



Fuel Cycle Facility Change Processes and NRC Prior Approval

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Discussion Overview

- Types of fuel cycle facility change processes
 - 70.72 changes
 - Licensing document changes
 - Construction changes
- Evaluating when NRC prior approval of facility changes is needed

70.72 Changes

- A configuration management system is required by 70.72(a) for:
 - Evaluating changes
 - Implementing changes
 - Tracking changes

Changes Evaluated Under 70.72(a)

- All changes to the:
 - Site
 - Structures
 - Processes
 - Systems
 - Equipment
 - Components
 - Computer programs
 - Activities of personnel

Evaluation of Changes - 70.72(a)

- Technical basis for change
- Impact on health and safety or control of licensed material
- Modifications to procedures including whether training or retraining is required before operation
- Authorization requirements
- For temporary changes, the approved duration
- Impact on the ISA, ISA Summary or other safety program information
- Evaluation process should be well defined and complete.
- Evaluations need to be documented, maintained, and are subject to inspection.

Implementation of Changes – 70.72(b)

- After evaluations from 70.72(a)
- After evaluation for the need for prior approval based on 70.72(c) criteria

70.72(c) Criteria for NRC Prior Approval

- New types of accidents not previously described in ISA Summary
 - New hazards
- New processes, technologies, or control systems for which the licensee has no prior experience
 - Relies on prior experience of facility
 - Can be evaluated at system level

70.72(c) Criteria for NRC Prior Approval

- Equivalent replacement of IROFS needed to meet the performance requirements
 - Considerations/attributes for evaluation
 - Availability and reliability of IROFS
 - Type of control
 - Safety function of the IROFS
- Altering a sole IROFS
 - Positive or negative alteration
 - Based on alteration of the safety function of the IROFS
- Prohibited by license condition or order

Tracking of Changes

- Updating process safety information
- Updating ISA
- Updating the ISA Summary
- Maintaining records

Determining the Need for Prior Approval

- Evaluations of 70.72(c) criteria part of process safety information
 - Maintained on site and not submitted to NRC annually
- Evaluations need justification for changes do not require prior NRC approval
 - Well defined process
 - Consistent determinations
 - Repeatable
 - Defendable
- Evaluations subject to inspection

Licensing Document Changes

- Changes under 70.32 evaluate effectiveness when determining whether prior approval of change is required
 - MC&A program
 - Physical protection Plan
 - Safeguards contingency plan
 - Emergency plan

- Changes to the License Application (LA)
 - Optional use of a license condition for providing criteria and commitments for making changes without prior approval

Evaluation of Licensing Document Changes

- Process similar to 70.72 process
 - Evaluations should be performed using a well-defined process
 - Evaluations need to be documented and maintained on site
 - Periodic summary of changes not requiring prior approval provided to NRC.
 - Evaluations subject to inspection or review

Construction Changes

- 70.72(a) states “The licensee shall establish 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. This system must be documented in written procedures and must assure that the following are addressed prior to **implementing** any change:”
- 70.72(b) states “Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is **implemented**. The evaluation of the change must determine, before the change is **implemented**, if an amendment to the license is required to be submitted in accordance with § 70.34.”

Construction Changes

- The term construction and activities associated with construction is defined in 70.4
- Construction applies to new and existing facilities
- Current policy regarding changes during construction and NRC prior approval is delineated in an NRC letter (ML102910229)
 - Changes requiring license amendments should be approved before changes are implemented
 - Construction is a part of implementation

Construction Changes

- NRO has a formal process for making changes during construction
 - Scoping review and preliminary approval of amendment for change
- No formal FCSS process
- Possible case by case review relief based on:
 - Applicant/Licensee need
 - Available staff resources

Annual Summary of Changes

- Brief summary of all changes to the facility required by 70.72(d)(2)
- Revised ISA Summary pages as required by 70.72(d)(3)
- Summary should provide sufficient information for a reasonable understanding by the staff of the changes
- Summary submitted 30 days after end of year
- Subject to inspection/review by staff