UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

September 22, 2006

NRC REGULATORY ISSUE SUMMARY 2006-14
ENFORCEMENT DISCRETION FOR FACILITY CHANGES UNDER 10 CFR 70.72(c)(2)

ADDRESSEES

All fuel cycle licensees regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Regulatory Issue Summary (RIS) to inform addressees that the staff is pursuing a rule change pertaining to items relied on for safety (IROFS). The revised language in the direct final rule for 10 CFR 70.72(c)(2) will more specifically define the conditions when licensees are not required to obtain NRC pre-approval to remove or replace previously-identified IROFS. This RIS informs addressees that, until the final rule becomes effective, the NRC will use enforcement discretion for those licensees that are in compliance with the requirements as stated in the direct final rule. No specific action nor written response is required.

SUMMARY OF ISSUE

10 CFR 70.72 contains the requirements for control of facility changes and the change process. Specifically, 10 CFR 70.72(c)(2) states:

> "The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change . . . does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary."

Several licensees have indicated that they believe that equivalent replacement of IROFS and 10 CFR 70.72(c)(2) are met, as long as the performance requirements of 10 CFR 70.61 are met. NRC does not necessarily agree with that position because NRC also believes that licensees need to ensure equivalent replacement for IROFS needed to meet the performance requirements of 10 CFR 70.61. However, NRC does agree that licensees should be afforded maximum flexibility in making changes to IROFS that are not needed to meet the performance requirements of 10 CFR 70.61. Accordingly, when licensees include IROFS that are not needed to meet the performance requirements in the baseline ISA summaries (i.e., submitted

ISA summaries plus NRC-approved changes to the ISA summaries) licensees should have flexibility to remove or replace those IROFS without NRC pre-approval or ensuring equivalent replacement. Note that the baseline ISA summaries do not include the annual updates to the ISA summaries because the updates should only contain those changes that do not need NRC pre-approval and thus, should not change the approved means of meeting the performance requirements. Also, NRC pre-approval is still required for removal of an IROFS needed to meet the performance requirements of 10 CFR 70.61 without equivalent replacement.

To provide the above flexibility, after the rule change 10 CFR 70.72(c)(2) will state:

> "The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change . . . does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary **and is necessary for compliance with the performance requirements in §70.61.**"

To provide guidance to licensees implementing equivalent replacement, the NRC recognizes that 10 CFR 70.72(c)(2) does not state that a change in the type of control used (e.g., from engineered to administrative) could not be an equivalent replacement. However, in order for a replacement to be equivalent, it would have to control the same parameter with at least the same level of reliability and efficacy as the IROFS being replaced. Parameter limits must also be maintained to values that are at least as restrictive. This means that capability, availability, and reliability of the IROFS need to be at least as restrictive.

In addition, if the equivalent replacement of an IROFS results in the creation of a new type of accident sequence[1] (i.e., introduces a new failure mode), then NRC pre-approval is still needed

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[1]Example of a replacement IROFS with an equivalent safety function creating a new type of accident sequence:

A solution tank is equipped with a level interlock. On generation of a high-level signal, a pump begins to pump the solution to another tank to prevent overflowing. The pump, the level probe, and the associated valving and instrumentation are classified as a criticality-related IROFS.

The licensee decides to replace the pump with a pump from another manufacturer. The new pump has the same pumping capacity, the same reliability, and performs the same safety function. Under 10 CFR 70.72(c)(2), it is an equivalent replacement.

However, the original pump had a very limited oil capacity, whereas the new pump has a large oil reservoir. The presence of large amounts of oil in an unsafe volume reservoir has created several new credible accident sequences, including: (1) leaking of oil through the plenum into the solution, which can cause an exothermic chemical reaction (whereas the only hazard before this was criticality); (2) leaking of oil onto the floor, where it can moderate spilled uranium from a nearby glovebox; and (3) accumulation of an unsafe mass of uranium in the unsafe volume oil reservoir. Note that none of these new hazards involves the pump's credited safety function.

to meet 70.72(c)(1)(i). New failure modes include, but are not limited to:

- Replacement IROFS' failure, even as an initiating event, has a different effect on that or any other system;
- Replacement IROFS' failure mode is different; or
- Replacement IROFS' failure results in a different type or severity category of consequence.

The staff cautions licensees that multiple changes to IROFS, with each change made without NRC pre-approval, may lead to situations that would have required NRC pre-approval if the overall change had been proposed as a single change and thus, a situation which may result in a violation of 70.72(c)(2). That situation would reduce a licensee's management of controls and the change process and increase risk. Therefore, NRC expects that licensees would evaluate each change versus the baseline ISA summaries. Additionally, NRC is developing an Enforcement Guidance Memorandum that will establish guidance and documentation requirements for granting enforcement discretion until the direct final rule becomes effective.

BACKFIT DISCUSSION

This RIS requires no action nor written response and is, therefore, not a backfit under 10 CFR 70.76. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

NRC has determined that this action is not subject to the Small Business Regulatory Enforcement Fairness Act of 1996.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). Existing requirements were approved by the Office Management and Budget, approval number 3150-0009.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

CONTACT

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA/

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Attachment: "Recently Issued NMSS Generic Communications"

Note: NRC generic communications may be found on the NRC public website at http://www.nrc.gov, under Electronic Reading Room/Document Collections.

Recently Issued NMSS Generic Communications

Date	GC No.	Subject	Addressees
09/14/06	RIS-06-19	Availability of Guidance on Radioactive Seed Localization	All NRC medical licensees.
08/31/06	RIS-06-18	Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients	All NRC medical licensees.
07/20/06	RIS-06-11	Requesting Quality Assurance Program Approval Renewals Online by Electronic Information Exchange	All 10 CFR Part 71 quality assurance program and certificate holders.
04/23/06	RIS-06-10	Use of Concentration Control for Criticality Safety	All licensees authorized to possess a critical mass of special nuclear material.
01/26/06	RIS-02-15, Rev. 1	NRC Approval of Commercial Data Encryption Products For the Electronic Transmission Of Safeguards Information	All authorized recipients and holders of sensitive unclassified safeguards information (SGI).
01/24/06	RIS-06-01	Expiration Date for NRC-Approved Spent Fuel Transportation Routes	The U.S. Nuclear Regulatory Commission (NRC) licensees who transport, or deliver to a carrier for transport, irradiated reactor fuel (spent nuclear fuel (SNF)).
01/13/06	RIS-05-27, Rev. 1	NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review	All 10 CFR Parts 71 and 72 licensees and certificate holders.
07/10/06	IN-06-13	Ground-Water Contamination Due to Undetected Leakage of Radioactive Water	All holders of operating licenses for nuclear power and research and test reactors including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor and those authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72 licenses to store spent fuel in water-filled structures.
07/06/06	IN-06-12	Exercising Due Diligence When Transferring Radioactive Materials	All materials licensees.
06/12/06	IN-06-11	Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery and Other Therapy Procedures	All medical licensees.

Date	GC No.	Subject	Addressees
03/31/06	IN-06-07	Inappropriate Use of a Single-parameter Limit as a Nuclear Criticality Safety Limit	All licensees authorized to possess a critical mass of special nuclear material.
03/21/06	IN-02-23, Supl. 1	Unauthorized Administration of Byproduct Material for Medical Use	All medical licensees.
01/19/06	IN-06-02	Use of Galvanized Supports and Cable Trays with Meggitt Si 2400 Stainless- Steel-jacketed Electrical Cables	All holders of operating licenses for nuclear reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; and fuel cycle licensees and certificate holders.

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