



DRAFT REGULATORY GUIDE

Contact: K. Morrissey
(301) 492-3130

DRAFT REGULATORY GUIDE DG-3037

(Proposed New Regulatory Guide)

GUIDANCE FOR FUEL CYCLE FACILITY CHANGE PROCESSES

A. INTRODUCTION

This regulatory guide discusses requirements in Title 10 of the *Code of Federal Regulations*, Part 70, "Domestic Licensing of Special Nuclear Material" (10 CFR Part 70) (Ref. 1), and describes the types of changes for which licensees are to seek prior approval from the U.S. Nuclear Regulatory Commission (NRC). The guidance discusses how licensees can evaluate potential changes to determine whether NRC approval is required before implementing a change. This regulatory guide also describes the level of information that the staff of the NRC considers acceptable for use in documenting and reporting changes made without prior NRC approval.

Operating experience from nuclear fuel cycle facilities shows that past incidents often resulted from changes implemented at the facility. In some cases, licensee management or personnel did not analyze, authorize, or understand the changes before implementation. In 2000, the NRC added Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," to 10 CFR Part 70, in part to include requirements for tracking, evaluating, and documenting changes to the facility and safety program at fuel cycle facilities.

These requirements appear in 10 CFR 70.72, "Facility Changes and Change Process," and apply to fuel cycle facility licensees possessing greater than a critical mass of special nuclear material and who are engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, or fabrication of mixed-oxide fuel or fuel assemblies.

Such fuel cycle facility licensees must 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, in accordance with 10 CFR 70.72(a). Such changes may be made by the licensee without prior approval of the NRC, provided that the changes meet the criteria of 10 CFR 70.72(c).

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC's interactive rulemaking Web page at <http://www.nrc.gov>; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by August 12, 2011.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>; and the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML110960051. The regulatory analysis may be found in ADAMS under Accession No. ML110960217.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 70 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0009. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number. This regulatory guide is a rule as designated in the Congressional Review Act (5 U.S.C. 801–808). However, the NRC has determined that this regulatory guide is not a major rule as designated by the Congressional Review Act and has verified this determination with OMB.

B. DISCUSSION

As required by 10 CFR 70.62(a), fuel cycle facility licensees must establish and maintain a safety program that demonstrates compliance with the provisions of 10 CFR 70.61, "Performance Requirements." In addition, 10 CFR 70.62(b) through (d) specify the elements of the safety program, which include process safety information, an integrated safety analysis (ISA), and management measures.

Because licensees use a wide variety of fuel cycle facility processes and methodologies for their ISAs, it is difficult to uniformly evaluate licensee practices against the requirements of 10 CFR 70.72. The NRC has noted inconsistencies among licensees' interpretations of the requirements for prior approval. Furthermore, the documentation that the licensee submits annually to the NRC and maintains at the facility site has not always contained sufficient information for the NRC staff to independently determine how the licensee evaluated proposed changes against the criteria for NRC prior approval in 10 CFR 70.72(c).

The NRC has found that licensees do not use a consistent definition of what comprises a new type of accident sequence in implementing their ISA process. However, all licensees perform hazards analyses to identify credible hazards in their facilities. Therefore, new types of accident sequences can be defined as accident sequences that result from a hazard that has not previously been described in the ISA summary as having consequences that could exceed the performance requirements unless mitigated or prevented. Changes that require licensees to add accident sequences to the ISA summary are not necessarily considered new types of accident sequences that require prior NRC approval.

Several of the criteria in 10 CFR 70.72(c) focus on changes to the ISA summary (e.g., changes in accident sequences and items relied on for safety (IROFS)). The ISA summary is a major element of the facility's safety program, and the NRC staff reviews it to maintain timely knowledge of changes to the facility and its safety program. As specified in 10 CFR 70.72(c), licensees may make changes without prior NRC approval if the changes are not prohibited by regulation, license condition, or order, and if the changes do not do one or more of the following:

- Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of 10 CFR 70.61 and that have not previously been described in the ISA summary (see 10 CFR 70.72(c)(1)(i)).
- Use new processes, technologies, or control systems for which the licensee has no prior experience (see 10 CFR 70.72(c)(1)(ii)).

- Remove, without at least an equivalent replacement of the safety function, an IROFS that is listed in the ISA summary and is needed for compliance with the performance requirements of 10 CFR 70.61 (see 10 CFR 70.72(c)(2)).
- Alter any IROFS listed in the ISA summary that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of 10 CFR 70.61 (see 10 CFR 70.72(c)(3)).

For changes that require NRC approval, the licensee must submit a license amendment request under 10 CFR 70.72(d)(1). Licensees should evaluate the attributes of the sole IROFS, considering its reliability, availability, and capability to mitigate or prevent an accident; the safety function associated with the IROFS; and any factors, such as applied management measures, that could affect the sole IROFS. The licensee must briefly summarize all changes to the safety program made in the previous year for which it did not receive prior NRC approval and submit them in an annual report to the NRC under 10 CFR 70.72(d)(2). Licensees must track all changes that affect the ISA summary and annually submit revised ISA summary pages under 10 CFR 70.72(d)(3).

As required by 10 CFR 70.72(f), licensees must maintain, until license termination, records of the changes to their facilities. These records must include written evaluations that document the bases for licensee determinations that prior NRC approval was not required to implement changes. In some cases, the analyses will be minimal, because the changes involve no known hazards. Often, it is clear that there are no safety implications or new types of accident sequences associated with the proposed changes. In such an instance, use of an initial screening mechanism to assess the safety impact of a change may be sufficient. Screening is the first stage review of a change to determine if no further evaluation is required. It may take the form of a checklist of characteristics used to determine if there are safety implications. As an example, a typical checklist question for screening would be: Does the change require the addition of accident sequences to the ISA summary? or, Will the change remove an IROFS? If the answer to either question is yes, further written evaluation could be required.

C. REGULATORY POSITION

1. Scope of 10 CFR 70.72
 - a. As required by 10 CFR 70.72(a), the licensee must establish a configuration management system to evaluate, implement, and track changes to its facility. In addition, as discussed above, 10 CFR 70.72(c) allows the licensee of a fuel cycle facility to make some changes without prior NRC approval. The licensee must evaluate such changes to ensure that any impacts on the safety of operations are identified, considered, and documented before the changes are implemented.
 - b. Examples of activities that the licensee must evaluate under the requirements of 10 CFR 70.72 include the following:
 - (1) facility, design, and process changes,
 - (2) all changes to the facility safety program, including the ISA, process safety information, and management measures, and
 - (3) proposed activities that involve changes to procedures or new procedures not previously evaluated as part of a facility, design, or process change.

2. Prior Approval under 10 CFR 70.72(c)
 - a. This section of the regulatory guide provides guidance for using the criteria specified in 10 CFR 70.72(c) to determine whether the licensee needs prior NRC approval before implementing a change. The written evaluation providing the bases for the determination that prior NRC approval is not required before a change is implemented should clearly document the licensee's reasoning. In this regard, simple reliance on the level of detail and description provided in the ISA summary is not sufficient.
 - b. Licensees should implement the guidance in this section through the facility's administrative process for configuration management. As required by 10 CFR 70.72(a) and (f), licensees must use their configuration management system to control and document how the facility change meets the criteria of 10 CFR 70.72(c) before they implement the change. To evaluate compliance with the regulations, licensees should use documented, facility-specific criteria, such as procedures, for each of the 10 CFR 70.72(c) requirements. The criteria should be sufficiently clear that an NRC reviewer or inspector could draw the same conclusion as to whether or not NRC approval would be required before making the change. Section C.3 of this regulatory guide provides guidance on meeting the documentation requirements specified in 10 CFR 70.72(f).
- 2.1 New Types of Accident Sequences (10 CFR 70.72(c)(1)(i))
 - a. Prior approval would be necessary if the new sequences had consequences exceeding the 10 CFR 70.61 performance requirements and were the result of hazards that previously did not have associated accident sequences listed in the ISA summary. New types of accident sequences include, for example, adding a sprinkler system to an area where the moderator is not currently available; or using a new chemical in an existing process (thereby creating a possible new hazard), unless the chemical is used elsewhere in the facility and is already described in the ISA summary.
- 2.2 New Processes, Technologies, or Control Systems (10 CFR 70.72(c)(1)(ii))
 - a. The NRC does not require prior approval for changes involving processes, technologies, or control systems for which the licensee has prior experience.
 - b. Licensees may evaluate a change against the 10 CFR 70.72(c)(1)(ii) criteria at the system or component level. Key factors to consider in making this evaluation are whether the licensee has prior experience and knowledge of the process, technology, or control system and whether the NRC granted prior approval for similar systems.
 - c. "Prior experience" refers to experience in normal or pilot plant operations and not just experience gained as part of limited-duration or scale research and development or testing.
 - d. Laboratory testing does not constitute a new process if it does not contain unmitigated hazards that exceed performance requirements.
- 2.3 Equivalent Replacement of the Safety Function (10 CFR 70.72(c)(2))
 - a. When replacing IROFS, the licensee's primary goal should be to meet the performance criteria, which are usually met using combinations of IROFS. The evaluation should consider the following questions:

- (1) Will the replacement IROFS prevent or mitigate all accident sequences that required the original IROFS to meet 10 CFR 70.61 performance requirements?
 - (2) Will the replacement IROFS be equally or more reliable than the original IROFS?
 - (3) Will the replacement maintain the preferred hierarchy of controls (i.e., engineered passive controls, engineered active controls, administrative controls, operator actions)?
- b. The licensee does not require prior NRC approval to make a change that removes an IROFS without a replacement, if the licensee can demonstrate that it will still meet the performance requirements. If a change will remove IROFS needed to meet the performance requirements, the licensee does not require prior NRC approval if the removed IROFS will be replaced by IROFS that are at least as effective at preventing or mitigating the accident. Licensees do not have to use IROFS put in place as part of a temporary change under 10 CFR 70.72(a)(5) as the basis for determining whether future replacement IROFS are equivalent.

2.4 Alteration of a Sole IROFS (10 CFR 70.72(c)(3))

- a. The NRC staff considers a sole IROFS to be of higher risk significance, because it is the only safety control credited with preventing or mitigating an accident that has consequences that could exceed the performance requirements. The term “alter,” as it is used in 10 CFR 70.72(c)(3), should be read as meaning any change to the IROFS that will modify, positively or negatively, any of the attributes associated with the safety function of the IROFS.
- b. Licensees should document the attributes of IROFS they considered and relied upon in their evaluations but do not need to fully describe them in the ISA summary.
- c. Modification of a sole IROFS for testing, calibration, or other management measures does not constitute alteration of the IROFS, provided the licensee performs the operation as specified in approved work instructions and procedures.

3. Documentation Requirements

- a. As required by 10 CFR 70.72(f), licensees must maintain, until license termination, records of the changes to their facilities. Types of changes that may warrant more detailed evaluations (i.e., beyond simple checklists indicating yes or no) 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 licensee should demonstrate that the ISA summary already lists accident sequences of the same type.
 - (2) For changes that will remove an IROFS, the licensee should demonstrate either that the IROFS being removed is not needed to meet the performance requirements or that it will be replaced with an IROFS that provides at least an equivalent safety function.
 - (3) For changes to a sole IROFS, the licensee 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).

- (4) For changes that include new processes, technologies, or control systems, the licensee should demonstrate that it has relevant prior experience and that the license authorizes this activity.
 - b. Section C.4, below, discusses the licensee's annual report required by 10 CFR 70.72(d)(2).
 - c. The procedure that implements the requirements of 10 CFR 70.72(c) should contain sufficiently detailed criteria to form the bases for these evaluations, although licensees may include additional criteria. A graded approach for the documentation of the evaluations, based on the safety significance, is acceptable.
4. Annual Summaries
- a. For licensee changes made without prior NRC approval, the NRC requires licensees to submit an annual report briefly summarizing all such changes made to the safety program in the previous year, in accordance with 10 CFR 70.72(d)(2). This provision's reference to 10 CFR 70.62(a)(2) is to the facility safety program records, which consist of the process safety information, the ISA, and the management measures. In reviewing the annual report, the NRC may request additional information or may inspect records at the site for selected changes.
 - b. The annual report should include the following information:
 - (1) a description of each change that allows a reasonable understanding of the change,
 - (2) the process or process areas and IROFS that were affected by the change, and
 - (3) the process or process areas and IROFS that were affected by the change, and any additional information, available for inspection at the site, that may expedite the staff's annual review of the changes, such as the reason for the change and references to the specific safety program records, date of the change, and unique change identifier.
 - c. As stated in Section B above, in accordance with 10 CFR 70.72(d)(3), licensees must also track all changes that affect the ISA summary and must annually submit revised ISA summary pages. The revised ISA summary should clearly indicate (e.g., using portion markings) the changes that have occurred during the past year. Licensees should indicate whether the changes to the ISA summary are a result of the following:
 - (1) physical changes to the facility,
 - (2) a change to an analysis, or
 - (3) an administrative change.

5. Other Changes

This section discusses changes that are outside the provisions of 10 CFR 70.72.

- a. Licensees may make changes to their licensing basis without prior NRC approval, as specified in the following regulations:
 - (1) emergency plans—10 CFR 70.32(i),
 - (2) safeguards contingency plan—10 CFR 70.32(g),

- (3) physical security plan—10 CFR 70.32(e),
 - (4) plan for physical protection of special nuclear material in transit—10 CFR 70.32(d),
 - (5) security practices and procedures—10 CFR 95.19, “Changes to Facility Practices and Procedures (Ref. 2), and
 - (6) other material control procedures—10 CFR 70.32(c)(1)(iii).
- b. Additionally, the NRC would consider a license condition to allow changes to licensing documents, such as the license application or supporting documents referenced in the license, without prior NRC approval. Requests for license conditions of this type should contain the following:
 - (1) criteria for determining whether prior NRC approval is required,
 - (2) documentation requirements for the licensee’s evaluation supporting the finding that preapproval is not required, and
 - (3) reporting frequency for providing changes to the NRC after implementing changes.
- c. Considerations for the need for prior approval should include the following:
 - (1) impact on NRC approved methodologies,
 - (2) changes to the commitments that support the safety bases approved by the NRC.
- d. Changes not requiring NRC prior approval would generally be administrative changes such as the following:
 - (1) modifying facility and process descriptions,
 - (2) enhancements or clarifications of text,
 - (3) grammatical corrections, or
 - (4) reformatting of text.
- e. Changes requiring NRC prior approval would generally be for the following types of changes:
 - (1) reduction in the effectiveness of commitments;
 - (2) modification to methodologies and associated assumptions used in developing the safety basis, such as the ISA and criticality methodologies;
 - (3) modifications to the NRC-approved safety bases; or
 - (4) changes that conflict with an existing license condition.

D. IMPLEMENTATION

The purpose of this section is to provide instruction to applicants and licensees on how they may use this guide to incorporate the information set forth in this regulatory guide as well as how NRC staff will implement backfitting rules if necessary. Backfitting is generally defined in 10 CFR 50.109 and 10 CFR 70.76 as a modification of or addition to existing designs or procedures or implementation of a new or amended staff position on an existing rule.

Applicant and Licensees' Use

Applicants for NRC licenses, license amendments, or design certifications and current NRC license or certificate of compliance holders may use the guidance in this document as one method of demonstrating compliance with the NRC regulations identified in this regulatory guide. Methods and solutions that differ from those set forth in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the alternative methods demonstrate compliance with the NRC regulations upon which this guide is based. Current licensees may continue to use the guidance that was found acceptable for complying with the referenced regulations as part of their license or certificate of compliance approval process as long as their current licensing basis remains unchanged.

A licensee who believes that the NRC staff is inappropriately imposing this regulatory guide as part of a request for a license amendment or request for a change to a previously issued NRC regulatory approval may file a backfitting appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines."

NRC Staff Use

This guide represents the staff's position on one methodology used to meet the requirements of the rule. During inspection, though staff may request the applicant/licensee to consider this guidance, other methods of meeting the requirements of the rule may be submitted. As this guidance is non-binding, the staff shall not require the applicant/licensee to adhere to this guidance. The methods described in this regulatory guide are not requirements and compliance with them is not mandatory. Hence, the recommendations in the regulatory guide are not considered backfit as defined in 10 CFR 70.76(a)(1).

If an existing licensee seeks a license amendment or a change that is related to new or revised guidance, the staff may require the licensee to use this regulatory guide as a prerequisite for NRC approval. Additionally, if there is a new guidance as a result of a new rule, and that rule creates a finding that (i) a modification is necessary to bring a facility into compliance with Subpart H of 10 CFR 70 (ii) a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee (iii) regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security, or, (iv) the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate, then the licensee/applicant shall be required to meet the intent of the rule, and the staff may use

the regulatory guide as a prerequisite for NRC approval. These are the only instances where the staff may be able to require the licensee/applicant to change its licensing basis. These circumstances are the only instances when backfitting does not require a backfit analysis.

GLOSSARY

accident sequence—An unintended sequence of events that could result in environmental contamination, radiation exposure, release of radioactive material, inadvertent nuclear criticality, or exposure to hazardous chemicals (provided that the chemicals are produced from licensed radioactive material).

alter—To change, positively or negatively, any of the attributes associated with the safety function of the sole items relied on for safety (IROFS).

integrated safety analysis (ISA)—A systematic analysis to identify facility and external hazards (e.g., radiological, criticality, fire) and their potential for initiating accident sequences, the potential accident sequences that could be initiated and their likelihood and consequences, and the IROFS. The ISA is an element of the safety program.

ISA summary—A document or documents submitted with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the ISA.

items relied on for safety (IROFS)—Structures, systems, equipment, components, and activities of personnel that are relied on either to prevent potential accidents at a facility that could exceed the performance requirements in 10 CFR 70.61 or to mitigate their potential consequences.

management measures—The functions performed by the licensee, generally on a continuing basis, that are applied to IROFS to ensure that the items are available to reliably perform their functions when needed. These functions include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements. Management measures are an element of the safety program.

process safety information—Information required by 10 CFR 70.62(b) pertaining to the hazards of the materials used or produced in the fuel cycle facility process, information pertaining to the technology of the process, and information pertaining to the equipment in the process. Process safety information is an element of the safety program.

safety program—The program required by 10 CFR 70.62(a), consisting of process safety information, the ISA, and management measures, that the licensee must establish and maintain to demonstrate compliance with the performance requirements in 10 CFR 70.61.

sole IROFS—IROFS that are the sole item either preventing or mitigating an accident for which the consequences could exceed the performance requirements of 10 CFR 70.61.

REFERENCES¹

1. 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Nuclear Regulatory Commission, Washington, DC.
2. 10 CFR Part 95, "Facility Security Clearance and Safeguarding of National Security Information and Restricted Data," U.S. Nuclear Regulatory Commission, Washington, DC.

¹

Publicly available NRC published documents are available electronically through the Electronic Reading Room on the NRC's public Web site at: <http://www.nrc.gov/reading-rm/doc-collections/>. The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.