Program Records are:

- a. Inspection Requirement. Verify that the licensee has established and maintained adequate records of the existing facility configuration as required by 10 CFR 70.62 and 70.64 (or 76.35).
- b. Inspection Guidance. The licensee should have a well-developed and documented configuration management program for generation and retention of documents that define the establishment and maintenance of the Integrated Safety Analysis (ISA) and other safety systems not part of the ISA.

Review whether the configuration management program documents define the site and facility licensing bases and unit process descriptions, including:

1. Piping and instrumentation diagrams;
2. Process materials flows;
3. Floor plans;
4. Special nuclear material movement controls;
5. Safety analyses for postulated accident pathways including safety limits and control systems to prevent accidents;
6. Maintenance requirements for the IROFS and other safety control systems;
7. Training requirements for the safety limits and control systems;
8. Maintenance, calibration and surveillance for safety control systems; and
9. Inspection and audit requirements.

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.

Review the configuration management 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 configuration management program is expected to keep design basis documentation current and maintain associated technical support information.

02.02 The requirements and guidelines for evaluating the facility Configuration Management Program Change Control process are:

- a. Inspection Requirement. Verify that the licensee has written effective procedures to properly address the following aspects of modifications in accordance with 10 CFR 70.72 (or 76.68):
 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, integrated safety analysis, or other safety program information developed.
- b. Inspection Guidance. The programmatic review of the configuration management change control process focuses on the effectiveness of the written procedures to accomplish the above requirements.
1. Determine if the licensee's procedures detail how to evaluate the basis for a 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, and updated inspection and audit requirements.
 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 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 configuration management 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.

02.03 The requirements and guidelines for evaluating the facility Configuration Management Program Records of Modifications are:

- a. Inspection Requirement. Verify that the licensee has written 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 (or 76.68).
- b. Inspection Guidance. 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.

The 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:

1. 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.
2. 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.
3. 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).
4. 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.

02.04 The requirements and guidelines for evaluating the licensee's performance of notifying NRC of changes made without prior NRC approval are:

- a. Inspection Requirement. Verify that the licensee has written effective procedures to properly inform the NRC of changes made without NRC prior approval and that the licensee provides revisions to program documents at specified intervals, as required by 10 CFR 70.72 (or 76.68).
- b. Inspection Guidance. Keep in mind that 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.

88071-03 RESOURCE ESTIMATE

An inspection performed using this inspection procedure is estimated to require 32 hours of inspector resources.

88071-04 REFERENCES

American National Standards Institute/American Nuclear Society (ANSI/ANS)-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.

Regulatory Guide 3.74, "Guidance for Fuel Cycle Change Processes," dated January 2012.

88070-05 PROCEDURE COMPLETION

Implementation of each applicable inspection requirement will constitute completion of this procedure. Individual inspection samples and breadth of review will be determined by the inspector based on requirement compliance, risk- significance of activity, and extent of the activity or records available, when specific sample sizes were not provided in the inspection guidance section.

END

Attachment:

Revision History for IP 88071

Attachment 1 - Revision History for IP 88071

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
N/A	07/28/06 CN 06-019	IP 88071 has been issued because of the need for a new Inspection Procedure for Configuration Management Programmatic Review.	N/A	ML061780381
N/A	ML13233A188 03/06/14 CN 14-007	The format of the IP was changed to comply with IMC 040; including the addition of the 'Procedure Completion' section. Certain language was removed which dictated when the IP should be performed as it's not part of the annual, core inspection program.	N/A	ML13347B015