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REGULATORY GUIDE

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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) before their implementation. This guidance also applies to certain applicants under 10 CFR Part 40, "Domestic Licensing of Source Material," that must comply with the requirements in Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," of 10 CFR Part 70 or with similar requirements in 10 CFR Part 40. The guide describes how licensees can evaluate potential changes to determine whether NRC approval is required before implementing them. This regulatory guide identifies an acceptable level of information to be provided by licensees when 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 implementing them. In 2000, the NRC added Subpart H to 10 CFR Part 70, in part, to include requirements for tracking, evaluating, and documenting changes made to fuel cycle facilities, and to licensee safety programs.

The NRC issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public.

Regulatory guides are issued in 10 broad divisions—1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

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The requirements governing these changes are stated in 10 CFR 70.72, "Facility Changes and Change Process," and pursuant to 10 CFR 70.60, apply to fuel cycle facility licensees that possess greater than a critical mass of special nuclear material and that 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). Licensees may make such changes without prior approval of the NRC as long as the changes meet the criteria in 10 CFR 70.72(c).

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).[1] However, OMB has not found it to be a major rule as designated in the Congressional Review Act.

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 in 10 CFR 70.72. The NRC has noted inconsistencies among licensees' interpretations of the requirements for prior approval. Also, the documentation that licensees submit annually to the NRC and maintain at facility sites has not always contained sufficient information for the NRC staff to independently determine how a 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 (IROFSs)). 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:

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[1] The "rule" designation under the Congressional Review Act is based upon a specific statutory definition and does not alter the fact that compliance with regulatory guides is not required.

- 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 in 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 in 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). 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 records of the changes to their facilities until license termination. 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 no safety implications or new types of accident sequences are associated with the proposed changes. In such cases, 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 whether any further evaluation is necessary. Screening may include the use of a checklist of characteristics to determine the existence of safety implications. Typical checklist questions for screening would include the following:

- Does the change require the addition of accident sequences to the ISA summary?
- Will the change remove an IROFS?

C. STAFF REGULATORY GUIDANCE

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 and be maintained by licensees on site.

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 in 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 to allow an NRC reviewer or inspector to draw the same conclusion as to whether NRC approval would be necessary before implementation of the change. Section C.3 of this regulatory guide provides guidance on meeting the documentation requirements in 10 CFR 70.72(f).

2.1 New Types of Accident Sequences (10 CFR 70.72(c)(1)(i))

Prior approval would be necessary if the new types of accident sequences had consequences exceeding the 10 CFR 70.61 performance requirements and if they resulted from hazards that previously did not have associated accident sequences listed in the ISA summary. New types of accident sequences may include, for example, the addition of a sprinkler system to an area where the moderator is not currently available; or the use of 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 that the licensee should consider when making this evaluation are whether it 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 an IROFS, the licensee's primary goal should be to meet the performance criteria, which is usually done using combinations of IROFSs. 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 the 10 CFR 70.61 performance requirements?

(2) Will the replacement IROFS be equally reliable to, or more reliable than, the original IROFS?

(3) Will the replacement IROFS maintain the preferred hierarchy of controls (i.e., engineered passive controls, engineered active controls, administrative controls, and operator actions)?

b. Prior NRC approval is not required 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 IROFSs needed to meet the performance requirements, prior NRC approval is not required if the removed IROFSs will be replaced by IROFSs that are at least as effective at preventing or mitigating the accident. Licensees do not have to use IROFSs put in place as part of a temporary change under 10 CFR 70.72(a)(5) as the basis for determining whether future replacement IROFSs 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 IROFSs that they considered and relied on in their evaluations of changes, but they do not need to fully describe the IROFSs in the ISA summary. 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.

c. Modification of a sole IROFS for testing, calibration, or other management measures does not constitute alteration of the IROFS as long as the licensee performs the operation as specified in approved work instructions and procedures.

3. Documentation of Facility Changes

a. As required by 10 CFR 70.72(f), licensees must maintain records of any changes made to their facilities under 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. 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 or IROFSs being removed are not needed to meet the performance requirements or that they will be replaced with an IROFS or IROFSs that provide 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 summary required by 10 CFR 70.72(d)(2).

c. The procedure that implements the requirements in 10 CFR 70.72(c) should contain sufficiently detailed criteria to form the bases for the change evaluations, although licensees may include additional criteria. A graded approach regarding the level of documentation supporting the 10 CFR 70.72(c) evaluations, based on safety significance, is acceptable.

4. Annual Summaries

a. For licensee changes that do not require prior NRC approval in accordance with 10 CFR 70.72(d)(2), licensees must submit annually a brief summary of changes made to the safety program in the previous year. . The reference to 10 CFR 70.62(a)(2) in this provision is to the facility safety program records, which consist of the process safety information, the ISA, and the management measures. In its review of the annual summary, the NRC may request additional information or may inspect records at the site for selected changes.

b. The annual summary of facility changes should describe each change in a manner that allows a reasonable understanding of the change. Additionally, the summary may include the following information to support the staff's review of the changes:

(1) the process or process areas and IROFSs that were affected by the change, and

(2) 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 may provide information that indicate whether the changes to the ISA summary resulted from 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 plans—10 CFR 70.32(g),

(3) physical security plans—10 CFR 70.32(e),

(4) plans for the 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 license amendment requests that a license condition be added to allow changes to licensing documents (*e.g.*, to the license application, or to supporting documents referenced in the license) without prior NRC approval. Requests for license conditions of this type should contain the following information:

(1) criteria for determining whether prior NRC approval is required,

(2) documentation requirements for the licensee's evaluation that supports 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 include the following:

(1) whether the change decreases the level of effectiveness of the design basis as described in the license application,

(2) whether the change results in a departure from the methods of evaluation described in the license application and used in establishing the design basis,

(3) whether the change results in a degradation in safety,

(4) whether the change affects compliance with applicable regulatory requirements, and

(5) whether the change conflicts with an existing license condition.

d. Changes to licensing documents that would not require prior NRC approval would generally be administrative changes such as the following:

(1) modifications to facility and process descriptions,
(2) enhancements or clarifications of text,
(3) grammatical corrections, or
(4) reformatting of text.

e. Changes to licensing documents that would require prior NRC approval would generally be for the following types of changes:

(1) reduction in the effectiveness of commitments,

(2) modifications 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 information on how applicants and licensees[2] may use this guide and information regarding the NRC's plans for using this regulatory guide. In addition, it describes how the NRC staff complies with the applicable Backfit Rule (10 CFR 70.76).

Use by Applicants and Licensees

Applicants and licensees may voluntarily[3] use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this regulatory guide for actions which do not require NRC review and approval such as changes meeting the 10 CFR 70.72(c) criteria. Licensees may use the information in this regulatory guide or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this regulatory guide, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be

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[2] In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Parts 50, 52 and 76; and the term "applicants," refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

[3] In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

considered backfitting even if prior versions of this regulatory guide are part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) NRC staff consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 70.76 (a)(1).

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require adherence to this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of this regulatory guide, issuance of a generic communication, or promulgation of a rule requiring the use of this regulatory guide without further backfit consideration.

Additionally, an existing applicant may be required to adhere to new rules, orders, or guidance if 10 CFR 70.76(a)(3) applies.

Conclusion

This regulatory guide is not being imposed upon current licensees and may be voluntarily used by existing licensees. In addition, this regulatory guide is issued in conformance with all applicable internal NRC policies and procedures governing backfitting. Accordingly, the NRC staff issuance of this regulatory guide is not considered backfitting, as defined in 10 CFR 70.76 (a)(1).

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 IROFSs.

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 IROFSs. 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 (IROFSs)—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 IROFSs 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—An IROFS that is the sole item either preventing or mitigating an accident for which the consequences could exceed the performance requirements in 10 CFR 70.61.

REFERENCES[4]

1. 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Nuclear Regulatory Commission, Washington, DC.

2. 10 CFR Part 40, "Domestic Licensing of Source Material," U.S. Nuclear Regulatory Commission, Washington, DC.

3. 10 CFR Part 95, "Facility Security Clearance and Safeguarding of National Security Information and Restricted Data," U.S. Nuclear Regulatory Commission, Washington, DC.

4. NUREG-1409, "Backfitting Guidelines ," U.S. Nuclear Regulatory Commission, Washington, DC.

[4] Publicly available NRC published documents are available electronically through the NRC Library 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.