

Attachment to NEI Letter from McCullum to Silva, August 8, 2016  
Industry-Proposed Resolutions to Key NRC Comments on NEI 12-04,  
*Guidelines for Implementation of 10 CFR 72.48*

On March 3, 2016, the NRC hosted a public meeting with the industry to discuss the NRC's three sets of comments on NEI 12-04, *10 CFR 72.48 Implementation Guidance*. The focus of that meeting was to discuss four fundamental issues distilled from the NRC's comments in an effort to allow the industry and the NRC to reach alignment on these issues.

This attachment provides the industry's synopsis of the discussion and path forward on the four fundamental issues that were discussed during that meeting. These four issues are considered fundamental because alignment between the NRC and industry on these issues is essential to proceed with the endorsement review of NEI 12-04 as a replacement for NEI 96-07, Appendix B.

In addition, clarification of seven additional key issues taken from References 1 through 3 on which we feel additional information provided now may address apparent NRC misunderstanding and eliminate future questions during the endorsement process.

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ISSUE NO.	ISSUE DESCRIPTION	NRC COMMENT REFERENCE*
<b>FUNDAMENTAL ISSUES</b>		
1	Definition and use of the word “implementation”	1 <sup>st</sup> NRC interim response, 7 <sup>th</sup> para.
2	General licensee processing of CoC holder 72.48s	1 <sup>st</sup> NRC interim response, 4 <sup>th</sup> para., and several related comments in 2 <sup>nd</sup> interim response
3	Quality assurance program purpose and scope versus 72.48	2 <sup>nd</sup> interim response, Enclosure 2, mark-up of NEI 12-04: Sections 1.2 (1 <sup>st</sup> para. and 4 <sup>th</sup> para., 2 <sup>nd</sup> bullet) and 2.2.2 (2 <sup>nd</sup> para.)
4	Method of evaluation	2 <sup>nd</sup> interim response, Enclosure 1, NRC Staff Position on Method of Evaluation Approval
<b>KEY ISSUES</b>		
5	Use of the word “change”	1 <sup>st</sup> NRC interim response, 3 <sup>rd</sup> para.
6	Changing site-specific processes	1 <sup>st</sup> NRC interim response, Enclosure 1, mark-up of NEI 12-04, last sentence of 2 <sup>nd</sup> para. in Section 2.1.5.1 (proposed to be moved to new 1 <sup>st</sup> para. of Section 2.1.5.3)
7	Mixing general licensee and specific licensee guidance	1 <sup>st</sup> NRC interim response, Enclosure 1, mark-up of NEI 12-04, Proposed new 1 <sup>st</sup> para. in Section 2.1.5.4
8	CoC holder 72.48 reviews for licensee-approved 72.48 changes	1 <sup>st</sup> NRC interim response, Enclosure 1, mark-up of NEI 12-04, Section 2.1.5.5
9	Answering 72.48(c)(2) Questions 1-7 or Question 8	2 <sup>nd</sup> NRC interim response, 3 <sup>rd</sup> para. and Enclosure 2, mark-up of NEI 12-04, Section 2.1.3.1
10	Documenting 10 CFR 72.48 evaluations	2 <sup>nd</sup> NRC interim response, Enclosure 2, mark-up of NEI 12-04, Section 2.1.3.2
11	Reporting 10 CFR 72.48 Evaluations	2 <sup>nd</sup> NRC interim response, Enclosure 2, mark-up of NEI 12-04, Section 2.1.4.1

\*NRC Letters dated 9/26/13 and 12/11/14

## DISCUSSION

### 1. Definition and Use of the Word “Implementation”

#### Summary of NRC Comments

- a) “The need to add the definition of implementation is not explained.”
- b) “Under the proposed definition of “implementation,” when the 60-day notification required by 72.48(d) is triggered would be different for CoC holders and licensees.”

#### Industry Response

Adding a definition of “implementation” was suggested by the NRC. The industry agreed a definition for the term would be appropriate to add to the guidance because it is integral to compliance with the 10 CFR 72.48 rule. 10 CFR 72.48(d)(6)(i) and (ii) requires general and specific licensees, respectively, to provide a copy of the record for any changes to a spent fuel storage cask design to the applicable CoC holder within 60 days of implementing the change. (For specific licensees, this requirement only applies if the licensee is using a cask design approved under Subpart L of 10 CFR 72.) Similarly, 10 CFR 72.48(d)(6)(iii) requires CoC holders to provide a copy of the record for any changes to a spent fuel storage cask design to any general or specific licensee using the cask design within 60 days of implementing the change. As described below, because CoC holders and licensees implement changes authorized pursuant to 10 CFR 72.48 differently, the point at which the 60-day clock starts under these reporting regulations should be different.

#### CoC Holder 72.48 Changes

CoC holders may make generic changes to the cask design as described in the cask UFSAR under the provisions of 10 CFR 72.48. If the 10 CFR 72.48 review concludes that NRC approval is not required, these changes may be considered immediately effective upon approval of the associated documentation. In particular, changes to the cask design are typically translated to drawings used in fabrication without further review. Thus, CoC holder changes approved under 10 CFR 72.48 are considered “implemented” by the CoC holder upon approval, which starts the 60-day clock for reporting per 10 CFR 72.48(d)(6)(iii). To avoid making the process overly complicated, CoC holders typically use this “implementation-upon-approval” practice for all 72.48 changes they authorize. CoC holder modifications immediately effective to the cask design or operation need to be communicated to the general licensees in a timely manner. Starting the 60-day clock upon approval of the 72.48 review ensures that licensees will receive the record of the change quickly and have time to understand the impacts of the change, if any.

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Licensee 72.48 Changes

Licensees, on the other hand, typically use the same approach to 10 CFR 72.48 implementation as they do for 10 CFR 50.59 implementation. That is, implementation is defined as deployment of the change in the field, i.e., turnover of the modified structure, system or component (SSC) to operations. For example, with respect to 10 CFR 50.59, Section 4.5 of NEI 96-07 (which has been endorsed by the NRC), states that “An activity is considered ‘implemented’ when it provides its intended function, that is, when it is placed in service and declared operable.”

This practice reflects the possibility that an approved design change could either be delayed in its implementation or even cancelled after approval but before being installed. This is the *latest* point at which the 60-day clock may start for a licensee to comply with the regulation, although it may choose to start the clock earlier. For instance, a procedure change or change to a method of evaluation (MOE) may be considered implemented upon approval of the 10 CFR 72.48 review and procedure approval documentation. (The large majority of licensee 10 CFR 72.48 changes are for procedure revisions.)

The later clock start for licensees to inform CoC holders of 10 CFR 72.48 changes is acceptable because it is less urgent for CoC holders to receive site-specific changes from licensees. CoC holders are under no obligation to modify their generic cask design or operation to reflect a licensee’s site-specific change. Furthermore, changes to a cask design or MOE by licensees (as opposed to cask operation) are rare and would likely involve significant interaction between the licensee and CoC holder during the design change phase of the activity, well before the 10 CFR 72.48 review is performed.

At the March 3, 2016, meeting between the NRC and industry, NRC staff noted that licensee changes to MOEs would have no “field installation” phase and it was unclear when the clock would start for such changes. The industry acknowledges this comment and will address this issue in the upcoming revision to the guidance.

**Proposed NEI 12-04 Guidance Change**

Review and revise the definition of “implementation” to clarify its meaning for CoC holders and licensees, including the issue of MOE changes by licensees. Consider adding examples of different types of changes by CoC holders and licensees and recommendations, as appropriate.

## 2. General Licensee Processing of CoC Holder 72.48 Changes

### Summary of NRC Comments

“If, in NEI’s view, a general licensee can – consistent with the 1999 statements of consideration (SOC) for the 1999 rule change<sup>1</sup> - adopt a generic activity without performing a separate 72.48 review, NEI will have to justify this position.”

### Industry Response

The SOC for the 1999 10 CFR 72.48 rule change states the following [industry’s emphasis]:

*“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.**”*

The previously-endorsed 72.48 guidance in NEI 96-07, Appendix B, Section B4.1.7 includes the above excerpt from the SOC and expands on it as follows:

*“When the cask CoC holder has screened/evaluated a cask design change under 72.48 and determined that prior NRC approval is not required, **a general licensee wanting to adopt the change would not be required to do a separate screening/evaluation for the change if the site-specific 72.212 evaluations are not changed.**”*

and:

*“However, the **general licensee should review their site-specific 72.212 evaluations to determine if any would be changed by the cask design change, and, if so, perform a 72.48 screening/evaluation as required by 10 CFR 72.212(b)(2)(ii).**”*

The industry has been successfully implementing the above guidance for 15 years. In fact, general licensees have expanded the use of 10 CFR 72.48 for adoption of CoC holder 72.48 changes beyond what the guidance currently states to include those CoC holder changes that require site-specific procedure changes, calculation changes and changes to previously-delivered hardware. As discussed below, those changes receive site-specific 72.48 reviews if needed for the change.

General licensees receive CoC holder-authorized 10 CFR 72.48 changes regularly. These changes, which include both permanent changes and disposition of fabrication deficiencies, fall into three categories for licensees:

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<sup>1</sup> 10 CFR 72.48 final rule 64 FR 53582, October 4, 1999.

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1. *The change is not applicable to the ISFSI (e.g., a modification to a PWR cask design for an ISFSI that exclusively stores BWR reactor fuel).*
2. *The change is applicable to the ISFSI and has no impact on the site 72.212 Report, procedures, calculations, or hardware (e.g., a modification of a cask design detail that has no effect on the generic cask design criteria or use of the cask in the field).*
3. *The change is applicable to the ISFSI and requires a change to the site 72.212 Report, procedures, calculations, and/or hardware.*

Each general licensee uses the equivalent of the above criteria to determine what, if any, actions are required if they wish to adopt a CoC holder-approved generic change that is applicable to its ISFSI. The general licensee's 10 CFR 72.48 process is applied, as appropriate, according to the nature of the associated activity at the site (i.e., 72.212 Report revision, procedure revision, etc.). Because there are no regulations or guidance directly addressing the process for general licensee review and adoption of CoC holder 19 CFR 72.48 changes, it may be applied by each general licensee in any suitable manner.

**Proposed NEI 12-04 Guidance Change**

Revise the guidance to add the above three-part categorization for general licensees to use in developing or modifying individual plant processes for reviewing and addressing the impact of incoming CoC holder 10 CFR 72.48 changes, as necessary. The guidance should ensure that general licensees apply the 10 CFR 72.48 review process appropriately for site-specific impacts. A flow chart for the process would be helpful and will be added to NEI 12-04. Revise other affected sections of the guidance as required.

**3. Quality Assurance Program Purpose and Scope Versus 10 CFR 72.48**

**Summary of NRC Comments**

The NRC's comments on NEI 12-04 appeared to challenge the previously-endorsed concept that "consequences," in the context of 10 CFR 50.59 and 10 CFR 72.48 means, exclusively, dose to the public. In addition, it appears that the NRC's comments mixed the purpose and scope of the 72.48 review with that of the reviews performed for the activity under the Quality Assurance program (QAP). In the March 3, 2016, meeting with the industry, the NRC clarified that they did not intend to challenge the previously-endorsed definition of "consequences," but to point out that dose consequences could be caused by conditions other than the loss of the cask confinement boundary.

## **Industry Response**

The industry agrees with the NRC's assertion that conditions other than loss of confinement could create increased dose under accident conditions. 10 CFR 72.48 is concerned exclusively with offsite dose consequences as a result of accidents and malfunctions as discussed in the ISFSI or cask FSAR and subject to the limits in 10 CFR 72.106. Offsite dose from normal or off-normal ISFSI operation are subject to the limits in 10 CFR 72.104 and dose to onsite personnel, including dose received during recovery actions associated with accidents are subject to the dose limits in 10 CFR 20. Section 72.48 does not require consideration of compliance with either 10 CFR 72.104 or 10 CFR 20 as part of the 10 CFR 72.48 review. Compliance with those regulatory limits are part of the offsite dose-monitoring program and the onsite 10 CFR 20 compliance monitoring program, respectively. As stated in Section 4.3.3 of NEI 96-07 (which has been endorsed by the NRC):

The consequences referred to in 10 CFR 50.59 do not apply to occupational exposures resulting from routine operations, maintenance, testing, etc. Occupational doses are controlled and maintained As Low As Reasonably Achievable (ALARA) through formal licensee programs.

Similar statements are included in the Statements of Consideration for Section 72.48, which indicates that normal operations are addressed by Part 20. (64 *Fed. Reg.* at 53591). The various elements of the QAP, as implemented by the CoC holder and the licensees, also help ensure compliance with 10 CFR 72.104 and 10 CFR 20, subject to NRC inspection and enforcement.

The 10 CFR 72.48 guidance (like the 10 CFR 50.59 guidance upon which it is based) makes a clear distinction between the purpose and scope of the QAP versus the purpose and scope of the 10 CFR 72.48 program. The QAP is a technical and compliance review process and the 10 CFR 72.48/50.59 reviews are tests to determine whether prior NRC approval is needed for a change. The design control criterion under the QAP, for example, provides reasonable assurance that a design modification is safe, technically correct, and in compliance with all applicable regulatory requirements. Likewise, other QAP criteria similarly address other processes (e.g., procedures, tests, inspections, special processes, etc.) to provide reasonable assurance that those processes are conducted safely and in compliance with applicable regulations.

On the other hand, the 10 CFR 72.48 and 10 CFR 50.59 reviews are performed strictly to determine if a change requires NRC approval before implementation. This is why the industry ceased referring to 10 CFR 50.59 and 10 CFR 72.48 reviews as "safety evaluations" when NEI 96-07 and NEI 96-07, Appendix B were first developed. This is not to say an error in design discovered during the 10 CFR 72.48 or 10 CFR 50.59 review would be ignored; it would be identified and addressed in the CoC holder's or licensee's corrective action program.

### **Proposed NEI 12-04 Guidance Change**

Review the NRC's markup of the guidance in this area and make clarifying changes, as necessary. In particular, revise the guidance to acknowledge offsite dose consequences from sources other than a loss of confinement.

#### **4. Method of Evaluation (MOE)**

##### **Summary of NRC Comments**

"Licensees and CoC holders have construed 10 CFR 72.48(a)(2)(ii) to mean that MOEs in FSARs for approved ISFSI and cask designs are approved MOEs. Under this view, such MOEs are "approved by NRC for the intended application," and can be used to make changes without having to obtain prior NRC approval under 10 CFR 72.48(c)(2)(viii). The staff does not agree with this view."

The above text is taken from the NRC's enclosure addressing MOE in its second set of interim comments on NEI 12-04 dated December 11, 2014 (ML14349A402). In the March 3, 2016, meeting with the industry, the NRC expanded upon their comments. First, staff asserted that the NRC does not approve an MOE unless it is submitted for approval in a topical report and the NRC issues a Safety Evaluation Report (SER) or other written approval. It was further stated that, in granting a CoC or an amendment to a CoC, the NRC approves the cask design presented in the initial application or amendment only, and may use a variety of methods for doing so, including using their own MOE to perform an independent evaluation of the design in a particular technical discipline.

According to the staff, an MOE used by a cask designer and described in the UFSAR may not be approved by the NRC, but because a cask *design* approved in a specific application has sufficient margin, the results are acceptable to the NRC for that application. The CoC holder or licensee needs to be aware of the constraints and limitations associated with an MOE for a specific application; methods described in a UFSAR should not be applied as a topical report. Thus, according to the staff, the MOE "described" in the cask FSAR is not approved, and may even have certain flaws (as documented by the reviewer in the SER) that the NRC found acceptable for that specific cask design or modified cask design based on the safety margins computed using the MOE.

In addition, the NRC's enclosure includes an interpretation of "intended application" that is more expansive than the original intent of this term in the industry's 10 CFR 72.48 (and 10 CFR 50.59) guidance. In the industry's guidance, "intended application" means using a calculational framework suitable for the technical problem being analyzed, including appropriate constraints and limitations. In the NRC's view, the "intended application" also refers to the particular license application submitted by a cask designer for a new CoC or by a CoC holder for an amendment to an approved CoC. Therefore, under this interpretation, an MOE described in the original cask FSAR would apply only to the original cask design and



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an MOE described in a revision to the cask FSAR published after a CoC amendment is approved would only apply to the version of the cask design approved in that CoC amendment. An MOE described in an FSAR revision applicable to a later cask design approved in a CoC amendment could not then be applied to casks loaded under a prior CoC amendment or the original CoC unless the licensing basis for those casks were updated to the later CoC amendment pursuant to 10 CFR 72.212(b)(4). The NRC stressed the importance of constraints and limitations pertaining to the use of a particular MOE that may be described in the SER. This is one of the reasons why the SER needs to be reviewed when using an MOE to evaluate the impacts of a proposed cask modification.

For specific licensees, there is only one active license amendment and FSAR revision (the latest of each) that apply to the ISFSI facility and all of the casks. Thus, MOEs described in the latest version of the ISFSI FSAR for specific license apply to all of the casks used at the ISFSI unless otherwise segregated by cask design or vintage, and distinguished as such in the FSAR.

**Industry Response**

The industry understands the NRC's concern with the potential for an overly expansive definition of an approved MOE. However, industry believes that the staff position summarized above overly narrows the definition of an approved MOE in a manner that is inconsistent with the long-standing precedent established under 10 CFR 50.59. The industry further believes that, when the NRC promulgated 10 CFR 72.48 the Commission intended for the dry storage change control process to be implemented under Part 72 in a manner consistent with how the reactor change control process is implemented under Part 50. This intent has been reinforced in existing NRC-endorsed industry guidance (NEI 96-07).

As provided in the Statements of Consideration for Section 72.48:

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 Fed. Reg. at 53599]

There is nothing in Section 72.48 or the Statements of Consideration that limits such approval to an MOE evaluated in an SER for a topical report.

This principle is discussed in Section 4.3.8.2 of NEI 96-07, which has been endorsed by the NRC. That guidance identifies two paths by which a MOE may be approved by the NRC. The first is an NRC SER approving a topical report with the MOE. The second path is:

the approval of a specific analysis rather than a more general methodology. In these cases, the NRC's approval has typically been part of a plant's licensing basis and limited to a given plant design and a given application. Again, a thorough understanding of the terms, conditions and limitations relating to the application of the methodology is essential. This information is usually

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documented in the original license application or license amendment request, the SER, and any correspondence between the NRC and the analysis owner that is referenced in the SER or associated transmittal letter.

This principle was recently applied by the NRC in a much-analyzed case involving the replacement steam generators (RSGs) for the San Onofre Nuclear Generating Station (SONGS). As part of its design evaluation for the RSGs, SONGS used the ABAQUS code (rather than the ANSYS code as described in the UFSAR) to perform structural analysis for the reactor coolant system (RCS). The NRC concluded that use of the ABAQUS for SONGS did not require a license amendment under 10 CFR 50.59, because ABAQUS had been “approved” as part of the licensing basis for another plant. In particular, the NRC determined that the Comanche Peak Updated Safety Analysis Report described use of ABAQUS to analyze the dynamic responses for high energy piping for systems other than the RCS. As a result, the NRC concluded that ABAQUS had been approved by the NRC.<sup>2</sup> This case, in conjunction with the guidance in NEI 96-07, clearly indicates that a MOE may be “approved by NRC for the intended application” if the MOE is identified for a similar purpose in the FSAR for another ISFSI (or cask) that has been licensed by the NRC.

The industry generally agrees with the distinction the NRC is making with respect to the use of MOEs described in different FSAR revisions applicable to specific CoC amendments (for CoC holders and general licensees). The industry understands that the use of FSAR MOEs must include consideration of FSAR and SER discussions of constraints and limitations. The CoC holder or licensee can apply that MOE for the intended application within the constraints and limitations described in the FSAR and SER, if any.

Based on the clarifications in the March 3, 2016, meeting, the industry reached alignment with the NRC that modifications to a cask design requiring analysis ideally need to be evaluated using the MOE described in the FSAR revision applicable to the CoC version (original CoC or amendment) to which those particular casks are certified for use. It is the CoC holders’ and licensees’ responsibility to determine the correct FSAR revision for the activity.

However, CoC holders sometimes have cask designs that are carried forward unchanged from one CoC amendment and associated FSAR revision to the next. For example, a CoC amendment to simply change from custom to standardized Technical Specifications would carry all system designs forward, with no analyses performed and no MOE changes included in the associated FSAR revision. In these cases, the CoC may be amended and FSAR may be revised but the design and analyses are not affected.

CoC holders also sometimes cross-reference FSAR analyses from a cask design approved by the NRC under one CoC to a cask design approved by the NRC under another CoC for the same component or system design. In such cases, a different FSAR revision could be adopted

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<sup>2</sup> NRC Inspection Report 05000361/2012010, and 05000362/2012010 (Nov. 9, 2012), p. 24.

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for previously certified casks with appropriate 72.48 review of those differences, without having to adopt the later CoC amendment per 10 CFR 72.212(b)(4).

**Proposed NEI 12-04 Guidance Change**

Clarify that MOEs described in the FSAR may be used to evaluate the effects of cask design or operational changes, giving due consideration to FSAR and SER discussions of MOE constraints and limitations.

Although ideally for CoC holders and general licensees the MOE(s) used to evaluate changes are the ones described in the version of the cask FSAR corresponding to the original cask design or the modified cask design authorized in a CoC amendment(s), as applicable, this is often not the case. There are situations where a cask design was carried forward unchanged from one CoC amendment to another and one FSAR revision to another or the physical configuration of the cask is the same as the design of a cask under a different CoC. Under these circumstances, use of MOEs from different licensing bases is acceptable provided that the “intended application” is the same (i.e., the MOE is applied to similar components under similar conditions) and all applicable constraints and limitations have been appropriately applied before the use of the MOE.

Note that specific licensees always use the latest FSAR revision.

**5. Use of the Word “Change”**

**Summary of NRC Comments**

“The NRC staff is not persuaded that there is a need to provide new guidance regarding the 10 CFR 72.48(a)(1) definition of "Change." For example, NEI proposes adding new guidance in this regard in [NEI 12-04] Section 1.3. Also, in several places, the proposed 2012 guidance differs from the 2001 guidance in using words such as 'modification' or 'activity' in place of 'change.' The staff's view is that revising the existing guidance in this regard introduces ambiguity and would thus not be appropriate.”

**Industry Response**

It is typical industry practice to review design modifications and procedure revisions using the Section 72.48 review process, whether or not the modifications or revisions are consistent with the FSAR. As discussed below, not all design modifications and procedure revisions (or similar activities) constitute a “change” as defined in 10 CFR 72.48(a)(1). Therefore, it is appropriate to differentiate “changes” as defined in Section 72.48(a)(1) from other types of design modifications and procedure revisions that are subject to applicability reviews and screens but not a full evaluation against the eight criteria in 10 CFR 72.48(c)(2).

The industry believes the guidance in NEI 12-04, Section 1.3, provides needed context and clarification with respect to interpreting the word “change” in the context of 10 CFR 72.48.

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Consistent with the title of the rule, changes, tests and experiments (CTEs) not otherwise requiring a change to the license or CoC must be reviewed against the criteria in 72.48(c)(2) to determine if NRC approval is required prior to implementation. That is, CTEs must receive a “full 72.48 evaluation” in the parlance of the NEI 96-07, Appendix B, and NEI 12-04. *All* proposed activities that constitute a change, test or experiment must receive a full 10 CFR 72.48 evaluation—with no exceptions. However, based on the 10 CFR 72.48 screening process, not all of the proposed activities are either changes, tests or experiments, and the NEI 12-04 guidance makes a clarifying distinction as described below.

There are three parts to a 10 CFR 72.48 review for a proposed activity, each of which serves to answer a specific question in the 10 CFR 72.48 process:

*Applicability:* Does 10 CFR 72.48 apply to part or all of the proposed activity (or parts thereof)?

*Screening:* Does the proposed activity (or parts thereof) to which 10 CFR 72.48 applies require an amendment to the license/CoC OR does it constitute a CTE, which requires a full 10 CFR 72.48 evaluation?

*Evaluation:* Does the proposed CTE require prior NRC approval because one or more of the criteria in 10 CFR 72.48(c)(2) is answered “yes”?

The 10 CFR 72.48 review may end after any of the phases of the review based on the nature of the proposed activity. Note that the focus of the discussion here forward is on defining the “C” of CTE. The guidance for determining whether a proposed activity is a test or experiment is not revised.

The definition of “change” in 10 CFR 72.48 is repeated in both NEI 96-07, Appendix B, Section B3.3, and in NEI 12-04, Section 3.6, verbatim, as follows:

“a modification or addition to, or removal from, the ISFSI facility or spent fuel storage cask design or procedures that affects: (1) a design function, (2) method of performing or controlling the function, or (3) an evaluation that demonstrates that intended functions will be accomplished.”

The intent of NEI 12-04 Section 1.3 is not to alter the definition of “change” in the guidance, but to clarify other elements of the guidance used to determine whether a proposed activity constitutes a “change” in the context of 10 CFR 72.48. This clarification is consistent with previously endorsed guidance pertaining to the interpretation of the word “affects” as used in the definition of “change” in 10 CFR 72.48.

As previously discussed, if a proposed activity is determined to be a “change” by the 10 CFR 72.48 screening process, a full 10 CFR 72.48 evaluation is required. NEI 96-07, Appendix B, Section B4.2.1 states that for a proposed activity to be considered a “change,” it must have an adverse effect on a design function, method of performing or controlling a design function, or

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a method of evaluation. Thus, a change is “adverse” by definition in the guidance and Section 72.48(a)(1). Proposed activities not having an adverse effect are not “changes” and do not require a full 10 CFR 72.48 evaluation.

Currently, NEI 96-07, Appendix B, uses the term “adverse change,” which is redundant. NEI 96-07, Appendix B, also refers, in some cases, to proposed activities as “changes” before the 10 CFR 72.48 screening process is complete. One cannot know whether a proposed activity to which 10 CFR 72.48 applies is a “change” until the 10 CFR 72.48 screening process is complete. As a result, NEI 12-04 has revised language to clarify and preserve the distinction between changes as defined in 10 CFR 72.48(a)(1) and those design modifications, procedure revisions, and other activities that do not have an adverse effect and therefore do not constitute a “change.”

In summary, NEI 12-04, Section 1.3, and other conforming revisions clarify the guidance without modifying the definition of “change.” NEI 12-04 simply recommends that proposed activities be referred to as something other than “changes” unless and until the 10 CFR 72.48 screening process concludes that the proposed activity will have an adverse effect and is, indeed, a “change.” Suggestions for use in describing a proposed activity before the 10 CFR 72.48 screening is complete or if the screening determines that the activity is not a “change” include “deletion,” “addition,” “revision,” “alteration” and “modification.”

### **Proposed NEI 12-04 Guidance Change**

Review the guidance and the NRC’s response to the above discussion to determine if additional clarification would be appropriate.

## **6. Changing Site-Specific Processes**

### **Summary of NRC Comments**

In the NRC’s mark-up of NEI 12-04, it is suggested that the last sentence of Section 2.1.5.1 pertaining to licensees processing required changes to site-specific documents “in accordance with their own change management programs” be deleted.

### **Industry Response**

It is not clear what the NRC objection is to this sentence. This sentence follows one that the NRC retains in its proposed mark-up of the document, which states:

“Accordingly, the 60-day reports to licensees of cask design changes implemented under 10 CFR 72.48 provided by the CoC holder only need to be reviewed for applicability to their plant/ISFSI and for impact on the site-specific evaluations and analyses, the 212 Report, and site programs and procedures.”

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The next sentence, referring to licensees processing changes to site-specific documents in accordance with “their own change management programs,” is accurate. Licensees process modifications to their site-specific evaluations and analyses, the 72.212 report, programs, and procedures in accordance with their own change management programs. In addition to 10 CFR 72.48, these change management programs include 10 CFR 50.59, 10 CFR 50.54 and license conditions for program controls, such as the fire-protection program. Licensees would use any and all site-specific change management programs that apply.

### **Proposed NEI 12-04 Guidance Change**

Add the above examples of “their own change management programs” to the guidance.

## **7. Mixing General Licensee and Specific Licensee Guidance**

### **Summary of NRC Comments**

In the NRC’s mark-up of NEI 12-04, a new first paragraph is added to Section 2.1.5.3, “General Licensee Use of CoC Holder-Generated Modification,” that states:

“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 need 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.”

The NRC’s mark-up suggests adding the same paragraph to the guidance for specific licensees in Section 2.1.5.4, except that references in the last sentence to site-specific evaluations and analyses, the 212 report, and site programs and procedures are not included.

### **Industry Response**

Adding this paragraph to Section 2.1.5.4 is not necessary or appropriate. A specific licensee is under no obligation to review or take any action with respect to a CoC holder generic cask design change unless that certified cask design is explicitly incorporated into the specific licensing basis by reference from the ISFSI license or UFSAR. Consideration of generic CoC holder changes to a cask design is otherwise optional for specific licensees, who would need to perform their own 10 CFR 72.48 review against their specific licensing basis to adopt any generic cask design change. The current proposed guidance for specific licensee in NEI 12-04 Section 2.1.5.4 states the following:

“If a site-specific licensee determines that a CoC holder’s modification should be adopted on site, they would review their site-specific ISFSI UFSAR to determine if a concomitant change and 10 CFR 72.48 screening/evaluation would be required. The answers/justification

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used in the 10 CFR 72.48 screening/evaluation may be taken from the CoC holder's §72.48 screening/evaluation if they could also apply to the site-specific licensee's screening/evaluation."

The guidance in NEI 12-04 adequately addresses specific licensee obligations with respect to CoC holder 10 CFR 72.48 changes.

### **Proposed NEI 12-04 Guidance Change**

Accept the new paragraph for the general licensee guidance in Section 2.1.5.3 but not for the specific licensee guidance in Section 2.1.5.4. The previous first (now second) paragraph in each of these sections will be reviewed to determine if further clarification is required, depending upon the resolution of item 2 above.

## **8. CoC holder 72.48 reviews for Licensee-Approved 72.48 Changes**

### **Summary of NRC Comments**

The NRC's proposed mark-up of NEI 12-04, Section 2.1.5.5, modifies the recommended actions for CoC holders upon receipt of licensee-performed 72.48 modifications to the cask design. The modified NEI 12-04 language proposed by the NRC states:

"When a CoC holder receives from a licensee records documenting a cask design change, it should review such records in a timely manner (e.g., within 60 days of receipt) to determine if the change should be adopted for generic use (see Figure 3). If so, the certificate holder **must perform a 72.48 screening/evaluation and determine whether a modification to the cask UFSAR is required** [industry emphasis added]. The answers/justification used in the CoC holder's 72.48 screening/evaluation may incorporate to the extent applicable the licensee's 72.48 screening/evaluation. A cask design modification that has been reported to the CoC holder by a general or specific licensee and then adopted by a CoC holder would need to be reported back to all general or specific licensees using that cask design in the 60-day report."

### **Industry Response**

The 10 CFR 72.48 process is strictly a determination as to whether NRC approval is required for a CTE prior to implementation. The CoC holder may use whatever process it deems appropriate to determine whether a licensee-initiated 10 CFR 72.48 modification to a cask design that the CoC holder wishes to adopt affects the cask design as described in the cask UFSAR (including any drawings).

If a revision to the generic cask design as described in the cask UFSAR is required, then that revision would be undertaken by the CoC holder. The CoC holder would, in that case, execute the design modification process under the design control element of their QA program, and develop an associated 10 CFR 72.48 review to determine if NRC review and

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approval is required for the modification. If CoC holder adoption of a site-specific cask design modification does not affect information in the cask UFSAR (e.g., the detail is not included on the drawings in the cask UFSAR), the CoC holder may screen out the modification.

**Proposed NEI 12-04 Guidance Change**

Accept the NRC's proposed text modifications that improve grammar and reader understanding, but not the portion suggesting using the 72.48 process to determine if a UFSAR amendment is required.



## **9. Answering 72.48(c)(2) Questions 1-7 or Question 8**

### **Summary of NRC Comments**

“The staff also identified several references in the guidance document, where NEI applied only the eighth criteria to changes regarding method of evaluation (MOE), implying that there was no need to review the change against the first seven criteria. The staff has determined that changes should be evaluated against all eight 10 CFR 72.48 criteria.”

The NRC’s proposed mark-up of NEI 12-04, Section 2.1.3.1, makes related text edits.

### **Industry Response**

The suggested changes to the NEI 12-04 guidance are contrary to already-endorsed guidance for 10 CFR 50.59 in NEI 96-07 and for 10 CFR 72.48 in NEI 96-07, Appendix B, Sections 4.2.1.3 and B4.2.1.3, respectively. Proposed activities *involving* MOEs as described in the cask UFSAR must be determined to be either a modification to an input parameter (directly, or as a result of a physical modification to the cask design) *or* a change to an MOE. This determination is made in the 10 CFR 72.48 screening process.

10 CFR 72.48(c)(2)(viii) applies only to MOEs. 10 CFR 72.48(c)(2)(i) through (vii) apply to CTEs not involving an MOE. Therefore, it is appropriate to segregate the applicability of these questions accordingly. This concept has been deeply embedded in the training, qualification and implementation programs for both 10 CFR 50.59 and 10 CFR 72.48 for over 15 years, based on the previously-endorsed guidance.

The industry recognizes that certain proposed activities may involve both a change to the cask design *and* a change to an MOE. In such cases, the industry recommends that the change to the MOE be evaluated first, and separately, under criterion (c)(2)(viii) to determine if the change to the MOE is a departure from an MOE that requires prior NRC approval. If the change to the MOE does not require prior NRC approval, the balance of the proposed activity (i.e., the design modification) must be reviewed under the other seven criteria in 10 CFR 72.48(c)(2) (if it is determined to have an adverse effect by the 72.48 screening).

### **Proposed NEI 12-04 Guidance Change**

Retain the current guidance pertaining to answering Questions 1-7 versus Question 8 and further clarify how the guidance should be used for proposed activities that involve both a modification to the cask design or operation and a change to an MOE.

## **10. Documenting 72.48 Evaluations**

### **Summary of NRC Comments**

The NRC's comment in the proposed mark-up of NEI 12-04, Section 2.1.3.2, states:

“Explain how this sentence is consistent with the meaning and intent of the 10 CFR 72.48(d) provisions regarding documentation and recordkeeping requirements.”

The sentence from the guidance being referred to states:

“This 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.”

### **Industry Response**

The industry's understanding of the 10 CFR 72.48(d) regulation is that records demonstrating compliance with the 10 CFR 72.48 rule includes only records documenting the responses to the questions posed in 10 CFR 72.48(c)(2). This is based on the language in 10 CFR 72.48(d)(1), which refers specifically to “records of changes...made pursuant to paragraph (c) of this section.” 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). Therefore, records of the screening of proposed activities that determined a full 10 CFR 72.48 evaluation against the criteria in 10 CFR 72.48(c)(2) was not required do not fall within the requirements of Section 72.48(d). This position is consistent with the 10 CFR 72.48 guidance in NEI 96-07, Appendix B, Sections B4.2.3 and B5, as well analogous sections of the 10 CFR 50.59 guidance in the base NEI 96-07 document.

Notwithstanding that the records of 10 CFR 72.48 screening not meeting the definition of “records” in 10 CFR 72.48(d)(1), the guidance does recommend that CoC holders and licensees maintain such records internally.

### **Proposed NEI 12-04 Guidance Change**

None.

## **11. Reporting 10 CFR 72.48 Evaluations**

### **Summary of NRC Comments**

The NRC's comments in the proposed mark-up of NEI 12-04, Section 2.1.4.1, states:

“Clarify whether this includes changes that were made or implemented that ‘screened out.’”

and

“Clarify whether licensees would also need to provide this information to the CoC holder per 72.48(d)(6)(i) and (ii).”

These two sentences refer to the statement in the guidance that the records referred to in the rule apply only to the records documenting review of proposed changes against the criteria in 10 CFR 72.48(c)(2) and the statement regarding CoC holders providing all UFSAR changes to the licensees.

### **Industry Response**

Please refer to the industry response to item 10 for background information. NEI 12-04 retains the recommendations from NEI 96-07, Appendix B, that CoC holders forward all changes to the cask UFSAR to licensees in a timely manner notwithstanding whether a full 72.48 evaluation was required for the UFSAR modification. Section 2.1.4.1 of the guidance 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 guidance, however, is not clear that licensees are recommended to share the record of cask design modifications similarly with the CoC holder.

### **Proposed NEI 12-04 Guidance Change**

The guidance will be clarified to state that licensees are expected 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. Sharing with the CoC holder of other cask UFSAR text, table, and figure revisions made by the licensee needs to be determined case-specifically based on the nature of the revisions. 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. Site-specific UFSAR revisions made by licensees do not need to be made by the CoC holder in the cask UFSAR.