

Response to NEI Letter from McCullum to Silva, August 8, 2016, Industry-Proposed Resolutions to Fundamental and Key Issues on NEI 12-04, “Guidelines for Implementation of 10 CFR 72.48,” Revision 0

Issue No. 1

Implementation is defined in NEI 12-04, Section 3.14, “Implementation of 72.48 Authorized Activity,” (at page 25). The NRC recommended revision of the definition of the term “implementation” in response to input from licensee and certificate of compliance (CoC) holder inspections in the NRC’s 1st Interim Response, page 2, 7th paragraph (Agencywide Document Access Management System (ADAMS) Accession Package No. ML13260A029) dated September 26, 2013. NEI’s reply (ADAMS Accession Package No. ML16251A024) dated August 8, 2016, included Attachment: Industry-Proposed Resolutions to Key NRC Comments on NEI 12-04, Guidelines for Implementation of 10 CFR 72.48 at page 4 (ADAMS Accession No ML16251A028). In its Industry-Proposed Resolutions, NEI agreed to revise the definition of “implementation of an activity” in NEI 12-04 by explaining how the term applies differently to a general and specific licensee and to a CoC holder.

The staff reviewed NEI’s reply and agrees with industry’s proposal to revise the definition of ‘implementation’ and address the staff comment on the definition and use of implementation. To help clarify the definition, the NRC supports NEI’s proposal to include examples of the types of changes expected to be implemented by CoC holders and licensees in NEI 12-04, Section 3.14. In addition, NEI will provide supplemental recommendations to help enhance NEI 12-04.

NEI’s August 8th attachment, “Licensee 72.48 Changes,” at page 4, 2nd paragraph (ML16251A028) states that “a procedural change or change to a method of evaluation (MOE) may be considered implemented upon approval of the 72.48 review and procedural approval documentation.” (Emphasis added.) The staff viewpoint is that when a change is implemented it is objective. The sentence should read “a procedural change or change to a method of evaluation (MOE) is considered implemented upon approval of the 72.48 review and procedural approval documentation.” The staff anticipates NEI’s proposed revisions and proposal to add examples to the guidance will resolve the staff’s concerns.

Issue No. 2

NEI 12-04, Section 3.4, “Adoption” (at page 16) states that a “general licensee can adopt a generic activity without performing a separate 72.48 review.” NEI 12-04, Section 4.7, “Cask Design Modifications Made by the CoC Holder and Adopted by a General Licensee” (at page 36) refers to the NRC’s Final rule which authorizes nuclear reactors, and independent spent fuel storage facilities, and certificate holders for spent fuel storage casks, to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. (See 64 FR 53582, 53601.)

The Commission stated in the statements of consideration (SOC) for the Final rule the obligations of a general licensee when it adopts a 72.48 change undertaken by a CoC holder (See 64 FR 53582, 53601, October 4, 1999 at Section O.1). Section O.1 of the SOC states:

The Commission envisioned that a general licensee who wants to adopt a change to the design of a spent fuel storage cask it possesses - which change was previously made to the generic design by the certificate holder under the provisions of Sec. 72.48 - *would be required to perform a separate evaluation under the provisions of Sec. 72.48 to determine the suitability of the change for itself.* (Emphasis added.)

In NRC's 1st Interim Response, page 1, 4th paragraph (ML13260A030) and comment number 14 in the NRC's 2nd Interim Response, Enclosure 2 "Redline Strike-out Version of NEI 12-04" (ADAMS Accession No. ML14349A406), dated December 11, 2014, the staff stated that NEI 12-04, Section 3.4 is inconsistent with Section O.1 of the SOC. NEI was asked to explain why a licensee should be permitted to adopt a generic activity without performing a separate 72.48 review, given the Commission's SOC on this issue.

NEI has proposed adding a three-part categorization to NEI-12-04 for general licensees to use to developing or modifying plant processes when reviewing and addressing CoC holder changes. NEI has also proposed adding a flow chart (slide 16) (ML16090A0520), similar to the one presented at the NRC public meeting conducted on March 3, 2016, for general licenses processing CoC holder 72.48 changes. The staff finds the addition of the three-part categorization and the proposal to add a flow chart should address the staff's concerns on Issue 2 because it provides the process and categories of changes that apply to general licensees.

Issue No. 3

The staff noted that NEI 12-04, Section 1.2, "Defense-In-Depth Design Philosophy and 10 CFR 72.48," (at page 2) and in Section 2.2.2, "Quality Assurance Program (QAP) and 72.48," (at page 14) (ML14349A406) deleted certain portions of NEI 96-07, Appendix B without explanation. Section 1.2 no longer lists maintaining retrievability of stored radioactive materials as one of the basic nuclear safety criteria for the design of an ISFSI. Section 1.2 now states that 10 CFR Part 72 contains other requirements, such as retrievability, that while not safety functions, must still be performed for regulatory compliance." The staff requested that NEI justify the omissions.

In the March 3, 2016, public meeting (ML16104A021), the NRC stated its comment on Section 1.2 was not meant to challenge the previously-endorsed definition of "consequences," but intended to point out that dose consequences could be caused by conditions other than a loss of the cask confinement boundary. NEI proposes to acknowledge that consequences of offsite doses may be due to a loss of confinement event. The staff finds that changes consistent with NEI's proposal would resolve the staff's concerns because it would acknowledge that offsite dose consequences can exist from sources other than a loss of containment.

The NRC also commented on a statement in Section 2.2.2 concerning the QAP design control process ensuring that a change is safe and in compliance with NRC's regulations. The staff pointed out that flawed evaluations and poor engineering judgement can still compromise safety.

The staff does not agree with a statement in NEI 12-04, Section 2.2.2, that "implementation of the QAP design control process ensures the change is safe and in compliance with regulatory

requirements.” The QAP alone will not ensure that the design is safe – there are engineering judgments and assumptions that go into a design, and just because a design change went through the QA process doesn’t mean it will prevent decisions/determinations that are based on incorrect assumptions. The staff believes NEI 12-04 should be revised to avoid categorical statements equating the QAP with safety of the modification. The NRC staff suggests substituting the following language: “implementation of the QA program design control process should ensure that the change is safe and in compliance with regulatory requirements.” The use of this language would resolve the staff’s concerns.

Issue Number 4

The NRC published the final rule for 10 CFR 72.48 on October 4, 1999 (64 FR 53582). The Commission discussed the factors the staff would consider in the approval of a method of evaluation in its statements of consideration (SOCs) (64 FR 53582, 53598).

Approval for intended application includes assuring that the approved method was approved for the type of analysis being conducted, **generically approved** for the type of facility using it, and that all terms and conditions for use of the method are satisfied. (64 FR 53582, 53598).

In its December 11, 2014, response to NEI on this issue, the staff explained that to determine whether a MOE is “approved by the NRC for the intended application” licensees and CoC holders need to consider the three criteria identified in the SOCs (2nd Interim Response, Enclosure 1, “NRC Staff Position on Method of Evaluation Approval,” dated December 11, 2014 at page 2 (ML14349A404).

The SOCs further state that the rule words were chosen to allow only a small degree of flexibility regarding methods. It states:

The rule requirements for evaluation methods would allow for use of generic topical reports as not being a “departure,” provided that the topical report is applicable to the facility and is used within the terms and conditions specified in the approved topical report. (64 FR 53582, 53599).

The staff’s December 11, 2014, response also explained that a topical report provides for or enables generic approval for an MOE under specific, restrictive circumstances: when (1) a licensee or CoC holder formally requests generic approval by submitting a topical report to the NRC; and (2) the NRC approves the generic use of an MOE by issuing a regulatory guide that documents approval of the MOE. (Enclosure 1, NRC Staff Position on Method of Evaluation Approval at page 2). The use of the MOE by any licensee or CoC holder is restricted to circumstances identified in the terms and conditions specified in the approved topical report.

NEI asserts that the SOCs do not explicitly limit “generic approval” to topical reports only (ML162151A028). The staff agrees there is no explicit limitation in the rule or the SOCs. However, another mechanism would be needed to provide the information to the staff so the staff can determine if that information can be evaluated and generically approved as is done in the topical report process. Approval of a topical report constitutes a generic approval of the MOEs discussed in the topical report. If the approved topical report is applicable to the facility and the type of analysis to be performed and use of the MOE would comply with the terms and conditions specified in the regulatory guide approving the MOE, then use of the MOE is not a

“departure” and the MOE may be used without obtaining a license or CoC amendment under 10 FR 72.48. (64 FR 53582, 53599; Enclosure 1, NRC Staff Position on Method of Evaluation Approval at page 2.

The current revision of NEI 96-07, Appendix B, Section B.4.3.8.2 and the draft NEI 12-04, Section 6.8, reflect the Commission’s position on MOE approval as it applies to 10 CFR 72.48:

It should be noted that the **NRC staff**, in reviewing dry cask storage designs, **historically has not generically approved methodologies referenced in FSARs for use by other licensees or vendors.** Instead it has made statements in its SERs, following the guidance in the Standard Review Plan that the design has been found to be acceptable in each review discipline area. **If, however, vendors or licensees choose to submit methodologies to the NRC for generic review and approval as part of applications for design approval or as separate topical reports, the staff will document NRC endorsement or approval in appropriate SERs.** Such endorsements or approval will facilitate vendors and licensees to use the 10 CFR 72.48 process that deals with approved methodologies. (Emphasis added).

The NRC’s practice regarding approvals of MOEs under 10 CFR Part 72 has been consistent since the Commission spoke on the matter in 1999. The staff does not generically approve MOEs that are referenced or described in cask or ISFSI FSARs. (64 FR 53582, 53598-99; Enclosure 1, NRC Staff Position on Method of Evaluation Approval). 10 CFR 72.48(c)(2)(viii) requires that a licensee or CoC holder obtain a license or CoC amendment prior to implementing a proposed change that would result in a departure from a MOE described in the FSAR, when the MOE is used in establishing the design bases or in the safety analyses. The Commission intended to limit changes that can be made to MOEs in FSARs. (64 FR 53582, 53598).

A departure from a MOE (as this phrase is used in the 10 CFR 72.48(c)(2)(viii) criterion) is defined in 10 CFR 72.48(a)(2) to mean: (i) changes to any of the elements of the MOE described in the FSAR, unless the analysis results are “conservative or essentially the same;” or (ii) any change from a MOE described in the FSAR to another MOE unless the new MOE “has been approved by NRC for the intended application.” (Enclosure 1, NRC Staff Position on Method of Evaluation Approval; 64 FR 53582, 53598).

The staff’s findings in SERs for licensing actions evaluate the acceptability of the design (or design changes, in the case of amendments) in each review discipline. This practice is consistent with the Commission’s statement in response to a petition for rulemaking (PRM 72- 3) that the “NRC SER contains staff conclusions on the adequacy of the cask design.” (64 FR 53582, 53605). Thus, the SER only contains the staff’s conclusions that a cask (or an ISFSI) design meets the regulations and how the staff arrived at those conclusions.

These staff conclusions regarding the adequacy of the cask or ISFSI design may be based, in part, on the staff finding a MOE in the FSAR sufficient to demonstrate that the cask or ISFSI design under review performs the required functions and meets the regulations. The staff may discuss the relevant MOE(s) in the basis of the staff’s conclusions. However, this may not always be the case. In situations where the staff findings do not rely on an MOE, there may be no discussion of the MOE in the SER.

The staff recognizes that the text cited above from NEI 96-07, Appendix B, and draft NEI 12-04 indicates the possibility of NRC generic review and approval of MOEs that are submitted as part of design approval applications. However, this type of request has not been part of any ISFSI license, cask certificate, or amendment application. Additionally, the current DSFM staff guidance and practice is not adequate to address such requests, reviews, and approvals for MOEs. To facilitate such requests and approvals in the future would require potentially significant efforts to modify internal staff guidance and practice.

Therefore, based on current and historical NRC practice as recognized in the industry guidance and identified in the SOCs, MOEs described in FSARs do not meet the generically approved criterion for being "approved for the intended application" (NEI 96-07; 64 FR 53582, 53598-99; Enclosure 1, NRC Staff Position on Method of Evaluation Approval). NEI raised the San Onofre Nuclear Generating Station (SONGS) replacement steam generators as an example of a MOE approval. The DSFM staff finds the SONGS example of a MOE approval is not consistent with the implementation guidance for 10 CFR 72.48(c)(2)(viii) in the SOCs (64 FR 53582, 53598), in Enclosure 1, NRC Staff Position on Method of Evaluation Approval, or in NEI 96-07, Appendix B.. The use of MOEs under Part 72 would only be considered acceptable by the NRC if that MOE was requested to be generically approved when the NRC approved the licensing action (license, CoC, amendment) in which the MOE was used. The SER for that licensing action would clearly state that the MOE was generically approved and describe: (1) the type of analysis for which the MOE is approved, (2) the type of facilities (e.g., types of storage cask designs) for which the MOE is approved, and (3) the terms and conditions of use of the MOE.

Clear guidance on when prior NRC approval of an MOE is required under 10 CFR 72.48(c)(2)(viii) is needed to resolve NRC inspection concerns with 72.48 evaluations which rely on the MOE criterion, Criterion 72.48(c)(2)(viii). The staff expects the proposed revision of NEI 12-04 will be consistent with the Commission's statements on MOE approval published in the final rule for 10 CFR 72.48 and will reflect the staff's viewpoints submitted in Enclosure 1, "NRC Staff Position on Method of Evaluation Approval," (ML14349A404).

Issue No. 5

This issue addresses the use of the word "change" as discussed in NRC's 1st Interim Response, page 1, 3rd paragraph (ML13260A029). The regulations at 10 CFR 72.48(a)(1) state:

"Change means a modification or addition to, or removal from, the facility or spent fuel storage cask design or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished." The staff originally stated that providing guidance on the definition of "change" would introduce ambiguity.

The staff identified several places in the proposed guidance (NEI 12-04) where the language differs from the existing guidance (NEI 96-07, Appendix B). Notably, NEI substituted the word "change" for the words "modification" and "proposed activity" without explaining the revisions. The NRC's 1st Interim Response, Enclosures 1 (ML13260A056) and 2 (ML13260A064) provided comments on NEI 12-04 Sections 4.6, "Modifications to Written Evaluations Required by 10 CFR 72.48" (at page 35); 4.7, "Cask Design Modifications Made By a CoC Holder and Adopted By a General Licensee" (pages 35 and 36); and 5.1.2, "Screening for Adverse Effect" (at pages 41 and 42).

The staff reviewed NEI's reply (ML16251A024) and now agrees that language to clarify the difference between a proposed activity and a change should be added to NEI 12-04. Differentiating "*proposed activities*" that do not have an adverse effect from "*changes*" that have an adverse effect [ON WHAT? safety] is useful. The staff favors using the term "proposed activities" for items that do not require a full 10 CFR 72.48 evaluation, rather than the term "changes". The staff agrees with NEI that providing guidance on the definition of "change" that uses these distinctions will clarify when an evaluation under 10 CFR 72.48(a)(1) is required. Inclusion of NEI's proposed language should resolve or address the staff comments in NRC's 1st Interim Response.

Issue No. 6

In the NRC's 1st Interim Response, Enclosure 1, "Selected NRC Staff Edits on NEI 12-04, 'Guidelines for 10 CFR 72.48 Implementation,' Revision 0 (Marked-up Copy)," at page 2, Section 2.1.5.1, 2nd paragraph (ML13260A056), the staff requested the deletion of text stating that licensees should process required changes to site-specific documents in accordance with their own change management programs. The staff reviewed NEI's reply (ML16251A024) and withdraws the comment.

The staff finds the language "their own change management programs" is acceptable because the statement is accurate. The staff supports NEI's proposal to add examples of licensee change management programs to NEI 12-04, Section 2.1.5.1, "Licensee Actions Upon Receiving CoC Holder-Authored Changes," at pages 10 and 11, and/or 2.1.5.3, "General Licensee Use of CoC Holder-Generated Modifications," (at page 11) because it should provide clarification. NEI's proposed changes to NEI 12-04 are expected to resolve the staff's concerns.

Issue No. 7

The staff commented on NEI 12-04 in the NRC 1st Interim Response, Enclosure 1, at page 3, Sections 2.1.5.3 (ML13260A056). The staff proposed adding the paragraph below to NEI 12-04, Section 2.1.5.3, "General Licensee Use if CoC Holder-Generated Modifications," at page 11:

A general licensee reviews the CoC holder changes made pursuant to 10 CFR 72.48 for applicability to its site and to determine whether any of the changes should be adopted at its site. Licensees are limited in their ability to incorporate changes to the cask design after the cask is loaded with spent fuel and placed in storage. Accordingly, for casks that are already loaded, the licensee only needs to review the CoC holder's changes for applicability to their plant/ISFSI and for impact on the site-specific evaluations and analyses, the 212 Report, and site programs and procedures.

NEI agreed to include this language in NEI 12-04, Section 2.1.5.3.

The staff proposed adding similar language to NEI 12-04, Section 2.1.5.4, "Site-Specific Licensee Use of CoC Holder-Generated Modifications," at pages 11 and 12. See the NRC's 1st Interim Response, Enclosure 1, at page 3 (ML13260A056). NEI argued in its response that specific licensees are not required to perform independent 10 CFR 72.48 reviews or evaluations or screenings of generic changes to cask designs made by a CoC holder, unless the certified cask design is incorporated explicitly into the specific licensee licensing basis (ML16251A024).

In this situation, a change made to a certified cask design in effect modifies the licensing basis of a cask, therefore, a specific licensee is required to 10 CFR 72.48 screenings/evaluations. The staff withdraws the proposed language because its concerns have been addressed. The staff finds this issue resolved.

Issue No. 8

The NRC staff proposed revisions to NEI 12-04, Section 2.1.5.5, “CoC Holder Actions Upon Receipt of Licensee-Generated Modifications,” at page 12. The NRC’s 1st Interim Response, Enclosure 1, at page 4, proposed modifying the recommended actions to be conducted by CoC holders upon receipt of licensee-approved 72.48 changes to a cask design (ML13260A056). NEI’s responded that the 10 CFR 72.48 process is for a CoC holder or licensee to determine if NRC approval is required before a cask design change is implemented. NEI states further, that the CoC holder may use whatever process it deems appropriate to determine if a licensee-initiated 10 CFR 72.48 modification to a cask design affects the cask design as described in the cask UFSAR. See Attachment: Industry-Proposed Resolutions to Key NRC Comments on NEI 12-04, Guidelines for Implementation of 10 CFR 72.48 at pages 15-16 (ML16251A028).

The staff accepts that when a CoC holder receives a record documenting a cask design change from a licensee, they should review the record in a timely manner (e.g., within 60 days of receipt) to determine if the change should be adopted for generic use. If the change is to be adopted for generic use, the certificate holder would review the cask UFSAR to determine if a modification to the UFSAR and a 10 CFR 72.48 screening/evaluation are required. The answers/justification used in the CoC holder’s 10 CFR 72.48 screening/evaluation may rely on or use the licensee’s 72.48 screening/evaluation, to the extent applicable. A cask design modification that has been reported to the CoC holder by a general or specific licensee and then adopted by the CoC holder would need to be reported back to all licensees using that cask design in the 60-day report. The staff withdraws the comment regarding which process must be used by a CoC holder for incorporating a licensee-generated modification.

Issue No. 9

The NRC staff proposed changes to NEI 12-04, Section 2.1.3.1, “Introduction” (at pages 7-8) and identified in the NRC’s 2nd Interim Response, (paragraph 3 of the cover letter) (ML14349A402) and Enclosure 2, “Redline Strike-out Version of NEI 12-04, ‘Guidelines for 10 CFR 72.48 Implementation,’ Revision 0 Including Marginal Comment,” Section 2.1.3.1, (at pages 8-9) (ML14349A406).

The staff decided that the eight criteria should always apply. A major point considered was that most MOE changes also involve changes that should be reviewed against the other seven criteria. NEI 96-07, Appendix B, Section B4.2.1.3, 1st paragraph, states that changes to MOEs (only) do not require evaluation against the first seven criteria. The staff agrees with NEI that 10 CFR 72.48(c)(2)(viii) applies to proposed activities involving MOEs. However, the staff points out that NEI should provide examples of situations where CoC holders and licensees should evaluate against only criterion viii (for MOEs only) and the other seven criteria (for the remainder of the modification or change).

The staff agrees with NEI (ML16251A028) that the current language in NEI 12-04 regarding the seven criteria versus the eighth criterion should be retained. The NRC staff supports NEI’s proposal to clarify how changes that involve both a modification to a cask or ISFSI design and a

MOE change should be treated. See NRC's 2nd Interim Response (ML14349A402) and "Industry-Proposed Resolutions" at page 17. The staff anticipates being able to close this issue, once NEI provides the NRC with clarifying language, as proposed.

Issue No. 10

NEI 12-04, Section 2.1.3.2, "Documenting 10 CFR 72.48 Evaluation," at page 8-9- states that "licensees may elect to use screening criteria to determine for which activities a full 10 CFR 72.48 evaluations should be performed." Furthermore, the proposed guidance states that licensees should document the bases for determinations that find changes meet the screening criteria, i.e., screen out. However, the proposed guidance goes on to state that such "documentation does not constitute the record of changes required by 10 CFR 72.48, and thus is not subject to the recordkeeping requirements of the rule." See NEI 12-04 at page 9. The NRC objected to this position and argued that it did not meet 10 CFR 72.48(d) in the NRC's 2nd Interim Response, Enclosure 2, Section 2.1.3.2 at page 10 (ML14349A406). NEI pointed out that design modifications, procedure revisions and similar activities that are screened out do not constitute a "change" as defined in 10 CFR 72.48(a)(1). See Attachment: Industry-Proposed Resolutions to Key NRC Comments on NEI 12-04, Guidelines for Implementation of 10 CFR 72.48 at page 18 (ML16251A028). The staff reviewed NEI's "Industry-Proposed Resolutions" (ML16251A028 at page 18) and agrees the activities, when screened out do not constitute changes subject to the recordkeeping requirements of 10 CFR 72.48(d) and do not need to be documented. In addition, the staff acknowledges the proposed language of NEI 12- 4, Section 2.1.3.2 recommends that documentation of proposed activities be maintained as quality assurance records. For these reasons, the staff withdraws its objections and considers Issue 10 resolved.

Issue No. 11

NEI 12-04, Section 2.1.4.1, "Reporting Changes via 72.48 Evaluations to CoC Holders and Licensees," at page 9 states:

It is recommended that CoC holders provide the documentation for all approved cask UFSAR and design changes to their users within 60 days of implementation, whether or not a full 72.48 evaluation was required for the change. This ensures that all users have a complete UFSAR, including interim changes, between formal UFSAR revisions.

The staff asked NEI whether the proposed revision of the guidance applies to changes that were made or implemented by CoC holders and licensees, but that were screened out in a 72.48 evaluation. See NRC's 2nd Interim Response, Enclosure 2, Section 2.1.4.1 at page 10 (ML14349A406).

The NRC asked NEI "to clarify whether licensees would also need to provide this information to the CoC holder per 72.48(d)(6)(i) and (ii)." (ML14349A406 at page 10). NEI acknowledges that the proposed guidance does not clearly recommend that licensees share the record of cask design modifications with the CoC holder. See Attachment: Industry-Proposed Resolutions to Key NRC Comments on NEI 12-04, Guidelines for Implementation of 10 CFR 72.48 at page 19 (ML16251A028).

In the "Industry-Proposed Resolutions," NEI proposed to revise the guidance to state that licensees are to share the record of cask design modifications made under 10 CFR 72.48 with the CoC holder, whether or not a full 72.48 evaluation was required. NEI suggests that UFSAR text, table, and figure revisions for casks made by the licensee, will be shared with the CoC holder based on the nature of the revisions. NEI proposed to further clarify recommended actions explaining that potentially generic cask UFSAR text, table, and figure revisions made by the licensees that do not involve a change to the cask design should be shared with the CoC holder. And NEI stated that site-specific UFSAR revisions made by licensees do not need to be made by the CoC holder in the cask UFSAR.

The staff reviewed NEI's reply and finds that NEI's proposed framework to revise the guidance addresses its concerns. Once NEI submits its revision for the NRC staff review, the staff will review the proposed text for adequacy.