

January 27, 2017

Ms. Janet R. Schlueter, Senior Director
Radiation and Materials Safety
Nuclear Energy Institute
1201 F Street NW, Suite 1100
Washington, DC 20004

SUBJECT: RESPONSE TO THE NUCLEAR ENERGY INSTITUTE'S REQUEST TO USE
NEI 14-14, "REGULATORY ISSUE RESOLUTION PROTOCOL," REGARDING
THE ISSUE ASSOCIATED WITH MEDICAL TREATMENT OF PERSONNEL AT
FUEL CYCLE FACILITIES

Dear Ms. Schlueter:

In accordance with Nuclear Energy Institute (NEI) 14-14, "Regulatory Issue Resolution Protocol, A Methodology for Resolving Regulatory Issues with Generic Implications for Fuel Cycle Facilities" (Agencywide Documents Access and Management System [ADAMS] Accession Number ML14337A168), the enclosed, "Issue Resolution Form" is provided to resolve the questions raised regarding the reporting of unplanned medical treatment of personnel as described in Title 10 of the *Code of Federal Regulations* (10 CFR) 40.60(b)(3) and 70.50(b)(3). This issue was raised by NEI, on behalf of its fuel cycle facility members, in 2015, through the NEI-14-14 process.

The path forward for the closure of this issue was discussed during our most recent public meeting held on October 12, 2016. A copy of that meeting summary can be found in the U.S. Nuclear Regulatory Commission's (NRC's) ADAMS under Accession Number ML16306A050. The path forward was also summarized in your letter to the NRC dated October 27, 2016 (ADAMS Accession Number ML16330A146).

Background

NEI 14-14 was endorsed by the NRC staff in a letter dated December 16, 2014 (ADAMS Accession Number ML14342A172) as a methodology for the NRC staff, NEI, and the fuel cycle industry to use in resolving generic regulatory issues.

By letter dated July 27, 2015 (ADAMS Accession Number ML15217A487), NEI, on behalf of its fuel cycle facility members, requested clarification of the NRC's reporting requirements contained in 10 CFR 40.60 and 70.50. NEI made this request to the NRC under the NEI 14-14 process. Specifically, NEI requested clarification of the 10 CFR 40.60(b)(3) and 70.50(b)(3) provisions for reporting the unplanned medical treatment of personnel with spreadable radioactive contamination on their clothing or body, and the provisions of 10 CFR 40.60(b)(1) and 70.50(b)(1) for reporting certain unplanned events involving the contamination of radiologically controlled areas occurring within a facility. By letter dated September 23, 2015 (ADAMS Accession Number ML15257A222), the NRC acknowledged the receipt of your July 27, 2015, letter.

Discussion

As you are aware, we are currently in Phase 2, "Screening," of the NEI 14-14 process. As described in NEI 14-14, during this phase, the potential generic regulatory issue is discussed to

ensure its full scope and impacts are described and documented, e.g., creation of a problem statement. The issue is then “screened” for acceptance by both organizations using the specific questions outlined in the screening criteria. Issues that do not meet the screening criteria would likely be dispositioned through an alternative course of action.

The staff position is the 10 CFR 40.60(b)(3) and 70.50(b)(3) reporting issues can be addressed through the existing NRC regulatory framework. To support the use of the existing framework to resolve these issues, the staff is providing additional guidance in the enclosed Appendix F, “Issue Closure Form,” entitled “Reporting of Medical Treatment of a Contaminated Individual.” This enclosure provides a proposed alternative course of action for resolving the 10 CFR 40.60(b)(3) and 70.50(b)(3) reporting issues.

Contamination Events

In your letter dated, October 27, 2016 (ADAMS Accession Number ML16330A146), you provided additional information for the NRC staff to consider in addressing a separate issue associated with contamination event reporting requirements in 10 CFR 40.60(b)(1) and 70.50(b)(1). This issue was also raised under the NEI-14-14 process. This topic will be addressed in a separate response, in accordance with the NEI-14-14 process.

Conclusion

The NRC staff notes that this was the first submittal under the NEI 14-14 process and recognizes the extensive time and effort associated with this request. As the initial submittal under NEI 14-14, all parties gained valuable insights about the protocol process. As discussed during the October 12, 2016, public meeting on the Cumulative Effects of Regulation (ADAMS Accession Number ML16306A050), the NRC recommends applying these lessons learned to inform future revisions of the NEI 14-14 protocol.

In accordance with 10 CFR 2.390 of the NRC’s “Agency Rules of Practice and Procedure,” a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC’s ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions, please contact Ms. Tilda Liu of my staff at (404) 997-4730, or via e-mail to Tilda.Liu@nrc.gov.

Sincerely,

/RA/

Craig G. Erlanger, Director
Division of Fuel Cycle Safety, Safeguards,
and Environmental Review
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Appendix F: Issue Closure Form

ensure its full scope and impacts are described and documented, e.g., creation of a problem statement. The issue is then “screened” for acceptance by both organizations using the specific questions outlined in the screening criteria. Issues that do not meet the screening criteria would likely be dispositioned through an alternative course of action.

The staff position is the 10 CFR 40.60(b)(3) and 70.50(b)(3) reporting issues can be addressed through the existing NRC regulatory framework. To support the use of the existing framework to resolve these issues, the staff is providing additional guidance in the enclosed Appendix F, “Issue Closure Form,” entitled “Reporting of Medical Treatment of a Contaminated Individual.” This enclosure provides a proposed alternative course of action for resolving the 10 CFR 40.60(b)(3) and 70.50(b)(3) reporting issues.

Contamination Events

In your letter dated, October 27, 2016 (ADAMS Accession Number ML16330A146), you provided additional information for the NRC staff to consider in addressing a separate issue associated with contamination event reporting requirements in 10 CFR 40.60(b)(1) and 70.50(b)(1). This issue was also raised under the NEI-14-14 process. This topic will be addressed in a separate response, in accordance with the NEI-14-14 process.

Conclusion

The NRC staff notes that this was the first submittal under the NEI 14-14 process and recognizes the extensive time and effort associated with this request. As the initial submittal under NEI 14-14, all parties gained valuable insights about the protocol process. As discussed during the October 12, 2016, public meeting on the Cumulative Effects of Regulation (ADAMS Accession Number ML16306A050), the NRC recommends applying these lessons learned to inform future revisions of the NEI 14-14 protocol.

In accordance with 10 CFR 2.390 of the NRC’s “Agency Rules of Practice and Procedure,” a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC’s ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions, please contact Ms. Tilda Liu of my staff at (404) 997-4730, or via e-mail to Tilda.Liu@nrc.gov.

Sincerely,

/RA/

Craig G. Erlanger, Director
 Division of Fuel Cycle Safety, Safeguards,
 and Environmental Review
 Office of Nuclear Material Safety
 and Safeguards

Enclosure:
 Appendix F: Issue Closure Form

DISTRIBUTION: KRamsey, NMSS APearson, NMSS BSmith, NMSS MBartlett, NMSS TNaquin, NMSS
 MLesser, R-II EMichel, R-II MSykes, R-II JBielecki, OGC CSafford, OGC RGibson, R-II
 MCrespo, R-II JRivera-Ortiz, R-II OLopez-Santiago, R-II

ADAMS Accession Package Number: ML16333A297 Letter: ML16064A053 * Via Email

OFC	FCSE/ERB	FCSE/ECB	FCSE/ECB	FCSE/PORSB	FCSE/FMB	OGC	FCSE
NAME	AWalker-Smith	TLiu *	MDiaz	MKotzalas *	RJohnson	JHull *	CErlanger
DATE	12/16/2016	1/18/2017	1/26/2017	1/24/2017	1/26/2017	1/18/2017	1/27/17