INSPECTION PROCEDURE 88070

PLANT MODIFICATIONS (ANNUAL)

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

88070-01 INSPECTION OBJECTIVES

Determine that the licensee established and implemented a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

88070-02 INSPECTION REQUIREMENTS

02.01 Sample Selection. Review a sample of plant modifications to verify that the licensee's change process ensured that appropriate evaluations were conducted according to the approved configuration management/configuration control procedures. Include the following types of changes in your review:

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 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 (LA) both submitted and approved by the NRC and those not submitted under a license amendment if permitted by license condition.

02.02 10 CFR 70.72 Facility Change Process.

a. Verify that the licensee has established a configuration management (CM) system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. Verify that

the configuration management system is documented in written procedures. Verify that the requirements in Title 10 of the U.S. Code of Federal Regulations (10 CFR) Section 70.72(a) were met and that the licensee addressed the following prior to implementing any change:

1. The technical basis for the change;

2. Impact of the change on safety and health or on the control of licensed material;

3. Modifications to existing operating procedures including any necessary training or retraining before operations;

4. Authorization requirements for the change;

5. For temporary changes, the approved duration (e.g., expiration date) of the change; and

6. The impacts or modifications to the integrated safety analysis or other safety program information.

b. Verify that affected on-site documentation involving 70.72 changes were updated promptly (10 CFR 70.72(e)).

02.03 10 CFR 70.72 Records Retention. Verify that the licensee maintains records of changes to its facility and that record retention complies with 10 CFR 70.72(f). As part of the verification, review the licensee's document retention policy to ensure that records created under 10 CFR 70.72 are lifetime records. Verify that these records include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval.

02.04 Management Measures. Verify that the applicant or licensee established management measures to ensure compliance with the performance requirements of 10 CFR 70.61. Determine whether the management measures, as it relates to the changes being evaluated under the inspection sample, ensure that engineered and administrative controls and control systems that are identified as IROFS pursuant to 70.61(e) are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function when needed. Verify compliance with the performance requirements of 70.61.

Verify that the management measure program meets the commitments specified in the license application. The management measures applicable to the licensee's plant modifications program include:

a. configuration management/configuration control

b. procedures

c. post-modification testing

d. maintenance/surveillance

e. training

f. corrective action program

g. audits

02.05 License Application Changes. If permitted by license condition, verify that the licensee is adequately evaluating the need for NRC pre-approval of changes made to the license application.

02.06 New Processes at Existing Facilities. Verify that the licensee has 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 that require a license amendment under 10 CFR 70.72.

88070-03 INSPECTION GUIDANCE

03.01 Sample Selection. During selection, prioritize modifications which impact safety controls, however, also try to obtain a sample of each category to verify that the licensee properly implemented a graded approach to reviews.

A typical sample size is approximately 10 modifications per inspector, dependent on the size and complexity of selected samples. Consider specific sample recommendations from the project inspector, project manager, and resident inspector (if applicable).

Request the following program procedures to aid with inspection preparation: (1) CM procedures that implement the plant modifications program, (2) 70.72 change process, (3) post-modification testing, (4) audits, (5) training and qualification, (6) records retention, and (7) LA change process, if applicable.

03.02 10 CFR 70.72 Facility Change Process.

a. Verify proper establishment and implementation of the licensee's 10 CFR 70.72 facility change process. Consider the following:

    1. 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 that the change will not adversely impact nuclear or chemical safety.

    2. Impact of the change on safety and health or control of licensed material. Verify that the licensee adequately evaluated each change and reached the proper conclusion as to whether the change could be made without prior NRC approval.

For modifications selected for review that did not require a license amendment, the inspector should verify the following:

(1) No sole IROFS preventing or mitigating an accident sequence that exceeds the performance requirements of 10 CFR 70.61 were altered.

(2) An item relied on for safety (IROFS) needed to meet the performance requirements of 10 CFR 70.61 was not removed, without an equivalent replacement of its safety function.

(3) No new process, technology, or control system was implemented that the licensee has no experience with.

(4) 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 70.72 evaluations to take the form of a simplified "yes/no" checklist unless the change is directly associated with one of the 70.72 evaluation questions 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 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 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. Modifications to existing operating procedures including any necessary training or retraining before operations. Verify that the licensee has updated operating procedures and conducted training on the procedures prior to implementation. Review a sampling of operator training records for specific changes. Consider whether the training is accomplished by reading and signing procedure revisions or by other forms of training such as classroom, briefings, and toolbox meetings. Determine whether the training is effective in addressing the change.

4. Authorization requirements for the change. Review the licensee's CM implementing procedure for specific requirements on change authorization. Plant modifications are typically reviewed by impacted safety groups such as Nuclear Criticality Safety (NCS), Environmental, Fire Protection, ISA, Licensing, Radiological Protection, and Operations prior to authorizing the change. The purpose of the review 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 CM software program. For the changes reviewed, verify that any action items identified by the review process were completed prior to field implementation.

5. Approved duration of temporary changes. Verify that temporary changes include an approved duration/expiration date. Determine if extensions are allowed and whether the procedure addresses the process for granting extensions including the required 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 that approved durations were specified and any extensions were properly authorized in accordance with the licensee's procedure. Any concerns should be discussed with licensee management as appropriate.

6. Impacts or modifications to the ISA or other safety program information. Verify that the licensee's 70.72 process includes an evaluation to determine if the change results in a potential impact to the ISA Summary. This evaluation is typically documented on the 70.72 evaluation form. 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 LA. Conduct reviews of revisions to the ISA Summary and other safety program documents to verify on-site documentation was promptly updated as a result of plant modifications. Consider whether these updates were processed immediately with little or no delay.

b. Verify that the licensee's CM procedure requires that affected onsite documentation such as procedures, drawings, and technical documents be updated promptly following implementation of the change. As required by 70.72(a)(3), operating procedures shall be updated prior to implementation of the change. Documents other than operating procedures needed for the safe operation of the facility, such as piping & instrument diagrams (P&IDs), electrical single line drawings, IROFS surveillance procedures, and ISA documents, should be updated within days or a few weeks after implementation of the change. Other less important supporting documentation such as training records that do not directly impact nuclear safety or plant operations should be updated within weeks or a few months following implementation of the change.

03.03 10 CFR 70.72 Records Retention. Determine if the licensee has safeguards in place to recover records in the event of a computer system failure or natural disaster. Determine if the licensee plans to maintain these records until the license is terminated.

03.04 Management Measures / License Application Requirements. Verify that the management measures program, as it relates to facility changes being evaluated under the inspection sample, is in compliance with the specific requirements in the license application and the implementing procedures.

a. Configuration Management.

1. Review the licensee's CM procedure to determine if the procedure adequately implemented commitments from the LA with respect to CM. The CM procedure should address the following processes:

(1) Establishment of technical design bases/criteria;

(2) Design development, review, and control;

(3) Project approval, initiation, and control;

(4) Evaluation of safety/licensing implications, including the need for new or revised safety analyses;

(5) Post-modification testing;

(6) Project readiness review/startup approval, operational turnover, and closeout; and

(7) Updating of safety basis documentation.

2. Conduct reviews of facility changes to ensure they were properly developed, reviewed, approved, and implemented according to the license's CM procedures. Verify the following:

(1) Adequate design information (e.g. drawings, calculations, vendor documents, and analyses) is available to support/implement the change;

(2) Validity of any design or technical assumptions contained in the technical basis or other design or safety basis documents;

(3) Process hazard analysis (PHA) is conducted for risk significant changes;

(4) Design bases, licensing bases, and performance capability of IROFS is not degraded as a result of the modification;

(5) System and components will function as required and support proper operation of interfacing systems;

(6) IROFS or safety controls are capable of performing their intended safety function;

(7) Applicable codes and standards committed to in the license such as National Fire Protection Association (NFPA) and American Nuclear Society (ANS) are flowed down as design requirements in the change package;

(8) Change does not invalidate the Natural Phenomena Hazards (NPH) structural analysis for the buildings or engineered equipment.

(9) Change is properly classified according to the modification type. NOTE: minor modifications do not typically require the same level of safety review as other types of changes;

(10) Modifications involving instrumentation & controls (I&C) have established bases for set points and associated uncertainties.

(11) Like-for-like changes do not impact the fit, form, or function of a component;

(12) The duration of temporary modifications is specified;

(13) No unintended system interactions including impact on interconnecting systems will occur as a result of the modification;

(14) Training or retraining of operators is conducted prior to operations turnover;

(15) Operating procedures are updated prior to placing the modification into operation; and

(16) Impacted documents including licensing basis documents such as the ISA Summary are updated promptly as a result of the change.

3. Conduct discussions with applicable process and safety engineers and operators to obtain insight on the operational and safety parameters of the modification and to verify that applicable design bases and assumptions were properly considered.

4. Conduct walk downs to verify that as-built equipment reflects the descriptions in the modification packages.

(1) Conduct a walk down of the applicable systems and the process equipment characteristics that are relied on for the adequate performance of safety controls. These characteristics include the dimensions of process equipment containing licensed material, the resilience of the material of construction to the environmental and process conditions of the equipment, and the locations and sequence of safety controls.

(2) Verify that the installed configuration is consistent with the design.

(3) Note neighboring process systems and utility lines to ensure that the licensee evaluated any potential interactions.

b. Procedures.

1. Review the procedures that implement applicable management measures programs to ensure that commitments specified in the LA are adequately flowed down into procedures.

2. Verify that the licensee is complying with CM and management measure procedures.

c. Post-Modification Testing.

1. Review post-modification test procedures and test results. Observe any tests in progress. Determine whether the test procedures adequately test the intended functions, and have appropriate acceptance criteria. Determine whether deviations from acceptance criteria are resolved appropriately. Determine whether:

(1) The boundary (consideration for all the components necessary for the IROFS to operate) of the IROFS was adequately considered in the test scope;

(2) Acceptance criteria for tested parameters are supported by the appropriate calculations or other engineering documents;

(3) Any Measuring & Test Equipment (M&TE) used during performance of the test was properly calibrated;

(4) Unintended system interactions do not occur;

(5) IROFS and safety controls can perform their required safety functions; and

(6) The modification test acceptance criteria have been met.

2. 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).

d. Maintenance/ Surveillance.

1. Ensure the licensee established adequate periodic surveillance testing for modifications that installed new IROFS (active-engineered or passive) or altered existing IROFS. Review the technical content of the test procedure to verify that it will satisfy the applicable license requirement and that IROFS are available and reliable. Refer to Inspection Procedure 88025, "Maintenance and Surveillance of Safety Controls," for additional guidance with respect to surveillance testing.

2. Ensure there is a technical basis for the established surveillance frequency.

e. Training.

1. Review the LA and site training procedure to determine the training and qualification requirements for engineers that perform 10 CFR 70.72 evaluations and ISA related work. Verify that engineers that perform 10 CFR 70.72 evaluations are qualified in accordance with the licensee's program procedure and license. Interview selected ISA engineers to determine that they are properly trained on the safety basis. Verify that they have an adequate understanding of their assigned duties.

2. Interview system engineers to verify that they are knowledgeable of their assigned systems and have an adequate understanding of applicable IROFS and safety controls.

3. Determine whether operators were trained on procedure revisions prior to placing the modification into service.

4. Verify, as applicable, that senior managers performing licensing, ISA, or CM functions meet the qualification requirements in the LA with respect to education and experience.

5. Verify that plant personnel are trained on the CM process if required by the LA or site training procedure.

f. Corrective Action Program.

1. Request the licensee to provide a list of condition reports related to configuration management/configuration control, engineering, post modification testing, and/or plant modifications.

2. Request the licensee to provide a list of condition reports related to the selected modifications.

3. Determine whether the licensee is identifying issues at an appropriate threshold and entering them into the corrective action program.

4. Determine whether the corrective actions were timely and appropriate.

g. Audits.

1. Review recent audits and assessments of the CM program to verify that the licensee is conducting them at the prescribed frequency.

2. Ensure that any findings are entered into the corrective action program for evaluation. Review the condition reports to ensure that the findings received adequate corrective actions.

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

4. Determine if the audit scope was documented in an approved audit plan. Verify that the audit scope was comprehensive and not superficial.

03.05 Changes to the License Application.

a. Review the licensee's procedure or document used to determine if NRC pre-approval of the change is required. 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 site.

b. Review a sampling of LA changes that did not require NRC pre-approval to determine if the licensee followed their approved change process and reached the correct conclusion.

c. Verify that the licensee maintained records that include written evaluations that provide the bases for determination that the change does not require prior NRC approval.

03.06 New Processes at Existing Facilities. Review the license amendment and safety evaluation report issued to approve the license amendment. Verify that the following design criteria was addressed by the licensee for any modification that required a license amendment:

a. Quality standards and records. Verify that 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 that the design provided adequate protection against the most severe documented historical natural phenomena event for the site.

c. Fire protection. Verify that the design provided adequate protection against fires and explosions.

d. Environmental and dynamic effects. Verify that 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 that the design provided adequate protection 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 that the design provided emergency capabilities to maintain control of licensed material and hazardous chemicals produced from licensed material in case of an accident. Verify that the evacuation of on-site personnel was considered and onsite emergency facilities and services that facilitate the use of available offsite services would be able to effectively provide support.

g. Utility services. Verify that the design provided continued operation of essential utility services.

h. Inspection, testing, and maintenance. Verify that 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 that the design provided for criticality control including adherence to the double contingency principle and compliance with the performance requirements of 70.61.

j. Instrumentation and controls. Verify that the design provided for inclusion of instrumentation and control systems to monitor and control the behavior of IROFS.

k. Facility and system design and facility layout must be based on defense-in-depth practices. Verify that the design incorporated, to the extent practicable, preference for the selection of engineered controls over administrative controls to increase overall

system reliability. Verify that the design incorporated features that enhance safety by reducing challenges to items relied on for safety.

88070-04 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 inspection should vary from 32 to 96 hours, depending on the level of information provided ahead of time by licensees in support of modification reviews and a function of the scope and number of changes made during the year.

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”

88070-06 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.

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	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