



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

February 6, 2020

Mr. Rodney McCullum  
Senior Director, Fuel and Decommissioning  
Nuclear Energy Institute  
1201 F Street NW, Suite 1100  
Washington, DC 20004

SUBJECT: STATUS REPORT ON THE U.S. NUCLEAR REGULATORY COMMISSION'S  
ENDORSEMENT OF REVISION 2 TO NUCLEAR ENERGY INSTITUTE 12-04,  
"GUIDELINES FOR TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS*  
72.48 IMPLEMENTATION," DATED SEPTEMBER 2018

Dear Mr. McCullum:

In your letter dated September 5, 2018 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML18250A256) the Nuclear Energy Institute (NEI) submitted the latest revision to NEI 12-04 "Guidelines for 10 CFR 72.48 Implementation," for the U.S. Nuclear Regulatory Commission (NRC) staff review and endorsement through the Regulatory Guide (RG) process. NEI 12-04 provides guidance for implementation of a change control process in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 72.48, and contains revisions to the current guidance contained in NEI 96-07 Appendix B, "Guidelines for 10 CFR 72.48 Implementation," dated March 2001 (ADAMS Accession No. ML 010670023), which is at this time endorsed by the NRC through RG 3.72 "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments."

The NRC staff is reviewing NEI 12-04 for endorsement. The NRC staff plans to document its endorsement in a future revision of Regulatory Guide 3.72, including any exceptions from the guidance that the NRC may take. Currently, the NRC staff has identified no major issues with the guidance. The NRC staff has identified a potential clarification and two exceptions to certain statements in NEI 12-04 noted in the enclosure, which are not final agency positions and will be considered further in the public comment process during development of the Regulatory Guide.

If you have any questions, please contact Mr. Marlene Davis at 301-415-7447 or  
[Marlene.Davis@nrc.gov](mailto:Marlene.Davis@nrc.gov).

Sincerely,

/RA/

Andrea L. Kock, Director  
Division of Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:  
Potential Clarification and Exceptions to  
Certain Statements in NEI 12-04, Revision 2

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<b>DATE</b>	01/28/2020	1/28/2020	1/28/2020	2/6/2020

## Potential Clarification and Exceptions to Certain Statements in NEI 12-04, Revision 2

1. NEI 12-04, Section 6.8, provides the following as one of several examples of changes that “are not considered departures from a method of evaluation:”

Use of a methodology revision that is documented as providing results that are essentially the same as or more conservative than either the previous revision of the same methodology or with another methodology previously accepted by the U.S. Nuclear Regulatory Commission (NRC) through issuance of a safety evaluation report (SER).

The regulation allows licensees to document a methodology revision either: (1) as a change to any of the elements of the methodology described in the final safety analysis report (FSAR) (as updated) (i.e., paragraph 72.48(a)(2)(i) of the departure definition), or (2) as a change from the methodology described in the FSAR (as updated) to another method (i.e., paragraph of the 10 CFR 72.48(a)(2)(ii) departure definition). The NRC staff’s current view is that if a methodology revision is documented as a change from the methodology described in the FSAR to another method using paragraph 10 CFR 72.48(a)(2)(ii) of the departure definition, then paragraph 10 CFR 72.48(a)(2)(i) of the departure definition (i.e., “the results of the analysis are conservative or essentially the same”) is not applicable.

2. NEI 12-04, Section 6.8.1, “Guidance for Changing One or More Elements of a Method of Evaluation (MOE)”

Regarding the use of uncertainty in evaluation methods, NEI 12-04, Revision 2, Section 6.8.1, has language to address the use of uncertainty as an element of a method when documenting a change under 10 CFR 72.48. The statement limits the analysis of uncertainty to being considered as an element only if it is addressed in a (method of evaluation (MOE)). The NRC staff’s current view is that every MOE has an uncertainty associated with it, and therefore, uncertainty should be considered every time, even if it is not addressed in the MOE.

3. Guidance for FSAR Supplements for License Renewal

The NRC staff is considering clarifying that the guidance of NEI 12-04 is applicable to information added to the FSAR for summary descriptions of the programs, activities for managing the effects of aging, and the evaluation of time-limited aging analyses that will support the bases for specific independent spent fuel storage installation license renewal.