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DRAFT REGULATORY GUIDE

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(Proposed New Regulatory Guide)

GUIDANCE FOR FUEL CYCLE FACILITY CHANGE PROCESSES

A. INTRODUCTION

Title 10, of the *Code of Federal Regulations*, Part 70, "Domestic Licensing of Special Nuclear Material" (10 CFR Part 70) (Ref. 1), applies to fuel cycle facility licensees that possess greater than a critical mass of special nuclear material and are engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, and fabrication of mixed-oxide fuel or fuel assemblies.

As required by 10 CFR 70.72(a), 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. Such changes may be made by the licensee without prior approval of the U.S. Nuclear Regulatory Commission (NRC), provided that the changes meet the criteria of 10 CFR 70.72(c).

This regulatory guide describes the types of changes for which licensees should seek prior approval from the NRC and discusses how licensees can evaluate potential changes to determine whether NRC approval is required before a change is implemented. This regulatory guide also describes the level of information that the NRC considers to be acceptable for documenting and reporting changes made without prior NRC approval.

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 Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; e-mailed to nrcrep.resource@nrc.gov; submitted through the NRC's interactive rulemaking Web page at http://www.nrc.gov. 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 17, 2009.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); 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. ML091200493.

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.

B. DISCUSSION

A near criticality at a low-enriched fuel fabrication facility in May 1991 caused the NRC to review its regulations for licensees that possess and process greater than a critical mass of special nuclear material. Operating experience from nuclear fuel cycle facilities shows that past incidents, including criticalities and near criticalities, often resulted from changes at the facility that were implemented after the license was issued. In many cases, the changes were not analyzed before implementation and were not authorized or understood by licensee management or personnel. In 2000, the NRC added Subpart H 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 are set forth in 10 CFR 70.72, "Facility Changes and Change Process."

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.

As stated above, 10 CFR 70.72(a) requires fuel cycle facility licensees to establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and personnel activities. As specified in 10 CFR 70.72(c), licensees may make these changes without prior NRC approval if the changes are not prohibited by regulation, license condition or order, and if the changes do not:

- 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 item relied on for safety (IROFS) that is listed in the ISA summary and needed for compliance with 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)].

To make changes not meeting these criteria, the licensee must submit a license amendment request pursuant to 10 CFR 70.72(d)(1). All changes to the safety program made in the previous year for which the licensee did not receive prior NRC approval must be briefly summarized and submitted in an

annual report to the NRC pursuant to 10 CFR 70.72(d)(2). Licensees must track all changes that affect the ISA summary and annually submit revised ISA summary pages pursuant to 10 CFR 70.72(d)(3). Additionally, 10 CFR 70.72(f) requires that licensees maintain, for inspection, records of all facility changes, including, for those changes made without NRC prior approval, written evaluations justifying such decisions.

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 in their interpretations of the requirements for prior approval. Furthermore, the documentation submitted annually to the NRC and maintained at the facility site has not always contained sufficient detail for the NRC to independently determine whether the licensee evaluated and documented the requirements for NRC approval in a manner consistent with the regulations.

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. In addition, as discussed above, 10 CFR 70.72(c) allows the licensee of a fuel cycle facility to make changes without prior NRC approval. The licensee must evaluate such changes before implementation to ensure that any impacts on the safety of operations are identified, considered, and documented before the changes are implemented.

b. The following activities are examples to which the requirements of 10 CFR 70.72 apply, thus requiring evaluation by the licensee:

(1) facility, design, and process changes,
(2) all changes to the facility safety program, which includes 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. 10 CFR 70.72(c) Prior Approval

a. This section of the regulatory guide provides guidance for using the criteria specified in 10 CFR 70.72(c) to determine whether prior NRC approval is needed before implementing a change. Several of the criteria in 10 CFR 70.72(c) focus on changes to the ISA summary (accident sequences and IROFS) because it is a major element of the facility's safety program which the NRC staff uses to maintain timely knowledge of changes to the facility and its safety program. The evaluation and determination that prior NRC approval is not required before a change is implemented depends upon the licensee's evaluation of the change, rather than upon the level of detail and description provided in the ISA summary.

b. Licensees should implement the guidance in this section through the facility's administrative process associated with configuration management. Licensees should use documented facility-specific criteria, such as procedures, for each of the 10 CFR 70.72(c) requirements to evaluate compliance with the regulations. The criteria should be sufficiently clear so that an NRC reviewer or inspector could draw the same conclusion as to whether or not NRC approval would

be required prior to making the change. 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 the change is implemented. Section 3 of this regulatory guide provides additional guidance on documentation requirements.

2.1 New Types of Accident Sequences

a. To evaluate whether a change requires prior NRC approval, licensees should use the criterion in 10 CFR 70.72(c)(1)(i). This criterion states that licensees may make a change without prior NRC approval if the change does not 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.

b. The NRC has found that in implementing their ISA process, licensees do not use a consistent definition of what comprises a new type of accident sequence. 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 the addition of accident sequences to the ISA summary are not necessarily considered new types of accident sequences that require prior NRC approval. If the new sequences have consequences exceeding the 10 CFR Part 70.61 performance requirements and are the result of hazards that previously did not have any associated accident sequences listed in the ISA summary, prior approval would be necessary. An example of a new accident sequence is adding a sprinkler system to an area where moderator is not currently available thereby creating the possibility of a new hazard, unless used elsewhere in the facility.

2.2 New Processes, Technologies, or Control Systems

a. Pursuant to 10 CFR 70.72(c)(1)(ii), prior NRC approval is not required for changes involving processes, technologies, or control systems for which the licensee has prior experience.

b. An evaluation of a change against the criteria in this part may be applied at the system or component level. A key factor for consideration in making this evaluation is whether the licensee has 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 a limited-duration or scale research and development or testing effort.

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

a. As stated in 10 CFR 70.72(c)(2), prior NRC approval is not required for a change that does not remove, without at least an equivalent replacement of the safety function, an IROFS that is listed in the ISA summary and is necessary to meet the performance requirements.

b. When replacing IROFS, the primary goal is to meet the performance criteria, which are usually met using combinations of IROFS. When IROFS are replaced, the evaluation should consider the following questions:

(1) Will the replacement IROFS prevent or mitigate all accident sequences that required the original IROFS that was needed 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 preferred hierarchy of controls be maintained (i.e., engineered passive controls, engineered active controls, administrative controls, operator actions)?

c. Prior NRC approval is not required to make a change that removes an IROFS without a replacement if the licensee can demonstrate that the performance requirements will still be met. If a change will remove IROFS needed to meet the performance requirements, prior NRC approval is not required 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

a. As stated in 10 CFR 70.72(c)(3), prior NRC approval is not required for a change that does not alter any sole IROFS that is needed to meet the performance requirements of 10 CFR 70.61.

b. The NRC staff considers a sole IROFS to be risk significant because it is the only safety control credited with preventing or mitigating an accident that has consequences of concern. 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. Licensees should describe these attributes in the ISA, but they do not need to fully describe them in the ISA summary.

c. Licensees should evaluate the attributes of the sole IROFS, giving consideration to the 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 likelihood of the IROFS.

d. Modification of a sole IROFS for testing, calibration, or other management measures required to meet the 10 CFR 70.61 performance criteria does not constitute alteration of the IROFS, provided the operation is performed 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, and these records must include written evaluations that document the bases for the determinations that prior NRC approval was not required to implement the 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 is sufficient. Listed below are examples of the 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:

(1) For changes that require the addition of accident sequences to the ISA summary, the licensee should demonstrate that there are existing accident sequences of the same type.
(2) For changes that will remove an IROFS, the licensee should demonstrate that either 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.
(4) For changes that include new processes, technologies, or control systems, the licensee should demonstrate that it has relevant prior experience and that this activity is authorized in the license.

b. The annual summary of all facility changes should include the following information:

(1) a description of each change that allows a reasonable understanding of the change that was made,
(2) the process or process areas and IROFS that were affected by the change, and
(3) additional information, such as the reason for the change, reference to the specific safety program records, date of the change, and unique change identifier.

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 is acceptable, based on the safety significance.

4. Annual Summary

a. 10 CFR 70.72(d)(2) requires licensees to submit an annual report to the NRC, briefly summarizing all changes made to the safety program in the previous year for which the licensee did not receive prior NRC approval. The regulation'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 management measures. The NRC may request additional information for selected changes as part of its review.

b. As stated above, licensees must track all changes that affect the ISA summary, and must annually submit revised ISA summary pages pursuant to 10 CFR 70.72(a)(3). The revised ISA summary should clearly indicate (e.g., using portion markings) the changes that have occurred during the past year. It would be beneficial, though not required, to 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

a. Licensees can 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 SNM in transit—10 CFR 70.32(d), and
(5) security practices and procedures—10 CFR 95.19.

b. Additionally, a license condition can be applied to allow changes to the safety analysis report without prior NRC approval. License conditions of this type should contain the following:

(1) criteria for preapproval,
(2) commitment to document the licensee's evaluation supporting the findings that preapproval is not required, and
(3) reporting frequency for providing changes to the NRC after implementation.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this draft regulatory guide. The NRC does not intend or approve any imposition of backfit in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. In some cases, licensees may propose an alternative or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for the facility change process.

REGULATORY ANALYSIS

1. Statement of the Problem

As specified in 10 CFR 70.72(c), licensees are allowed to make changes to their facilities and safety programs without prior NRC approval. Because licensees use a wide variety of fuel cycle facility processes and methodologies for their ISAs, application of the requirements of 10 CFR 70.72 has been inconsistent. Although the regulation defines broad categories of changes that require prior NRC approval, there is still significant room for licensee interpretation. Consequently, the NRC has noted inconsistencies among licensees in the types of changes for which prior approval is sought. Further, the documentation submitted annually to the NRC, and documentation maintained at the facility site, has not always been sufficient for the staff to independently determine whether licensees' changes were appropriate without prior NRC approval.

2. Objective

This guidance attempts to balance the need for consistent application of the regulatory requirements of 10 CFR 70.72 with the fact that fuel cycle facilities conduct a wide range of operations and thus have different purposes, designs, and safety programs. The objective of this regulatory action is to ensure that licensees clearly understand the following:

- the types of facility changes that require prior approval from the NRC,
- the considerations for an adequate change evaluation,
- the types of change documentation that licensees must maintain on site for inspection, and the types of documentation that must annually be submitted to the NRC.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

Do not issue a new regulatory guide.
Issue a new regulatory guide.

Alternative 1: Do Not Issue a New Regulatory Guide

Under this alternative, the NRC would not issue any guidance. If NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, or NRC. However, the "no-action" alternative would not address the identified concerns with the absence of NRC guidance, leaving the possibility for inefficiency and confusion among NRC staff and licensees. The NRC would continue to address issues with fuel cycle facility changes on a case-by-case basis. This alternative provides a baseline condition from which any other alternatives will be assessed.

Alternative 2: Issue a New Regulatory Guide

Under this alternative, the NRC would issue a new regulatory guide. This option would lessen confusion among licensees regarding the implementation of 10 CFR 70.72, improve the quality of their facility change evaluations and documentation, and facilitate the efficient NRC review and inspection of facility changes.

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide. The impact to the public would be the voluntary costs associated with reviewing and providing comments to NRC during the public comment period. The value to NRC staff and its licensees would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document.

Conclusion

Based on this regulatory analysis, the NRC staff recommends the issuance of a new regulatory guide. The staff concludes that the proposed action will enhance fuel cycle facility safety by providing clear guidance to evaluate and document facility changes. It could also lead to cost savings for both NRC and industry by reducing the need to request and provide additional information regarding facility changes.

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 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 items relied on for safety. 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 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, 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.

REFERENCES[1]

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 such as Regulations, Regulatory Guides, NUREGs, and Generic Letters listed herein are available electronically through the Electronic Reading room on NRC's public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. Copies are also available for inspection or copying, for a fee, from 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.