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August 8, 2016

Ms. Patricia Silva  
Chief, Inspections and Operations Branch  
Division of Spent Fuel Management  
Office of Nuclear Materials Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Subject:** Industry Summary of Meeting with the NRC Pertaining to NEI 12-04, *Guidelines for 10 CFR 72.48 Implementation*, Revision 0, Dated August 2012

**References:**

1. U.S. Nuclear Regulatory Commission letter *Final Response to the September 10, 2012 "Guidelines for 10 CFR 72.48 Implementation," Revision 0*, Patricia A. Silva to Rod McCullum, dated April 24, 2015 ML15110A197
2. U.S. Nuclear Regulatory Commission letter *2<sup>nd</sup> Interim Response to September 10, 2012 "Guidelines for 10 CFR 72.48 Implementation," Revision 0*, Patricia A. Silva to Rod McCullum, dated December 11, 2014 ML14349A402
3. U.S. Nuclear Regulatory Commission letter *Interim Response to September 10, 2012 "Guidelines for 10 CFR 72.48 Implementation," Revision 0*, Eric Benner to Rod McCullum, dated September 26, 2013, ML13260A030, ML13260A056, and ML13260A064

**Project Code: 689**

Dear Ms. Silva:

The 10 CFR Part 72.48 change control process provides an enforceable regulatory mechanism for U.S. Nuclear Regulatory Commission (NRC) to assure that industry appropriately evaluates the need for the NRC to review and approve certain proposed changes to the ISFSI or cask design or operation prior to implementation. The regulatory review performed pursuant to 10 CFR 72.48 is distinct from the activities performed under licensees' and CoC holders' quality assurance (QA) programs to ensure proposed changes ISFSI or cask design or operation are safe, effective and in compliance with all regulatory requirements. Hence, the 10 CFR 72.48 process is a vital element of an effective and efficient regulatory process—

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especially for a relatively low-risk activity such as dry cask storage where most detailed design and operational information should, most appropriately, be managed under licensee and CoC holder control.

The Nuclear Energy Institute (NEI)<sup>1</sup> appreciates the NRC staff's significant efforts and interactions with industry pertaining to its review of NEI 12-04, *Guidelines for 10 CFR 72.48 Implementation*, Revision 0, dated August 2012. This open and transparent dialogue has been highly beneficial towards establishing clear guidance on the implementation of an effective change control process per 10 CFR 72.48, an important element of a stable and predictable regulatory framework for dry cask storage. We have completed our summary of the discussions held with the staff during the most recent public meeting on March 3, 2016. The attachment to this letter provides the industry's synopsis of the discussion and path forward on the four fundamental issues that were discussed during that meeting. These four issues are considered fundamental because alignment between the NRC and industry on these issues is essential to proceed with the endorsement review of NEI 12-04 as a replacement for NEI 96-07, Appendix B.

In addition, as agreed upon in that meeting, we have included in the attachment clarification of seven additional key issues taken from References 1 through 3 on which we feel additional information provided now may address apparent NRC misunderstanding and eliminate future questions during the endorsement process.

We have distilled the NRC's three-part response to this proposed guidance (References 1 through 3) in an effort to address the basic difference of opinion between the industry and NRC staff as to the role of the QA program versus the 72.48 program and where the level of detail threshold for control (by either licensees and CoC holders or through NRC approval) should reside that we see as underlying most of the NRC's comments. Resolution of these 11 issues will allow the industry to address the NRC's comments in a clear and effective manner to support timely endorsement of NEI 12-04.

We request that the NRC review the attached information and provide a written response to each issue by no later than September 2, 2016, so that the industry can confirm alignment and move forward with a revision to NEI 12-04 that is consistent with these agreed-upon resolutions. Once we have submitted a revision to NEI 12-04 (expected two months after receipt of the NRC's response to this letter), we recommend that the NRC endorse a revised NEI 12-04 through a revision to Regulatory Guide 3.72. Upon endorsement by the NRC, NEI 12-04 would replace NEI 96-07, Appendix B. We would then remove Appendix B from NEI 96-07; however, no changes to the guidance in NEI 96-07 or its other appendices pertaining to 10 CFR 50.59 would be necessary. Until NEI 12-04 is endorsed by the NRC, NEI 96-07 Appendix B continues to remain an acceptable approach to meet 10 CFR 72.48.

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<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

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Please contact me at your earliest convenience regarding the scheduling of the proposed public meeting or if you have any additional questions regarding the industry's plans to complete the NEI 12-04 guidance.

Sincerely,

A handwritten signature in black ink, appearing to read "Rodney McCullum", written over a light gray rectangular background.

Rodney McCullum

c: Mr. Mark D. Lombard, NMSS/DSFM, NRC  
NRC Document Control Desk

Attachment: Industry-Proposed Resolutions to Key NRC Comments on NEI 12-04, *Guidelines for Implementation of 10 CFR 72.48*