
INSPECTION PROCEDURE 88070

PLANT MODIFICATIONS (ANNUAL)

Effective Date: 01/01/2021

PROGRAM APPLICABILITY: IMC 2600B, 2630A, 2694A, 2696A

88070-01 INSPECTION OBJECTIVES

Verify the licensee has established and implemented a configuration management system (CMS) to evaluate, implement, and track changes to the facility in accordance with the requirements in Title 10 of the U.S. Code of Federal Regulations (10 CFR) Section 70.72 (if applicable) and the licensing basis of the facility.

Verify the licensee has established management measures for changes to the facility in accordance with 10 CFR 70, Subpart H (if applicable) and the conditions of the license.

Verify that modifications involving new processes at existing facilities meet the requirements in 10 CFR 70.64.

88070-02 INSPECTION REQUIREMENTS AND GUIDANCE

02.01 Sample Selection

a. Inspection Requirements

Select a sample of plant changes/modifications to verify the licensee is conducting evaluations according to the CMS required in 10 CFR 70.72 and/or the license conditions.

b. Inspection Guidance

1. The implementation of this procedure starts with selecting changes or modifications to review in accordance with the subsequent requirements in this procedure. The annual summary of changes required by 10 CFR 70.72 (d)(2) and (d)(3) (or as stated in the license) are generally the best starting point for the sample selection. During selection, prioritize modifications which impact safety controls, however, also obtain samples in different categories to verify the licensee properly implemented a graded approach to reviews. Consider the following types of changes for the sample selection:

- (a) Major modifications that involved the design of new processes at existing facilities,

- (b) Hardware or field changes potentially involving Items Relied on for Safety (IROFS) or credited safety controls,
 - (c) Software modifications potentially related to licensed material,
 - (d) Minor modifications to non-safety equipment that do not trigger in-depth reviews,
 - (e) Procedure changes for operations potentially related to licensed material,
 - (f) Like-for-like replacements of hardware,
 - (g) Temporary modifications related to licensed material operations,
 - (h) Changes that impacted the Integrated Safety Analysis (ISA) Summary, and/or
 - (i) Changes made to the license application both approved by the NRC and those not submitted to the NRC under a license amendment.
2. A typical sample size is approximately **five to ten modifications per inspector**, dependent on the size and complexity of selected samples. Consider specific recommendations from the project inspector, project manager, and resident inspector **for the sample**.
3. During inspection preparation activities, request the following program procedures from the licensee (as applicable):
- (a) **CMS as required in 10 CFR 70.72 (or change process described in the facility's license)**
 - (b) post-modification testing
 - (c) audits
 - (d) training and qualification
 - (e) records retention
 - (f) **license application** change process

02.02 Facility Change/Modification Process

a. Inspection Requirements

1. Verify the licensee has established a **CMS** to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel **in accordance with 10 CFR 70.72 (if applicable) and/or the conditions of the license**. **Verify the CMS**

is documented in written procedures, and the procedures and modifications selected for inspection addressed the following aspects prior to implementing any change:

- (a) The technical basis for the change;
 - (b) Impact of the change on safety and health or on the control of licensed material;
 - (c) Modifications to existing operating procedures including any necessary training or retraining before operation;
 - (d) Authorization requirements for the change;
 - (e) For temporary changes, the approved duration (e.g., expiration date) of the change; and
 - (f) The impacts or modifications to the ISA, ISA Summary, or other safety program information developed in accordance with 10 CFR 70.62.
2. Verify the licensee's evaluation of changes properly determined whether an amendment to the license was required based on the criteria in 10 CFR 70.72(c).
 3. Verify affected on-site documentation associated with the selected changes was updated promptly in accordance with 10 CFR 70.72(e) or the conditions of the license.
 4. If a license amendment was required prior to the implemented change, verify the licensee submitted an amendment request to the NRC in accordance with 10 CFR 70.34 and 10 CFR 70.65.
 5. For changes that did not require NRC pre-approval and/or affect the ISA Summary, verify the licensee submitted a brief summary of changes and revised ISA Summary pages in accordance with 10 CFR 70.72(d).

b. Inspection Guidance

1. This inspection requirement is focused on the implementation of the licensee's CMS to verify compliance with 10 CFR 70.72 or the applicable change process described in the license. As applicable, verify the licensee's procedures and the modifications selected for inspection addressed the following aspects:
 - (a) Technical basis for the change. The technical basis should provide (1) an explanation of the proposed change, (2) what is to be changed and how, and (3) is the change safe to make and why. The level of detail in the document should be commensurate with the complexity and safety significance of the change. For example, a minor change with little or no safety impact may only require a simple qualitative explanation. However, for more complex changes, it may be necessary to develop calculations, technical reports, and safety evaluations to serve as the technical basis for the change. At a minimum, there should be enough information available

to allow appropriate supervisory, management, technical, and regulatory review of the change to ensure it will not adversely impact nuclear or chemical safety.

- (b) Impact of the change on safety and health or control of licensed material. Verify the licensee adequately evaluated each change and reached the proper conclusion as to whether the change could be made without prior NRC approval.
- (c) Modifications to existing operating procedures including any necessary training or retraining before operations. Verify the licensee has updated **the affected** operating procedures and conducted training on the **modified** procedures prior to **beginning operations**. **Review a sample of operator training records for specific changes to assess whether the level of training provided is consistent with the training requirements in the license.**
- (d) Authorization requirements for the change. Review the licensee's **CMS** implementing procedure(s) **to verify they include authorization requirements for plant changes**. Plant modifications are typically reviewed by impacted safety groups such as Nuclear Criticality Safety (NCS), **Emergency Preparedness**, Environmental, Fire Protection, Chemical Safety, ISA, Licensing, Radiological Protection, and Operations prior to authorizing the change. The purpose of the review **by impacted safety groups** is to (1) concur on the change, (2) identify potential impacts to the safety or licensing basis, and (3) identify action items and documents that will require revision in support of the change. Authorization is typically documented on a work clearance permit or other similar form or may take the form of signature or a time/date stamp in a **CMS** software program. For the changes reviewed, verify action items identified by the review process were completed prior to field implementation.
- (e) Approved duration of temporary changes. Verify temporary changes include an approved duration/expiration date. **The CMS procedures may allow extensions to temporary modifications with the proper approvals and justification.** In some cases, the licensee may place a limit on the number of extensions that can be granted, or the licensee may require higher levels of approval for multiple extensions. Review a sampling of temporary modifications to verify approved durations were specified and any extensions were properly authorized in accordance with the licensee's procedure.
- (f) Impacts or modifications to the ISA or other safety program information. Verify the licensee's **CMS** includes an evaluation to determine if the change results in **an impact to the ISA Summary and other documents that are part of the safety program**. This evaluation is typically documented on a **10 CFR 70.72** evaluation form. **Safety program documents that could be impacted by modifications include procedures, drawings, technical documents, engineering calculations, process hazard analysis (PHA), and training records.** There may also be questions to determine if the change impacts other licensing basis documents such as the Emergency Plan, Fundamental Nuclear Material & Control Plan (FNMCP), Quality

Assurance Plan (QAP), and license application. Review the modification package for the selected facility changes to verify impacted documents are properly identified.

2. For selected modifications that did not require a license amendment, the inspector should verify the licensee's evaluation provided valid technical basis to demonstrate the following:
 - (a) No sole IROFS preventing or mitigating an accident sequence that exceeds the performance requirements of 10 CFR 70.61 were altered.
 - (b) An IROFS needed to meet the performance requirements of 10 CFR 70.61 was not removed, without an equivalent replacement of its safety function.
 - (c) No new process, technology, or control system was implemented that has not been evaluated by the licensee.
 - (d) No new types of accident sequences that require IROFS were created that were not already described in the ISA.

Based on the guidance contained in NRC Regulatory Guide (RG) 3.74, "Guidance for Fuel Cycle Facility Change Processes," it is acceptable for 10 CFR 70.72 evaluations to take the form of a simplified "yes/no" checklist unless the change is directly associated with one of the 10 CFR 70.72 evaluation criteria listed above. For example, changes to a sole IROFS should demonstrate that the change is not an alteration (i.e., the change will not modify, positively or negatively, any of the attributes associated with the safety function of the IROFS). The justification for answering "no" should be clearly documented in the 10 CFR 70.72 evaluation and simply checking the box "no" would not be an acceptable response. The inspectors should use the guidance contained in RG 3.74 to assist them in their review of 10 CFR 70.72 evaluations. In addition, verify that the 10 CFR 70.72 evaluation properly concluded whether NRC pre-approval of the change was required.

3. Verify the licensee's CMS procedure requires that on-site documentation affected by a change performed under 10 CFR 70.72 is updated promptly. For the purpose of this procedure, "promptly" generally means within the timeliness expectations established in the CMS procedures. As required by 10 CFR 70.72(a)(3), operating procedures shall be updated prior to implementation of the change.
4. No additional guidance.
5. No additional guidance.

02.03 Management Measures.

a. Inspection Requirements

Verify the licensee established **appropriate** management measures for IROFS, or if applicable, for other credited safety controls that were affected by the facility changes selected for the inspection sample. Verify the management measures ensure that affected IROFS (or credited safety controls) are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed to comply with the performance requirements of 10 CFR 70.61 or applicable conditions of the license.

b. Inspection Guidance

Verify the management measures applied to the selected facility changes comply with the specific requirements in the license application and the implementing procedures. The management measures applicable to the CMS or facility change/modification process include:

1. Configuration Management

Verify the licensee implemented the applicable aspects of Configuration Management described in the CMS procedures and the license application. Configuration Management for IROFS affected by plant changes/modifications may involve the following processes or attributes:

- (a) Establishment of technical design bases/criteria – This includes incorporating the design requirements of applicable codes and standards committed to in the license to the change package (e.g. National Fire Protection Association (NFPA) and American Nuclear Society (ANS)).
- (b) Unintended system interactions – This includes considering the impact on interconnecting systems, during design and implementation of the modification.
- (c) Set points – Modifications involving instrumentation & controls (I&C) have established bases for set points and associated uncertainties.
- (d) Design development, review and control process – Design and technical assumptions contained in the technical basis, safety analyses, or other design/safety basis documents are revised and validated as necessary. Additionally, the validity of the existing Natural Phenomena Hazards (NPH) structural analysis for the buildings or engineered equipment should be confirmed.
- (e) Like-for-like changes – This includes ensuring the changes do not impact the fit, form, or function of the IROFS.

- (f) Post-modification testing – This includes identification of post-modification testing requirements and necessary criteria to verify IROFS (or credited safety controls) will function as required
- (g) Project approval, initiation, and control process – This includes project readiness review/startup approval, operational turnover, and closeout.
- (h) Classification of Modification/Change – Changes are properly classified according to the modification type outlined in CMS procedures (e.g. minor modifications, temporary modification, procedure revision, etc.).

Interview applicable process and safety engineers and operators to obtain insights on the operational and safety parameters of the modification and to verify that applicable design bases and assumptions were properly considered.

Conduct walk downs to verify, **to the extent possible**, that as-built equipment reflects **the design description in the modification packages**. During walk downs, **consider** neighboring process systems and utility lines to ensure the licensee evaluated any potential interactions.

2. Procedures

Review risk significant procedures affected by the modifications and verify the licensee followed its procedure control process and the management measure attributes described in the license application.

3. Post-Modification Testing

Review post-modification test procedures and test results, **and if possible**, observe any **post-modification** test in progress. **Consider the following in the review:**

- (a) The boundary of the IROFS or credited safety control (i.e. the components necessary for the safety function to operate) is adequately considered in the test scope;
- (b) The test procedures have appropriate acceptance criteria to demonstrate the intended function(s) of the IROFS or credited safety controls;
- (c) Any Measuring & Test Equipment (M&TE) used during performance of the test is properly calibrated;
- (d) Unintended system interactions do not occur **during testing**;
- (e) The modification test acceptance criteria have been met and IROFS or credited safety controls can perform their required safety functions;
- (f) Deviations from acceptance criteria are resolved appropriately.

NOTE: Licensees often use existing procedures, such as surveillance procedures, for post-modification testing. Although performance of existing

procedures may have been reviewed by inspectors, inspectors still need to determine the appropriateness of using the existing procedures for validating the modification (as opposed to simply confirming continued operability).

4. Maintenance/ Surveillance

Ensure the licensee established adequate periodic surveillance testing for modifications affecting IROFS or credited safety controls (active-engineered or passive). Review the technical content of the surveillance test procedure to verify it meets the applicable license requirements. Refer to Inspection Procedure 88020, "Operational Safety," for additional guidance with respect to surveillance testing.

5. Training

Verify, on a sampling basis, that licensee staff involved in the facility changes selected for review are qualified in accordance with the license application and plant procedures.

Verify the licensee identified and conducted the necessary training to implement the modification as described in the license application and plant procedures.

6. Problem Identification and Resolution (Corrective Action Program)

Request the licensee to provide a list of condition reports related to the CMS, configuration management/configuration control management measure, post modification testing, and/or plant modifications. Review a sample of condition reports to determine whether the licensee is identifying issues in the areas of CMS, configuration management/configuration control management measure, post modification testing, and/or plant modifications, entering them into the corrective action program, and correcting the condition as required by license, procedure, and or NRC requirements. Licensees with an approved CAP will have their corrective action program inspected in accordance with IP 88161, "Corrective Action Program (CAP) Implementation at Fuel Cycle Facilities." Corrective actions as a result of violations will be inspected in accordance with IP 92702, "Follow-Up on Traditional Enforcement Actions Including Violations, Deviations, Confirmatory Action Letters, and Orders."

7. Audits

Review recent audits and assessments of the CMS to verify the scope and frequency of the audits are in accordance with the license application and site/plant procedures. Consider whether safety-significant findings are entered in the CAP for evaluation. Review a sample of condition reports resulting from audits to verify the findings were resolved consistent with the management measures described in the license application.

Verify that audits are performed by qualified individuals consistent with the requirements of the audit program procedure as described in the license application. In some cases, the audit should be led by an external party and may require lead auditor certification.

02.04 License Application Changes

a. Inspection Requirements

Verify the licensee is evaluating changes to the license application, including the need for NRC pre-approval, in accordance with the license requirements.

b. Inspection Guidance

Review the licensee's procedure or document used to determine if NRC pre-approval of the change is required for changes to the license application. Typically, NRC pre-approval of changes is required for changes that result in a reduction in commitments. Refer to license conditions for specific criteria applicable to the facility.

For selected license application changes that did not require NRC pre-approval, determine if the licensee followed their approved change process and reached the correct conclusion.

Verify the licensee maintains records of evaluations performed for changes to the license application in accordance with applicable procedures. Licensee evaluations should provide the bases for determination that a change to the application did not require prior NRC approval.

NOTE: The provisions of 10 CFR 70.72 are not applicable to changes to the license application unless the license includes a condition to (or the licensee commits to) follow 10 CFR 70.72 to evaluate changes to the application.

02.05 New Processes at Existing Facilities

a. Inspection Requirements

1. For changes that involved new processes and the licensee determined that NRC approval was not required in accordance with 10 CFR 70.72, verify the licensee provided appropriate technical and regulatory basis for not needing prior NRC approval. Additionally, verify the licensee addressed the requirements of 10 CFR 70.64, including the baseline design criteria and the concept of defense-in-depth, for the design of new processes at existing facilities. For facilities not subject to the requirements of 10 CFR 70.72, verify that any new process has been evaluated for NRC pre-approval in accordance with the conditions of the license.
2. For changes that involved new processes and were submitted to the NRC for review and approval, verify that the licensee implemented the change consistent with the license amendment and safety evaluation report.

b. Inspection Guidance

1. Verify that the following design criteria was addressed by the licensee for any modification involving a new process at an existing facility:

- (a) Quality standards and records. Verify the design of the new process was developed and implemented in accordance with management measures such that the performance requirements of 10 CFR 70.61 will be met. Determine whether appropriate records of these items (post maintenance testing and walk downs, accident sequence assessment, operator training, etc.) are being held by the facility until license termination.
- (b) Natural phenomena hazards. Verify the design provided adequate protection against the most severe documented historical natural phenomena event for the site.
- (c) Fire protection. Verify the design provided adequate protection against fires and explosions.
- (d) Environmental and dynamic effects. Verify the design adequately accounted for the environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.
- (e) Chemical protection. Verify the design **adequately protects** against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.
- (f) Emergency capability. Verify the design provided emergency capabilities to maintain control of licensed material and hazardous chemicals produced from licensed material in case of an accident. Verify the evacuation of on-site personnel was considered and on-site emergency facilities and services that facilitate the use of available offsite services would be able to effectively provide support.
- (g) Utility services. Verify the design provided continued operation of essential utility services.
- (h) Inspection, testing, and maintenance. Verify the design of IROFS provided for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.
- (i) Criticality control. Verify the design provided for criticality control including adherence to the double contingency principle and compliance with the performance requirements of **10 CFR 70.61**.
- (j) Instrumentation and controls. Verify the design provided for inclusion of instrumentation and control systems to monitor and control the behavior of IROFS.

Verify that **f** facility and system design and facility layout **is** based on defense-in-depth practices. Verify the design incorporated, to the extent practicable, preference for the selection of engineered controls over administrative controls to increase overall system reliability. Verify the design incorporated features that enhance safety by reducing challenges to IROFS.

2. Changes that involve new processes at existing facilities and were submitted to the NRC for approval do not require an in-depth inspection of the baseline design criteria. The inspection should be focused on verifying the licensee implemented the change in accordance with the license amendment and the safety evaluation report.

NOTE: The review of changes involving new processes does not need to be a separate inspection sample. Inspectors can select a new process within their sample and implement all the applicable requirements of this procedure.

02.06 Records Retention

a. Inspection Requirements

Verify the licensee maintains records of changes to its facility in accordance with 10 CFR 70.72(f) (if applicable) and the conditions of the license. Review the licensee's document retention policy to verify records created under 10 CFR 70.72 are lifetime records and include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval.

b. Inspection Guidance

Determine if the licensee has measures in place to retain records of changes to the facility/licensing documents in accordance with 10 CFR 70.72(f) (if applicable) and the conditions of the license. Licensees should consider having a document control system for plant changes and the ability to recover records in the event of a computer system failure, accidental damage, or natural disaster. Licensees shall maintain these records until the license is terminated or as stated in the license.

88070-03 RESOURCE ESTIMATE

The size of the inspection team formed to implement this inspection procedure will vary depending on the scope and number of changes made during the year. Engineering (e.g., mechanical, electrical, structural, etc.), chemical safety, radiation protection, fire protection, and criticality safety personnel should be selected, as appropriate, for the team. The hours of on-site inspection are as described in IMC 2600 Appendix B.

This procedure does not apply to fuel fabrication facilities that have a corrective action program credited by the NRC in accordance with Regulatory Guide 3.75, "Corrective Action Programs for Fuel Cycle Facilities."

88070-04 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 the inspector's evaluation of the licensee's compliance with requirements, the risk-significance of the activities, and the extent of the records available for the activities, when specific sample sizes were not provided in the inspection guidance section.

| 88070-05 REFERENCES

10 CFR 70, Domestic Licensing of Special Nuclear Material

10 CFR 70.61, Performance Requirements

10 CFR 70.62, Safety Program and Integrated Safety Analysis

10 CFR 70.64, Requirements for New Facilities or New Processes at Existing Facilities

10 CFR 70.72, Facility Changes and Change Process

Regulatory Guide 3.74, "Guidance for Fuel Cycle Facility Change Processes"

NUREG-1513 "Integrated Safety Analysis Guidance Document"

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

American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.1-2014, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," American Nuclear Society, La Grange Park, IL, 2014

IP 88025, "Maintenance and Surveillance of Safety Controls"

END

Attachment:
Revision History for IP 88070

Attachment 1 - Revision History for IP 88070

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)
N/A	ML061780363 09/05/06 CN 06-020	IP 88070 has been issued because of the need for a new Inspection Procedure for Permanent Plant Modifications.	N/A	ML061780357
N/A	ML13233A187 02/26/14 CN 14-006	The revision does not include any significant technical changes. The scope of the procedure was expanded via de-emphasizing permanent modifications in lieu of safety significant modifications. Plant Safety Committees, a section from the Management Organization IP, was included in the revised IP.	N/A	ML13347B004
N/A	ML16181A153 09/20/16 CN 16-023	Removed the project manager role from the plant modification selection process as a result of FCSE project managers discontinuing the annual ISA Summary and 70.72 review. Also decreased the maximum expected resources from 120 to 80 hours.	N/A	ML16232A186
N/A	ML18102A499 08/21/18 CN 18-027	Revision in its entirety to improve sample selection guidance, clarify inspection requirements and guidance, provide additional guidance on management measures, delete guidance on plant safety committees, and reformat document.	Training for inspectors on the revision by end of September 2018.	ML18100A645
N/A	ML20324A731 12/14/20 CN 20-071	Major revision to incorporate recommendations from the Smarter Fuel Cycle Inspection Program (ML20077L247 and ML20073G659).	N/A	N/A