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September 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 2, "Guidelines for 10 CFR 72.48 Implementation"

Project Number: 689

References:

1. Nuclear Energy Institute letter *Transmittal of NEI 12-04, Revision 1, "Guidelines for 10 CFR 72.48 Implementation,"* Rodney McCullum to Patricia Silva, dated March 5, 2018, ML18068A607
2. Nuclear Regulatory Commission letter *U.S. Nuclear Regulatory Commission Comments On Nuclear Energy Institute 12-04 "Guidelines For Title 10 Of The Code Of Federal Regulations 72.48 Implementation," Revision 1,* Patricia Silva to Rodney McCullum, dated August 22, 2018, ML18218A188

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 2 to NEI 12-04, "Guidelines for 10 CFR 72.48 Implementation." Revision 2 addresses Issues 1 and 3 identified in Reference 2 and is otherwise identical to Revision 1. Accordingly, Revision 2 completely supersedes Revision 1 and should be used as the basis for the Draft Regulatory Guide endorsing NEI 12-04 that was described in Reference 2. We look forward to the opportunity to review NRC's regulatory position on Issue 2 during the public comment period on the Draft Regulatory Guide.

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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We remain appreciative of NRC's engagement in 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 to provide 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 continued 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
Ms. Aida Rivera-Varona, NMSS/DSFM, NRC
Mr. Michael Layton, NMSS/DSFM, NRC
Mr. Marc Dapas, NMSS, NRC
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