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May 29, 2015

Ms. Patricia A. 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 Plans to Respond to NRC's Final Response to the September 10, 2012, NEI Submittal of 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 Nuclear Energy Institute (NEI)<sup>1</sup> appreciates the completion of U.S. Nuclear Regulatory Commission (NRC) staff's review of NEI 12-04, *Guidelines for 10 CFR 72.48 Implementation*, Revision 0, dated August

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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.

2012. Clear guidance on the implementation of an effective change control process per 10 CFR 72.48 is an important element of a stable and predictable regulatory framework for dry cask storage. We are reviewing the NRC's final response, along with both previous interim responses to this submittal and intend to address all comments. However, before we address these comments, we would like to request a public meeting to discuss an important and unresolved issue: the question of what level of detail of information should be included in dry storage system licenses and Certificates of Compliance (CoCs) versus what level of information should be included in Safety Analysis Reports (SARs) and other documents that are under licensee and CoC holder control.

The industry believes that this unresolved issue stems from confusion between the role of the 10 CFR Part 72.48 change control process and the role of licensee/CoC holder quality assurance programs. The 10 CFR Part 72.48 change control process provides an enforceable regulatory mechanism to evaluate the need for prior NRC approval of certain proposed changes to the ISFSI or cask design or operation. The regulatory review performed pursuant to 10 CFR 72.48 is distinct from the activities performed under licensees' and CoC holders' Quality Assurance programs to ensure proposed changes ISFSI or cask design or operation are safe, effective and in compliance with all regulatory requirements. The 10 CFR 72.48 process is a vital element of an effective and efficient regulatory process—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. However, this process does not supplant the processes that actually control the information and assure safety. Yet, it continues to be evident, in the NRC's three-part response to this proposed guidance as well as in other public interactions, that a fundamental difference of opinion exists 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.

The industry believes that this fundamental difference of opinion must be resolved before the 10 CFR Part 72 change control process can be effectively implemented, regardless of what guidance is in place. The industry has submitted a Petition for Rulemaking (PRM 72-7) seeking to establish, by rule, criteria that would better define where the threshold at which NRC approval of dry cask storage information is required. We also understand and appreciate that the NRC is looking at this same question as part of the staff's initiative to risk-inform the Part 72 regulations (as discussed in the January 15, 2015, public meeting between the NRC and the industry). Our purpose in requesting a public meeting is to assure that both the industry and NRC staff have a common understanding of threshold issue before finalizing this proposed guidance.

Once we have reached such an understanding and the industry has resolved all of the NRC's comments (as provided in the three references 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-

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04 is endorsed by the NRC, NEI 96-07 Appendix B continues to remain an acceptable approach to meet 10 CFR 72.48.

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 "Rod McCullum", written over a light gray rectangular background.

Rod McCullum

c: Mr. Mark D. Lombard, NMSS/DSFST, NRC  
Ms. Catherine Haney, NMSS, NRC  
NRC Document Control Desk