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March 5, 2018

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

Subject: Transmittal of NEI 12-04, Revision 1, "Guidelines for 10 CFR 72.48 Implementation"

Project Number: 689

References:

1. Nuclear Energy Institute letter *Transmittal of NEI 12-04, Revision 1, Draft A, "Guidelines for 10 CFR 72.48 Implementation,"* Kristopher Cummings to Patricia Silva, dated September 5, 2017, ML17249A095, ML17249A094
2. U.S. Nuclear Regulatory Commission letter *U.S. Nuclear Regulatory Commission Comments on Nuclear Energy Institute Submittal: NEI 12-04 "Guidelines for Title 10 of the Code of Federal Regulations 72.48 Implementation," Revision 1, Draft A,* Patricia A. Silva to Rodney McCullum, dated November 30th, 2017, ML17335A028, ML17335A029
3. Nuclear Energy Institute letter *Industry Summary of Meeting with the NRC Pertaining to NEI 12-04, "Guidelines for 10 CFR 72.48 Implementation," Revision 0, Dated August, 2012,* Rod McCullum to Patricia Silva, dated August 8, 2016, ML16251A025, ML16251A028

Dear Ms. Silva:

On behalf of our members, the Nuclear Energy Institute (NEI)¹ is transmitting to the U.S. Nuclear Regulatory Commission (NRC) Revision 1 to NEI 12-04, "Guidelines for 10 CFR 72.48 Implementation." Revision 1

¹ The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

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completely supersedes Revision 1, Draft A (Reference 1). NEI 12-04 Revision 1 addresses comments identified by the NRC in their November 30, 2017 letter (Reference 2) and during a series of public meetings (Reference 3). Also enclosed is a separate table with resolutions to each of the numbered NRC comments in Reference 2.

We thank NRC for the extensive, open, and transparent dialogue which has informed this guidance – and resulted in a common understanding of how the 10 CFR 72.48 change control process can be most effectively implemented. We recommend that the NRC endorse Revision 1 to NEI 12-04 through a revision to Regulatory Guide 3.72. NEI does not seek endorsement of the examples in Appendices A and B or Reference 6.8.3 in the guidance.

The 10 CFR 72.48 change control process provides an enforceable regulatory mechanism for the 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 to the 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 – especially for an activity such as dry cask storage where there is a considerable amount of detailed design and operational information that does not affect public health and safety which should, most appropriately, be managed under licensee and CoC holder control.

Thank you for your time and attention on this important matter. If you have any questions, please contact me.

Sincerely,



Rodney McCullum

Enclosures

c: Mr. Raynard Wharton, NMSS/DSFM/IOB, NRC
Mr. Antony Hsia, NMSS/DSFM, NRC
Mr. Michael Layton, NMSS/DSFM, NRC
Mr. Marc Dapas, NMSS, NRC
Mr. Scott Moore, NMSS, NRC
NRC Document Control Desk