
INSPECTION PROCEDURE 88117

FACILITY CHANGES (LICENSE APPLICATION) AND CHANGE PROCESS (10 CFR 70.72) (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: 2630

88117-01 INSPECTION OBJECTIVES

The objectives of this procedure are to provide the requirements and guidance for evaluating the CB&I AREVA MOX Services, LLC (MOX Services) change control program. Specifically the evaluation is to determine whether the following aspects of the MOX Services change control program meet U.S. Nuclear Regulatory Commission (NRC) issued license or certificate requirements:

01.01 To determine that the MOX Services maintains adequate quality assurance records of changes to its facility or design carried out under Chapter 16 of the license application for the Mixed Oxide Fuel Fabrication Facility (MFFF) and under Title 10 *Code of Federal Regulations* (10 CFR) 70.72 of the Integrated Safety Analyses Summary.

01.02 To verify that MOX Services Quality Assurance (QA) records include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval. To verify that these records are maintained until termination of the license.

01.03 To determine whether MOX Services has established an effective change control process to evaluate, implement, and track changes that may impact the integrated safety analysis (ISA) and the licensing basis of the facility.

88117-02 INSPECTION REQUIREMENTS AND INSPECTION GUIDANCE

The inspector should verify that the design changes were appropriately classified and the controls of that classification were applied in accordance with MOX Services NRC-approved QA Plan. The inspector should also verify that MOX Services has fulfilled the requirements for evaluation of proposed design changes and modifications in accordance with 10 CFR 70.72 and Chapter 16 of the license application (LA).

02.01 Programmatic and Administrative Controls

- 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 and Chapter 16 of the LA. Verify that the procedures include:

1. Impacts to information in the LA or Integrated Safety Analysis Summary (ISAS),

2. Impact to regulatory commitments,
 3. Impact to Environmental Report,
 4. Revisions to Nuclear Safety Evaluations or Nuclear Criticality Safety Evaluations.
 5. Requirements for MOX Services safety committees to review proposed design changes and modifications.
- b. Inspection Guidance. The inspector should review changes that were made to MOX Services procedures related to the control of the change process. MOX Services has defined its Licensing Basis Configuration program in Project Procedure (PP) 8-6 which is entitled "Licensing Basis Configuration Management." This document discusses the responsibilities of various parties within MOX Services related to the change process. The document also refers to PP 9-3, "Design Control," which discusses the process for reviewing design changes prior to the evaluating the change under PP 8-6.

MOX Services documents the evaluation in the change process by using an Applicability Determination Form (ADF). The ADF is used to document the evaluation of the change. The ADF is also a permanent QA record. There are two sections of the ADF form. The first section is the applicability determination which provides a brief summary and reason for the change. There is a series of questions that are answered by the preparer to determine whether additional screening for LA/ISAS changes are needed.

The second portion of the form is a series of questions related to impacts to the LA or ISAS. The questions should be consistent with those contained in Chapter 16 of the LA. If the answer to any of the questions in Section 2 is yes, then a summary evaluation should be written and should contain the changes to LA and ISAS that will be integrated into those documents. In the event that a License Amendment is needed, the changes shall not be made until approved by the NRC. The final determination should be signed off by the Licensing Manager. The inspector should verify that the licensee/Construction Authorization holder has followed their administrative process.

The inspectors should ensure that the revisions to the procedures related to the change process do not compromise the intent of the change program in Chapter 16 of the LA and are consistent with the intent of the guidance provided in Regulatory Guide (RG) 3.74, "Guidance for Fuel Cycle Facility Change Process."

02.02 Facility Change Records

- a. Inspection Requirements.
 1. Verify that MOX Services has maintained records of any changes made to its facilities in accordance with 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. Verify that for changes to the LA, MOX Services maintained records regarding the determination that no license amendment was needed in accordance with Chapter 16 of the LA.

b. Inspection Guidance.

1. The inspection staff should select a sample of changes reported by MOX Services as part of the annual update to the LA and ISAS. The samples selected should include a variety of disciplines and emphasize the changes with a higher degree of safety significance. The technical disciplines may include fluid mechanics, heating, ventilation, and air conditioning (HVAC), process piping, chemical safety, criticality safety, fire safety, emergency power, structure, load handling, electrical power, the sintering furnace, and software. The sample should also contain a few ADFs in which the results of the evaluation determined that a change to the LA or ISAS was not needed.

The inspector should evaluate the sampling of ADFs to determine whether the change process outlined in Chapter 16 of the license application and the requirements of 10 CFR 70.72 are functioning as required and whether evaluations were properly screening changes in order to ensure that the applicants' commitments related to the regulatory requirements of 10 CFR Part 70 have been met.

The inspection staff may elect to use military standard MIL-STD-105D, Sampling Procedures and Tables for Inspection by Attributes, as guidance for selecting the sample size. It should be noted that MIL-STD-105D does not consider the relative importance between different populations. Using MIL-STD-105D, the following sample sizes for the review of ADF's would be recommended:

Number of Changes	ADF's selected
2-8	2
9-15	3
16-25	5
26-50	8
51-90	13
91-150	20
151-280	32
281-500	50
501-1200	80

2. The inspector should evaluate whether any changes identified by MOX Services in the annual updates should have been sent into the NRC for prior approval via an amendment.

88117-03 RESOURCE ESTIMATE

Inspection resources necessary to complete this inspection procedure are estimated to be 32-96 hours of inspection per facility visit. The basics of this inspection procedure should be conducted commensurate with ongoing construction activities.

88117-04 REFERENCES

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

88117-05 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.

END

Attachment 1 - Revision History for IP 88117

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 (Pre-Decisional, Non-Public)
N/A	ML16173A352 09/20/16 CN 16-023	Initial issuance. Researched commitments for the last four years and found none.	No	N/A