



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

March 25, 2016

MEMORANDUM TO: Victor M. McCree  
Executive Director for Operations

FROM: K. Steven West, Chairman */RA/*  
Committee to Review Generic Requirements

SUBJECT: COMMITTEE TO REVIEW GENERIC REQUIREMENTS:  
MINUTES OF MEETING NUMBER 440

By memorandum of January 19, 2016, the Office of Nuclear Material Safety and Safeguards (NMSS) requested that the Committee to Review Generic Requirements (CRGR, the Committee) review and endorse proposed Interim Staff Guidance (ISG), "Guidance for the Evaluation of Acute Chemical Exposures and Quantitative Standards" (Agencywide Documents Access and Management System [ADAMS] Accession No. ML15307A098). With its request, the staff provided to the Committee a chronology and discussion of regulatory, legal and policy implications related to the issuance of the ISG; its responses to public comments related to backfitting and technical issues; its responses to the questions posed in Appendix C of the CRGR charter, and the proposed final ISG. The Committee noted from the staff's submittal that the Office of the General Counsel had no legal objection to the proposed ISG and that the Advisory Committee on Reactor Safeguards had reviewed the ISG and recommended that it be issued (ADAMS Accession No. ML15293A314).

On January 28, 2016, the CRGR held Meeting Number 440 with the staff to discuss the ISG (ADAMS Accession No. ML15307A532). The list of meeting attendees is enclosed. Marilyn Diaz, with the support of Shana Helton, Robert Johnson, and James Hammelman, all of NMSS, briefed the CRGR and addressed the Committee's questions. The staff's presentation materials are located in ADAMS Accession No. ML16029A332. In sum, the staff stated that it would use the ISG to review chemical hazard analyses conducted by fuel cycle facility licensees. The staff stated its position that the integrated safety analysis (ISA) should describe certain quantitative standards and consider chemical hazards including inhalation and dermal and ocular exposures, and that issuance of the ISG would not constitute backfitting. The staff asked the Committee to endorse the ISG and its positions regarding backfitting.

Subpart H of 10 CFR Part 70 sets forth the requirements that a fuel cycle facility licensee must meet in conducting its ISA. The performance requirements of 10 CFR 70.61(b) state that the risk of each "credible" high-consequence event must be limited through engineered or administrative controls as specified in 10 CFR 70.61(e), and must be identified as items relied on for safety (IROFS) in the ISA pursuant to 10 CFR 70.62(c). The regulation states that the controls must be applied such that high-consequence events are "highly unlikely," or their

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consequences are less severe than those specified in 10 CFR 70.61(b)(1)-(4). The 10 CFR 70.61(b)(4) provisions describe the chemical exposures that are deemed to be high-consequence events.

Fuel cycle licensees use hazardous chemicals to process and manufacture reactor fuel. According to the staff, these chemicals have the potential to result in chemical exposures to workers through inhalation and through dermal and ocular exposures. In accordance with the requirements of 10 CFR 70.65(b)(7), a licensee must describe in its ISA summary the quantitative standards it proposed to assess the consequences to an individual of acute chemical exposure to licensed materials or chemicals produced from licensed materials. The quantitative standards help licensees understand the severity of potential accidents and manage hazards by identifying analyzed events as resulting in high or intermediate consequence. When questioned, the staff informed the Committee that it believes that fuel cycle facility licensees have generally considered dermal and ocular exposures in their ISAs and that all fuel fabrication licensees have proposed a quantitative standard for the hazardous chemical hydrogen fluoride.

The staff informed the CRGR that issuance of the ISG would not constitute backfitting as defined in the applicable backfitting provisions of 10 CFR 70.76. Nevertheless, beginning as early as 2008, the Nuclear Energy Institute (NEI) has expressed concerns about staff positions regarding dermal and ocular exposures and quantitative standards (ADAMS Accession No. ML083360632). More recently, in a letter to the staff of March 26, 2014 (ADAMS Accession No. ML14086A270), NEI asserted that implementing this ISG on existing licensees would result in additional regulatory actions and, therefore, would constitute an unanalyzed backfit. The staff refuted this claim in its response to NEI dated September 15, 2014 (ADAMS Accession No. ML14251A150). Later, in a letter of November 7, 2014 (ADAMS Accession No. ML14322B019), to the NRC General Counsel, NEI restated its backfitting concerns. On March 4, 2015, the staff published the draft ISG in the *Federal Register* for public comment. Later, the staff supplemented the *Federal Register* Notice to include a specific request for comments on the backfitting questions and extended the public comment period (ADAMS Accession No. ML15093A088). The staff received a number of public comments associated with backfitting and revised the ISG to address those comments.

The staff informed the CRGR that it will incorporate the ISG in the next revision of NUREG 1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," as guidance to staff for evaluating chemical hazards when reviewing applications for new facilities or new processes at existing facilities, and applications for license renewal. The staff also informed the Committee that it plans to gather additional information on the chemical safety program from licensees that are subject to subpart H requirements through routine inspections. The staff would use such information to inform possible future regulatory actions.

During the meeting, the CRGR focused its discussion with the staff on the following: the applicable regulatory requirements and how they have been applied by the staff and licensees; the staff's position on the use of quantitative standards and dermal and ocular exposures; the staff's position on backfitting and the longstanding industry concerns about dermal and ocular exposures and standards; NEI's backfitting claim received in 2014; the public comments

submitted in response to the proposed ISG and the staff's responses to those comments (including industry comments); certain aspects of the language and terminology used in the proposed ISG and its supporting documentation; and the structure and organization of the proposed ISG. The CRGR also questioned the staff about its plans for implementing and using the ISG, if approved, and the staff's plans to use the ISG to gather or assess additional information for future regulatory decision making.

Overall, on the basis of its review of the proposed ISG and the staff's supporting documents, and its consideration of the clarifying information provided by the staff during the meeting, the CRGR concluded that (1) ISAs are required by the regulations of subpart H to consider all acute chemical exposures including inhalation and dermal and ocular exposures, (2) the proposed quantitative standard required by 10 CFR 70.65(b)(7) requires licensees to identify events as high or intermediate chemical exposure consequences as required in 10 CFR section 70.61; (3) the proposed ISG itself, if properly implemented as described by the staff, would not modify any requirement or staff position, nor would it relax or reduce any existing requirement. The CRGR also believes that the staff has not changed its position and has been consistent in articulating its position in response to industry concerns since 2007. For these reasons, during the meeting the CRGR preliminarily concluded that issuance of the proposed ISG would not impose any new staff position, any new requirement, or present a backfit. However, the CRGR did not endorse the proposed ISG pending staff reconsideration of certain aspects of the proposed ISG and its supporting documents.

Specifically, the CRGR found that the staff's reasoning behind its planned inspections was not clear and convincing. It appeared to the Committee that the inspection activity was unrelated to the proposed ISG and, therefore, should not be presented in the context of the ISG nor performed using the ISG. The CRGR requested that the staff reconsider this aspect of its presentation on the ISG. The CRGR also asked the staff to consider revisions to its proposed ISG to clarify that it would only be applicable to license renewals, new license applications, and new processes outside of a particular licensee's current licensing basis. The CRGR also asked the staff to consider revisions to the proposed ISG to enhance consistency throughout the document and to reflect the language and terminology of the applicable regulations.

In response to the Committee's requests, on February 19, 2016, and March 8, 2016, the staff provided to the CRGR its revised ISG (ADAMS Accession No. ML16056A301) and its revised discussion of regulatory, legal and policy implications related to the issuance of the final ISG (ADAMS Accession No. ML16056A308). The staff's significant changes to its discussion document included:

1. Added plain English regulatory basis and identified the scope of the NRC chemical safety charter.
2. Deleted information about the inspections that were discussed during the CRGR meeting, and clarified that, unrelated to the ISG, the staff is considering inspections for existing facilities to obtain additional information about the scope and nature of ISAs that address chemical safety. The ISG will not be used for these inspections. (The staff will address any inspection plans in its upcoming Commission paper.)
3. Removed redundant material about the regulatory requirements.

4. Clarified and improved the accuracy of its discussion about historical documents and events, e.g., information notices and correspondence with NEI.

The staff's significant changes to its proposed ISG included:

1. Consolidated information about the regulatory requirements that had been dispersed throughout the original ISG.
2. Removed language that could be interpreted to mean the ISG contained requirements.
3. Modified the technical material and discussion to improve clarity and accuracy.

The CRGR members reviewed the revised documents and concluded that the revisions addressed the questions and comments made by CRGR during its meeting with the staff. On the basis of its review of the materials the staff included with its review request of January 19, 2016, its consideration of the clarifying information the staff provided during CRGR Meeting 440, and its follow-up review of the revised ISG and supporting discussion paper provided on February 19, 2016, and March 8, 2016, respectively, the CRGR reaffirmed its conclusion that the proposed ISG would not impose a new staff position, any new requirements or a backfit. Furthermore, the CRGR endorsed the revised proposed ISG.

This memorandum documents the CRGR's final review and endorsement of the proposed ISG entitled "Guidance for the Evaluation of Acute Chemical Exposures and Quantitative Standards" (ADAMS Accession No. ML16056A301), and completes Committee action on the staff's request of January 19, 2016. The CRGR appreciated the time and effort the staff expended to complete the work needed to support the CRGR review, and was impressed by the quality and thoroughness of the staff's meeting presentation and follow-up.

Enclosure:  
CRGR Meeting No. 440  
List of Attendees

**CRGR MEETING No. 440**  
**LIST OF ATTENDEES**  
**(January 28, 2016)**

**CRGR Members**

K. Steven West, Chairman  
Brian J. McDermott, NSIR  
Joseph G. Giitter, NRR (for John W. Lubinski, NRR)  
Mark D. Lombard, NMSS (for Scott W. Moore, NMSS)  
Gary M. Holahan, NRO  
Edward L. Williamson, OGC  
David C. Lew, RI

Les R. Cupidon, CRGR Staff

**NRC Staff**

Joel T. Munday, NMSS  
Shana R. Helton, NMSS\FCSE  
Margie A. Kotzalas, NMSS\FCSE\PORSB  
Jonathan Marciano, NMSS\FCSE\PORSB  
Robert K. Johnson, NMSS\FCSE\FMB  
James E. Hammelman, NMSS\FCSE\FMB  
Marilyn Diaz, NMSS\FCSE\FMB  
Dennis R. Damon, NMSS\FCSE\PORSB  
Sabrina D. Atack, NMSS\FCSE\PORSB  
John T. Hull, OGC\GCLR\HLWFCNS  
Carrie M. Safford, OGC\GCLR\HLWFCNS  
Edwin M. Hackett, ACRS

Enclosure

**DISTRIBUTION:**

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Commissioner Ostendorff  
Commissioner Baran  
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Glenn M. Tracy, DEDM  
Robert J. Lewis, AO  
Edwin M. Hackett, ACRS  
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Joel T. Munday, NMSS  
Jennifer L. Uhle, NRO  
Gary M. Holahan, NRO  
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Marc Dapas, Region IV  
CRGR r/f

**ADAMS Accession No.: ML16032A047**

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DATE	03/25/16	02/11/16	03/25/16

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