

Fundamental Issues Regarding 10 CFR 72.48 Implementation and NEI 12-04

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for the

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Background

- NRC endorsed NEI 96-07, Appendix B in Regulatory Guide 3.72, excluding reference documents and clarifying the use of examples
- NEI submitted updated guidance for the implementation of 10 CFR 72.48 in 2012 with a goal of NRC endorsement to replace NEI 96-07, Appendix B
- NRC submitted 3 sets of comments from 2013 through 2015 (146 unique comments plus document markup)
- At the 2015 REG CON meeting, NRC and industry agreed on a path forward

Objective of the Guidance Update

- Address lessons learned from industry and NRC 10 years after 1999 rulemaking
 - Substantially revised rule to be consistent with 50.59
 - Added CoC holder 72.48 authority
- Enhance and clarify the existing, NRC-endorsed guidance in NEI 96-07, Appendix B to be more helpful to industry users and NRC inspectors
- Stay consistent with 50.59 guidance where commonalities with 72.48 guidance exist
- Maintain previously-endorsed elements of the guidance

Purpose of Meeting

- NRC and NEI agreed to discuss certain fundamental issues before proceeding with a revision to the document
- A common understanding of these fundamental issues is important to licensee and CoC holder implementation of 10 CFR 72.48
- Goal is to support revision of the guidance and NRC review for endorsement

Fundamental Issues

1. Definition and use of the word “implementation”
2. General licensee processing of CoC holder 72.48s
3. Purpose and scope of 72.48 versus QA program
4. Approval of cask design and use of methods of evaluation described in the ISFSI or cask FSAR

NRC Comments by Issue

No.	Fundamental Issue	NRC Comment Letter
1	Definition and use of the word “implementation”	1 st NRC interim response letter, 7 th para.
2	General licensee processing and adoption of CoC holder 72.48s	1 st NRC interim response letter, 4 th para., and several related comments in 2 nd interim response dated 12/11/14
3	72.48 purpose and scope versus QA program purpose and scope	2 nd interim response, Enclosure 2, mark-up of NEI 12-04: Sections 1.2 (1 st para. and 4 th para., 2 nd bullet) and 2.2.2 (2 nd para.)
4	Approval of cask design and methods of evaluation	2 nd interim response, Enclosure 1, NRC Staff Position on Method of Evaluation Approval

1. Definition and use of the word “implementation”

- Summary of NRC comment (NEI 12-04, Section 3.14)
 - 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

1. Definition and use of the word “implementation”

- Adding a definition of “implementation” was suggested by the NRC (NRC presentation dated 3/28/11)
- Industry agreed this needed to be clarified
- Because CoC holders and licensees implement 72.48 changes differently, industry recommends that the 60-day clock should trigger differently

1. Definition and use of the word “implementation”

- CoC holders implement activities under their 72.48 authority which, once approved, are immediately effective modifications to the cask design or operation as described in the FSAR
 - Changes to cask hardware
 - Changes to the cask FSAR (e.g., operations, maintenance)
- Licensees authorize activities under 72.48 that are not implemented until used in the field
 - Usually cask loading/operating procedures

1. Definition and use of the word “implementation”

- Immediately effective CoC Holder modifications 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 ensures the general licensees will have time to understand the impacts of the change, if any, and make site-specific changes
- Licensees, on the other hand, use the same approach to 72.48 implementation as they do for 50.59.
 - Deployment of the change in the field
- The 60-day clock for licensees to inform CoC holders is less urgent from a timing standpoint because the change is site-specific
 - The clock can start later

2. GL Processing CoC Holder 72.48s

- Summary of NRC comments (NEI 12-04, Sections 2.1.5.1, 3.4, and 4.7)
 - If, in NEI's view, a GL can – consistent with the 1999 SOC* - adopt a generic activity without performing a separate 72.48 review, NEI will have to justify this position

* Statements of Consideration for 72.48 final rule 64 FR 53582, October 4, 1999

2. GL Processing CoC Holder 72.48s

- NEI 12-04 does not change endorsed guidance in NEI 96-07 Appendix B in this regard
- Both NRC's comment and NEI 96-07B, Section B4.1.7 cite the NRC's SOC:

“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.”

2. GL Processing CoC Holder 72.48s

- NEI 96-07, Appendix B, Section B4.1.7 goes on to state:

“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”

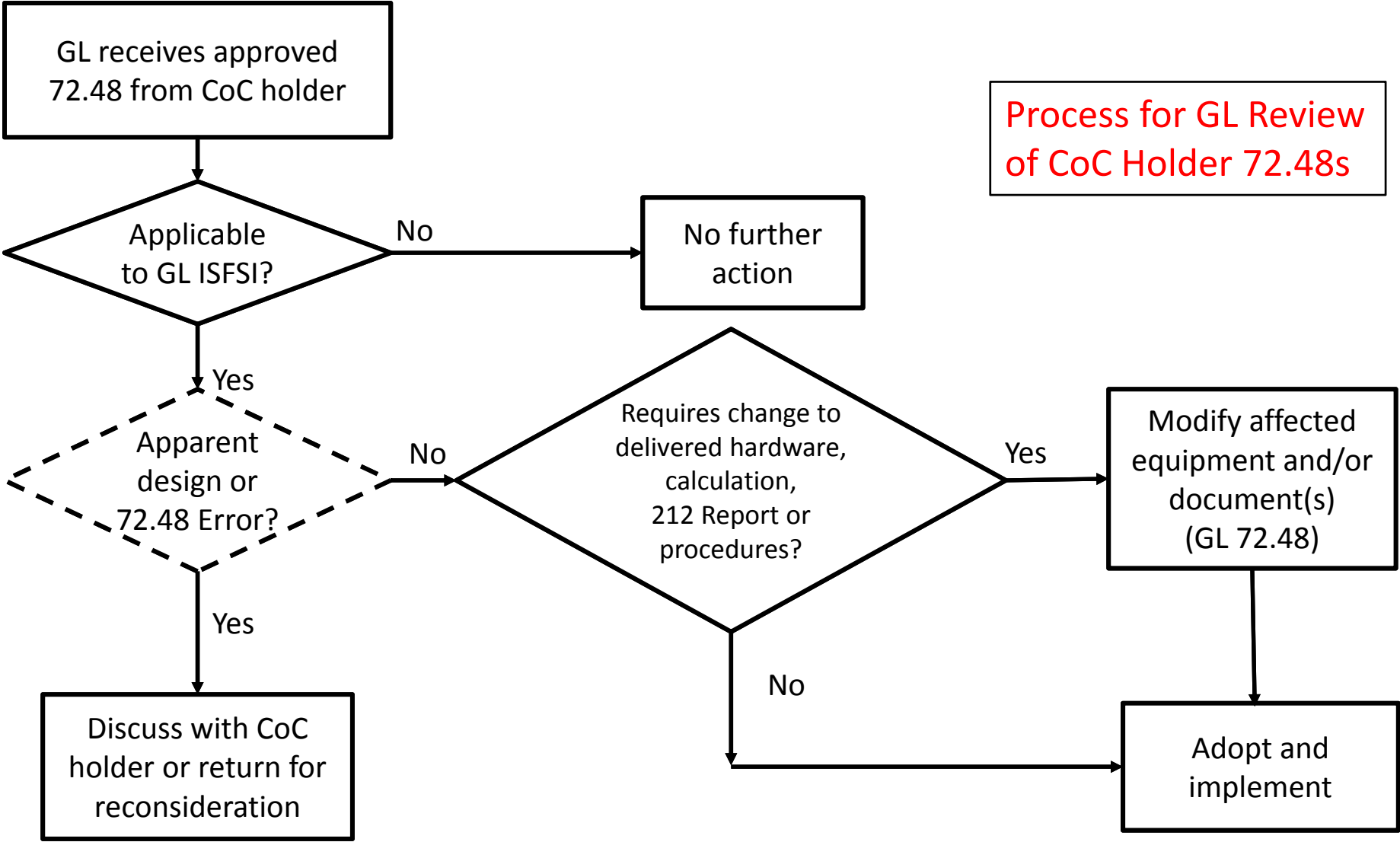
2. GL Processing CoC Holder 72.48s

- 96-07B, Section B4.1.7 further states:
*“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).”***
- Based on experience, GLs appropriately expand this concept to include procedures, calculations, and impacts on delivered hardware

2. GL Processing CoC Holder 72.48s

- 10 CFR 72.48 does not address GLs performing a “suitability review”
- GLs do review CoC holder 72.48s and apply their own 72.48 process where required, consistent with the rule and the endorsed guidance
- Some GLs may choose to go farther
- The GL process for handling CoC holder 72.48s is provided on the following figure

Process for GL Review of CoC Holder 72.48s



3. 72.48 Purpose and Scope versus QA Program

- Summary of NRC comments (NEI 12-04, Sections 1.2 and 2.2.2)
- NRC is challenging the previously endorsed concept that “consequences” in the context of 50.59 and 72.48 means, exclusively, dose to the public.
 - This concept is deeply embedded in industry training and qualification for these change processes
- While there are other consequences of a loss of a design function, ensuring design functions are met is part of the QA program, not 72.48
 - If during a 72.48 review a design or procedural error is discovered that affects confinement, criticality control, or shielding effectiveness, it is addressed in the corrective action program

3. 72.48 Purpose and Scope versus QA Program

- The QA program is distinctly different and separate from the 72.48 review
- The design control element of the QA program is where the proposed design change is reviewed for accuracy, compliance with regulations, and assurance that safety functions will be performed
- Other elements of the QA program similarly address procedures, tests, inspections, and special processes

3. 72.48 Purpose and Scope versus QA Program

- 72.48 is strictly a regulatory review to determine whether an activity that has already been approved internally via the QA program requires prior NRC approval to implement
- Industry and NRC collaboratively decided years ago, as reflected in the updated and endorsed 10 CFR 50.59 guidance, to stop referring to 50.59 reviews as “safety evaluations”
- This philosophy carries over to 72.48

4. Approval of Cask Designs vs. Methods of Evaluation (MOE)

- Summary of NRC comments (NEI 12-04, Section 5.1.5)

- NRC's enclosure pertaining to MOE, paragraph 3:

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

- It is not clear what specific section of the guidance is being alluded to in NRC's comment

4. Approval of Cask Designs vs. Methods of Evaluation (MOE)

- NEI 12-04 MOE guidance follows these principles:
 - Consistency with the currently endorsed guidance in NEI 96-07B
 - Consistency with 50.59 MOE guidance (recently updated in Appendix E to NEI 96-07)
 - Nearly all proposed changes to an MOE must be evaluated against Criterion viii in 10 CFR 72.48(c) to determine whether prior NRC approval is required
 - NEI 96-07B and NEI 12-04 limit screening out MOE changes

4. Approval of Cask Designs vs. Methods of Evaluation (MOE)

- NEI 12-04 adds a step-by-step process for users to first decide whether a proposed activity is a change to an MOE*
- If the activity is a change to an MOE, it automatically screens in and is subject to the 10 CFR 72.48(c)(viii) test to determine if it is a “departure” requiring NRC approval
- If the activity is not a change to an MOE (i.e., merely an altered input parameter), it must be screened to determine whether it is a “change” requiring a full 72.48 evaluation

*Change to an element of a method or a new method

4. Approval of Cask Designs vs. Methods of Evaluation (MOE)

- Consistent with NRC comments, NEI 12-04, Section 6.8 states that methodologies described in an FSAR are not approved for use at other ISFSIs or on other cask designs absent an approved topical report
- NEI 12-04, Section 6.8 also states that MOEs are approved for that ISFSI or that cask system “to the extent the MOEs are used as described in the ISFSI or cask FSAR”
- The intent of this clarification is to reinforce that other activities (e.g., cask modifications) requiring analysis must use the analysis method as described in the approved FSAR

Path Forward for Updated 72.48 Guidance

- NRC considers the information provided here today on these fundamental issues
- Industry submits in a letter for NRC's consideration proposed resolutions to seven other key issues identified in NRC's comments on NEI 12-04 :
 1. Use of the word "change" in 72.48 context
 2. Guidance for changing GL site-specific processes
 3. Mixing GL and SL guidance in NEI 12-04
 4. CoC holder reviews of GL 72.48s
 5. Answering Questions 1-7 versus just Question 8 in 72.48(c)
 6. Requirements for CoC holder and GL submittal of 72.48 reviews to the NRC
 7. Requirements for CoC holder submittal of 72.48 reviews GLs

Path Forward for Updated 72.48 Guidance

- NRC provides written feedback on these 11 fundamental and key issues
- Provided we have alignment on the 11 fundamental and key issues, NEI 12-04 will be revised and re-submitted for NRC endorsement, replacing NEI 96-07, Appendix B

Proposed Schedule

Action	Due Date
Industry letter to NRC addressing 7 additional key issues	March 25, 2016
NRC written response on 11 fundamental and key issues	June 3, 2016
With alignment on issues, Industry submits Revision to NEI 12-04	September 30, 2016
NRC revises RG 3.72 to endorse NEI 12-04	May 31, 2018