

April 29, 2010

Janet R. Schlueter
Director, Fuel and Material Safety
Nuclear Generator Division
Nuclear Energy Institute
1776 I Street, NW
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Washington, DC 20006-3708

SUBJECT: RESPONSE TO INDUSTRY COMMENTS FOLLOWING MARCH 10 PUBLIC MEETING ON TITLE 10 OF THE CODE OF THE FEDERAL REGULATIONS 70.72

Dear Ms. Schlueter:

Thank you for your facilitation of industry comments on the subject matter discussed during the March 10, 2010, public meeting as well as the follow-up comments provided in your letter of March 29, 2010 (ML101030203). As you may recall, the topic of the public meeting was to present U.S. Nuclear Regulatory Commission's (NRC's) proposed position relative to "at-risk" change implementation for instances when NRC prior approval is required prior to making the change consistent with the regulations present in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.72(d). There was some confusion expressed at the meeting that positions presented also encompassed changes allowed without prior NRC approval under 10 CFR 70.72(c) and I would like to clarify that was not the intent. The NRC would like to provide the following information in response to some of the concerns expressed in your March 29, 2010, letter.

1. Industry believes that NRC staff has changed its interpretation of 10 CFR 70.72 and is implementing these new interpretations through both its licensing and inspection activities. Notwithstanding the March 10, 2010, public meeting, industry believes that these new interpretations are being implemented without an opportunity for public discussion, adequate explanation of the staff's regulatory or technical basis, or consideration of the backfitting provisions contained in 10 CFR 70.76. Furthermore, industry states that the impact of any such change in interpretation must be thoroughly evaluated and analyzed, and any modifications to the rule to impose a revised NRC expectation should be conducted through a rulemaking in accordance with the Administrative Procedure Act, although at this time, industry does not believe rulemaking is needed to modify 10 CFR 70.72 based on ten years of safe implementation.

The NRC has not implemented any new interpretations in its licensing and inspection activities relative to "at-risk" change implementation. NRC staff have only recently, within the past 12 months, determined that additional guidance is needed for this issue; primarily due to changes constructed at new licensee sites that required NRC approval prior to being made. The NRC staff has actively involved the public and intends to continue public involvement in resolving this issue. As I mentioned during the meeting, industry will be provided an opportunity to comment

on any guidance that is developed prior to its issuance. Also, as indicated during the public meeting, the Office of Nuclear Materials Safety and Safeguards (NMSS) is considering the appropriateness of the NRC staff's position in light of the information provided, including whether a rulemaking is warranted.

2. Industry believes that recent staff interpretations regarding the timing of change "implementation" are inconsistent with accepted past practice in this area as 10 CFR 70.72 does not differentiate between changes occurring during facility construction or significant plant modifications and changes occurring at operating facilities. Industry also states that continuation of construction does not equal implementation and should not be a driver for enforcement at this stage.

and

3. Industry believes that there are instances where a licensee can make decisions to implement new or changed operations and, provided the licensee is operating consistent with 10 CFR 70.72, enforcement action would not be appropriate. The NRC staff's reference to deliberate misconduct on the Example 5 slide of the staff's presentation at the March 10, 2010, public meeting is inappropriate in a situation such as this where licensees are attempting to engage NRC to address evolving staff concepts of compliance.

The intent of the March 10, 2010, public meeting was to address how changes are to occur if prior NRC approval is required before making the change. Situations when a licensee conducts new or changed operations prior to receiving the requisite NRC approval would constitute a violation of 10 CFR 70.72(d)(1). The staff will review the points made at the meeting to determine if the stated NRC position requires further clarification or modification. The NRC staff will work with licensees to the extent reasonable with regards to change implementation and would consider any information gained through these interactions when determining whether rule violations have occurred and the significance of any such violations.

4. Industry is concerned with the delay in the issuance of the final version of DG-3037, "Guidance for Fuel Facility Change Process," which was issued in June 2009 for comment. Industry is concerned that the NRC may include positions communicated in the March 10, 2010, public meeting in the guide prior to its release.

DG-3037 is anticipated to be issued as a final regulatory guide in the near future. At this time, NRC has no intention of further modifying the initial version of the regulatory guide to address the positions discussed at the March 10, 2010, public meeting. Any modification to the regulatory guide to address issues raised during, or in response to, the public meeting would be through a revision to the guide that would be issued for public comment prior to final issuance.

In accordance with 10 CFR 2.390(d) of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). The change request summary and other enclosures to letter 10-004 will be withheld from the public in accordance with 10 CFR 2.390(b).

The NRC staff looks forward to further discussions on the 10 CFR 70.72 change process and its implementation. Should you have any questions, please do not hesitate to contact me at 301-492-3206 or via e-mail at Michael.Tschiltz@nrc.gov.

Sincerely,

/RA/

Michael D. Tschiltz, Deputy Director
Fuel Facility Licensing Directorate
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

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Sincerely,

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Michael D. Tschiltz, Deputy Director
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