

**Selected NRC Staff Edits of Comments on NEI 12-04,
“Guidelines for 10 CFR 72.48 Implementation”**

Staff Edits of Proposed Section 2.2.3 Comments Regarding Positions Stated in NRC Regulatory Issue Summary 2012-05

2.2.3

10 CFR 72.48 and the 212 Report

Changes subject to 10 CFR 72.48, that are proposed by the general licensee or by the CoC holder, and used by the general licensee must be reviewed by the general licensee prior to their use implementation of the activity at the ISFSI, to assess their for impact on the site's 212 Report and supporting analyses and evaluations. Modifications to those documents must be made as required in accordance with 10 CFR 72.212(b)(7).

The 212 Report documents compliance with the CoC and evaluations performed pursuant to 10 CFR 72.212(b)(5), (b)(6) and (b)(8). **[INSERT THE FOLLOWING FROM RIS 12-05]:** Pursuant to 10 CFR 72.212(b)(5), general licensees must perform written evaluations (1) before using a cask and (2) before applying the changes authorized by an amended certificate of compliance (CoC) to a previously loaded cask. In the past, a general licensee only used the written evaluation to demonstrate the suitability of a selected cask design at its site before its first use. The current rule, 10 CFR 72.212(b) allows general licensees to apply changes authorized by a CoC amendment as codified by NRC in 10 CFR 72.214, “List of Approved Spent Fuel Storage Casks,” to a previously loaded cask without express NRC approval provided that the licensee demonstrates through a written evaluation, that the loaded cask then conforms to the CoC amendment codified in the list of approved spent fuel storage casks set forth in 10 CFR 72.214. Therefore, general licensees can also use the written evaluation to demonstrate the conformance of a loaded cask to a newer CoC amendment.

10 CFR 72.48(c)(1) states that a licensee or certificate holder may, without prior NRC approval, “make changes in the facility or spent fuel storage cask design as described in the FSAR (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated)” as long as the criteria in 10 CFR 72.48(c) are satisfied.

Section 72.212(b)(5) requires the general licensee to perform a written evaluation before using a cask and before applying the changes authorized by an amended CoC to a previously loaded cask. Section 72.212(b)(6) requires the general licensee to review the Safety Analysis Report referenced in the CoC or amended CoC and the related NRC Safety Evaluation Report, prior to use of the general license, to determine whether or not the reactor site parameters, including analyses of earthquake intensity and tornado missiles, are enveloped by the cask design bases considered in these reports. Section 72.212(b)(7) requires the general licensee to evaluate any changes to the written evaluations required by paragraphs (b)(5) and (b)(6) of 10 CFR 72.212, using the requirements of 10 CFR 72.48. The change authority granted in 10 CFR 72.48 requires a general licensee to determine whether prior NRC approval is necessary before changes can be made to the cask FSAR. A 10 CFR 72.212 evaluation alone is not sufficient to address a needed change to the FSAR scope. Pursuant to 10 CFR 72.212(b)(7), a 10 CFR 72.48 evaluation must also be performed. The 10 CFR 72.212 evaluation may identify the need to perform additional evaluations under 10 CFR 72.48 for authority to change the FSAR. In other words, a general licensee does not satisfy the change authority requirements in Part 72 if

it performs an analysis or written evaluation to load, store, operate, or accept conditions outside of the FSAR without first satisfying the criteria of a 10 CFR 72.48 evaluation.

[END OF INSERTED TEXT]

Consistent with [the above discussion guidance](#) in NRC Regulatory Issue Summary 2012-05 “Clarifying the Relationship between 10 CFR 72.212 and 10 CFR 72.48 Evaluations,” if any of the evaluations described in the 212 Report deviate from information in the cask UFSAR, ~~these~~ such evaluations need to be reviewed in accordance with 10 CFR 72.48 to determine if a CoC amendment is required. This includes evaluations described in the initial version of the 212 Report, which is normally issued prior to loading the first cask and placing it into service at an ISFSI. The 212 Report, including the initial version, is not a substitute for a 72.48 review.

If the initial issuance of the 212 Report contains no deviations from the cask UFSAR, then no 72.48 review is required. ~~However, all~~ ~~Thereafter, other than editorial or administrative corrections, any changes~~ ~~modifications~~ to the 212 Report ~~thereafter that are not considered editorial or administrative corrections or involve strictly administrative or managerial issues~~ require a 72.48 review pursuant to 10 CFR 72.212(b)(7).

~~Staff Edits of Proposed Section 2.1.5 Comments Regarding 10 CFR 72.212 Reporting Requirements~~

2.1.5 Miscellaneous Guidance

2.1.5.1 Licensee Actions Upon Receiving CoC Holder-Authored Changes

Licensees are not required to approve generic CoC holder changes implemented under 72.48. ~~nor do general licensees perform duplicate 10 CFR 72.48 reviews for changes being adopted per Definition 3.4.~~ CoC holders have full authority to implement changes under 72.48 as the design authority and owner of the generic cask licensing basis. This is not to say licensees should not review the technical and regulatory documentation of CoC holder changes made pursuant to 10 CFR 72.48. They should do so as part of periodic vendor oversight audits and assessments, and provide appropriate feedback to improve the CoC holder’s 10 CFR 72.48 program. Guidance for ~~users~~ licensees choosing to adopt generic CoC holder changes is provided in Sections 2.1.5.3 and 2.1.5.4.

[note: revised versions of the following struck-thru text are inserted into sections 2.1.5.3 and 2.1.5.4 below] ~~Furthermore, due to the nature of spent fuel storage cask use and the general license process, 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, 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. Licensees should process any required changes to site-specific documents in accordance with their own change management programs.~~

2.1.5.2 Reporting of Defects and Deficiencies

Licensees and CoC holders are required to report certain defects or deficiencies in any spent fuel storage structure, system, or component to the NRC in accordance with the reporting requirements in 10 CFR 72.75 and 10 CFR 21. Accordingly, safety significant information

related to a specific spent fuel storage system design will be provided to the NRC in a timely manner and any safety significant concerns communicated to the licensees via NRC generic correspondence for disposition. 10 CFR 72.48 would only apply if compensatory actions are taken to address the defect or deficiency that deviate from the cask or site-specific ISFSI UFSAR (see Section 4.9), or if a procedure or 212 Report revision is required.

2.1.5.3 General Licensee Use of CoC Holder-Generated Changes Modifications

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.

If a general licensee determines that a ~~generic~~ CoC holder design or UFSAR change modification is applicable and should be used ~~adopted at their its site ISFSI~~, the general licensee ~~must would perform an impact evaluation (e.g., procedures, 212 Report, etc.) and perform 10 CFR 72.48 screenings/evaluations. as required by their internal change review process for the impacted documents. The answers/justification used in the 10 CFR 72.48 screening/evaluation may be taken from~~ Such licensee evaluations may incorporate the CoC holder's §72.48 screening/evaluation to the extent it is applicable at ~~the its ISFSI site,~~ and these evaluations need to capture any required changes to site-specific documents. ~~if they also apply to the general licensee's screening/evaluation.~~

A change modification that has been reported to the general licensee by the CoC holder and then used by the general licensee would not need to be reported back to the CoC holder in a 60-day report because the CoC holder initially generated the modification and will have already performed the appropriate regulatory reviews and updated the generic licensing basis documents, as needed.

2.1.5.4 Site-Specific Licensee Use of CoC Holder-Generated Changes Modifications

A specific 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 and impact on their plant/ISFSI and UFSAR.

If a ~~site~~-specific licensee determines that a CoC holder's design or UFSAR change modification is applicable and should be used ~~adopted at its on site~~, the licensee must ~~they would review their site-specific ISFSI UFSAR to determine if a concomitant change and perform 10 CFR 72.48 screenings/evaluations. would be required.~~ Such licensee evaluations may incorporate ~~The answers/justification used in the 10 CFR 72.48 screening/evaluation may be taken from~~ the CoC holder's §72.48 screening/evaluation to the extent it is applicable at ~~the ISFSI's site and~~ these evaluations need to capture any required changes to site-specific documents. ~~if they could also apply to the site-specific licensee's screening/evaluation.~~

A change that has been reported to the ~~site-specific~~ licensee by the CoC holder and then ~~incorporated-used~~ by the ~~site-specific~~ licensee would not need to be reported back to the CoC holder in a 60-day report because the CoC holder initially generated the ~~modification-change~~ and will have already performed the appropriate regulatory reviews and updated the generic licensing basis documents, as needed.

2.1.5.5 CoC Holder Actions Upon Receipt of Licensee-Generated Changes Modifications

When a CoC holder receives ~~from a licensee a copy of the~~ records documenting for a cask design ~~change, modification from a licensee, they~~ it should review ~~such records the record~~ in a timely manner (e.g., within 60 days of receipt) to determine if ~~they should adopt~~ the change ~~should be adopted~~ for generic use (see Figure 3). If so, the certificate holder ~~must perform a 10 CFR 72.48 screening/evaluation and would review the cask UFSAR to~~ determine whether if a modification to ~~the cask UFSAR that document and a 10 CFR 72.48 screening/evaluation~~ is required. The answers/justification used in the ~~CoC holder's~~ 10 CFR 72.48 screening/evaluation may ~~incorporate to the extent it is applicable be taken from~~ the licensee's 72.48 screening/evaluation. ~~if they could also apply to the CoC holder's screening/evaluation.~~ 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 general or specific licensees using that cask design in the 60-day report.

Staff Edits of Proposed Section 3.4 Comments Regarding the Definition of "Adoption"

3.4 ADOPTION

Definition

Adoption means the process by which a licensee ~~uses a change developed~~ ~~chooses to use a~~ ~~generic activity authorized~~ by a CoC holder under 10 CFR 72.48, or ~~the process by which a~~ CoC holder ~~uses a change developed~~ ~~adopts an activity made~~ by a licensee user of the cask.

Discussion:

A specific licensee ~~must evaluate~~ proposed changes against its site-specific UFSAR, in accordance with 10 CFR 72.48. ~~would need to perform a 72.48 review of the activity against their site-specific ISFSI UFSAR. A general licensee can adopt a generic activity without performing a separate 72.48 review. The activity would~~ A general licensee ~~must evaluate~~ ~~Proposed changes must be reviewed~~ against ~~the its~~ ~~site's~~ 212 Report, procedures, and programs, in accordance with 10 CFR 72.48. Revisions required to be made to those documents as a result of ~~using adopting~~ changes developed by a CoC holder ~~the generic activity may~~ would require ~~the licensee to perform~~ a 10 CFR 72.48 review. ~~under the licensee's program.~~ CoC holders would need to perform a 72.48 review of the ~~proposed change activity~~ against their cask ~~design ISFSI~~ UFSAR. Additional guidance for applying this definition is provided in Sections 2.1.5.1, 2.1.5.3, 2.1.5.4, and 2.1.5.5.

Staff Edits of Proposed Sections 4.6 and 4.7 Comments Regarding the Use of the Word "Change"

4.6 MODIFICATIONS-CHANGES TO WRITTEN EVALUATIONS REQUIRED BY 10 CFR 72.212

10 CFR 72.212(b)(7) requires that a general licensee evaluate any ~~changes~~ ~~modifications~~ to the written evaluations required by 10 CFR 72.212 using the requirements of 10 CFR 72.48(c). This includes ~~changes~~ ~~modifications~~ to evaluations performed directly in the 212 Report and evaluations documented separately and incorporated by reference into the 212 Report. See Section 2.2.3 for additional guidance. Also, as discussed in Section 4.3, editorial/administrative corrections to the 212 Report are not subject to review under 10 CFR 72.48.

4.7 CASK DESIGN ~~CHANGES~~ ~~MODIFICATIONS~~ MADE BY A COC HOLDER AND ADOPTED BY A GENERAL LICENSEE

The *Federal Register* notice issuing the final rule for 10 CFR 50.59 and 72.48 (64 FR 53582, October 4, 1999) stated the following in Section O.1 on page 53601:

“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.”

When the cask CoC holder has implemented a ~~modification-change~~ under 10 CFR 72.48, general licensees using that cask system may adopt that ~~modification-change~~ (Definition 3.4). General licensees would not necessarily need to perform a separate 10 CFR 72.48 screening/evaluation for the ~~modification-change~~ if the site-specific 212 Report, supporting analyses/evaluations or site procedures are not affected by the ~~generic modificationchange~~ being adopted. The general licensee should review these site documents to determine if any would require a ~~modification-change~~ to use the ~~generic~~ change approved by the CoC holder, and, if so, perform a 10 CFR 72.48 review for the ~~modification-change~~ to that site document. The answers and/or justification used in the site document revision 10 CFR 72.48 screening/evaluation may be taken from the CoC holder’s 10 CFR 72.48 screening/evaluation if they ~~could~~ also apply to the site screening/evaluation.

Staff Edits of Proposed Section 5.1.2 (first paragraph) Comments Regarding Screening of Changes to Design Basis Limits for Fission Product Barriers

5.1.2 Screening for Adverse Effects

A 10 CFR 72.48 evaluation is required for proposed ~~activities-changes~~ that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished (*i.e.*, “changes”). ~~Activities Changes~~ that have none of these effects, or have positive effects, may ~~generally~~ be screened out. ~~However, any change that alters a design basis limit for a fission product barrier – positively or negatively – is considered adverse and must be screened in because it involves such a fundamental alteration of the facility design that a change, even in the conservative direction, needs to receive prior NRC review.~~

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~~5.1.3 Screening of Proposed Activities Changes to the ISFSI Facility or Spent Fuel Storage Cask Design as Described in the UFSAR~~

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~~Only proposed activities changes affecting SSCs that would, based on supporting engineering and technical information, have adverse effects on design functions require evaluation under 10 CFR 72.48. Proposed activitiesChanges that have positive or no effect on design functions may generally be screened out. However, any changemodification toof a design basis limit for a fission product barrier would “alter” that limit and must be screened in. considered a change and be screened in. Note that this type of change will also require a “yes” response to the 10 CFR 72.48(e)(2)(vii) evaluation criterion and require prior NRC approval.~~

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