



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 30, 2000

MEMORANDUM TO: Susan F. Shankman, Deputy Director
Licensing and Inspection Directorate
Spent Fuel Project Office, NMSS

THRU: Michael Tokar, Chief
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office, NMSS

FROM: Chester Poslusny, Senior Project Manager
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office, NMSS

SUBJECT: MEETING WITH NUCLEAR ENERGY INSTITUTE TO DISCUSS
GUIDANCE FOR IMPLEMENTING CHANGES TO 10 CFR 72.48

On September 7, 2000, representatives from the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Reactor Regulation (NRR), the Nuclear Energy Institute (NEI), and industry conducted a public meeting at the Nuclear Regulatory Commission's (NRC's) office in Rockville, Maryland. Attachment 1 is a list of attendees. The meeting was noticed on August 24, 2000.

The purpose of the meeting was to discuss the disposition of NRC comments and questions on NEI's guidance document for implementing changes to 10 CFR 72.48, NEI 96-07 Appendix B, *Guidelines for 10 CFR 72.48 Evaluations*, dated June 15, 2000. Attachment 2 is a matrix summarizing the staff comments and how NEI dispositioned each. Attachment 3 is a revised redline/strikeout version of the Appendix. The matrix reflects that the majority of the staff comments have been incorporated into the revised guidance document.

The discussions focused on those items in the matrix that require additional clarification, review, and discussion for resolution. Each is discussed as follows:

1. Relationship between 10 CFR 72.102 and 72.48

The NEI guidance states that a certificate of compliance holder or licensee need not evaluate changes affecting a 10 CFR 72.104 dose calculation against 10 CFR 72.48, but instead should evaluate against the regulatory limit included in that section of the regulation. The staff suggested that at a minimum, a change affecting a 10 CFR 72.104 dose should be screened against 10 CFR 72.48 criteria. NEI agreed to reconsider the wording in the guidance document.

2. NRC approved methods

The staff suggested including a more detailed definition in the document but agreed to review the current version in Appendix A and to meet with NRR staff to better understand the approved 10 CFR 50.59 guidance in the same area. It was agreed that a near-term meeting might be needed to resolve the issue.

3. Final Safety Analysis Report (FSAR) of record for a general license

The staff had suggested that a general licensee would establish its design basis (FSAR as updated) when casks were first loaded at an independent spent fuel storage installation (ISFSI), but NEI suggested that the FSAR would be better established as the design basis earlier in the design stage when a vendor provided a certification that the purchase specifications had been incorporated into the safety analysis report (SAR). The staff agreed to revisit this comment and to consider the proposed revision to the Appendix.

4. Review of 10 CFR 72.48 evaluations within a 60-day period of issuance

NEI questioned the safety benefit and vendor responsibility to address this apparent administrative burden. Both the staff and NEI agreed to review the regulatory requirements and basis for this activity. This might result in a revision to the language in the guidance document.

5. Staff comment on criticality basis list

The staff had questioned the items in the table of typical fission product barrier design limits. The reviewer who had developed the question was not present at the meeting, and it was agreed that clarification on the comment would be provided after the meeting.

6. 10 CFR 72.212 versus 10 CFR 72.48 Issue

The current wording in the revised 10 CFR 72.212 states that: *the licensee shall evaluate any changes to the written [72.212] evaluations required by this paragraph using the requirements of 72.48(c)*. In its June 15, 2000, submittal letter, NEI stated that this requirement could result in a general licensee requiring an amendment to a CoC that he cannot request. NEI has addressed this issue in its guidance but suggests that a rule change is needed to clarify the requirement. The staff agreed to revisit this item.

7. Section B.2 discussion of failed fuel

The staff suggested that this section be revised to delete the use of the term "undamaged cladding" because it could cause confusion. NEI agreed to revise this section.

NEI suggested that some type of pilot program be considered to identify how well the program would be implemented either before or after the planned workshop in March 2001. NEI stated that it would consider this option.

No regulatory decisions were made at this meeting. Please contact me if you have any questions about this meeting.

Attachments:

- 1. Attendance List
- 2. Disposition of NRC Comments on NEI 96-07 Appendix B
- 3. Revised Redline/Strikeout Version of Appendix B

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No regulatory decisions were made at this meeting. Please contact me if you have any questions about this meeting.

Attachments:

1. Attendance List
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Attachment 1

Attendance List

**NRC/NEI MEETING
DISCUSS GUIDANCE FOR IMPLEMENTING
CHANGES TO 10 CFR 72.48
SEPTEMBER 7, 2000**

ATTENDANCE LIST

<u>NAME</u>	<u>ORGANIZATION</u>	<u>PHONE</u>
Chet Poslusny	NRC/NMSS/SFPO	301-415-1341
Randy Robins	Virginia Power	804-273-2252
Terry Sides	Southern Nuclear	205-739-8110
Glenn Michael	Arizona Public Service Co.	623-393-5750
Altheia Wyche	SERCH Lichesning/Bechtel	301-228-6401
Dave Foss	PECO Energy	717-456-4311
Tara Neider	Transnuclear	914-347-2345
Robert Quinn	BNFL	831-438-6444
Wayne Hodges	NRC/NMSS/SFPO	301-415-2398
Kim Gruss	NRC/NMSS/SFPO	301-415-8586
Kirke Lathrop	NRC/NMSS/SFPO	301-415-8553
Ken Erwin	NRC/NMSS/SFPO	301-415-2443
Lynnette Hendricks	NEI	202-739-8109
Eileen McKenna	NRC/NRR	301-415-2189
Neil Jensen	NRC/NMSS/SFPO	301-415-1637
Jerry Phillabaum	PECO Energy	610-765-5509
Elaine Keegan	NRC/NMSS/SFPO	301-415-8517
Sheena Whaley	NRC/NMSS/SFPO	301-415-1911
Russ Bell	NEI	202-739-8087
Carl Withee	NRC/NMSS/SFPO	301-415-8534
Randy Hall	NRC/NMSS/SFPO	301-415-1336
Mike Tokar	NRC/NMSS/SFPO	301-415-3567
Phil Brochman	NRC/NMSS/SFPO	301-415-8592
Jack Guttman	NRC/NMSS/SFPO	301-415-8510
Christopher Jackson	NRC/NMSS/SFPO	301-415-2947

Attachment 2
Disposition of NRC Comments
on NEI 96-07 Appendix B

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

General Comments

NRC Comment	Proposed NEI Disposition
1. Include a section to deal with a dual-purpose cask. Discussion is needed to consider effects of a 72.48 change on the Part 71 Certificate of Compliance (CoC).	Added a new Section 1.2.5.
2. UFSAR vs. SAR, FSAR references. Provide a consistent reference to the updated FSAR throughout the document.	Utilized "UFSAR," except in places where a verbatim replication of the regulation was desired and "FSAR (as updated)" was utilized.
3. Define fission product barriers with and without failed fuel. In the case of canned failed fuel, there may not be two barriers.	Clarified Section B2.0. Also, clarified Section B4.3.7 to say that "[e]ven if the cladding is not explicitly credited in the UFSAR as a fission product boundary, such as when damaged fuel is stored in a cask, effects of a proposed activity on cladding should still be considered when answering this 72.48(c)(2)(vii) criteria because the undamaged cladding integrity would continue to be important to maintain retrievability and sub-criticality."
4. Analyses for a cask are done for normal, off normal, and accident conditions. Most of the analysis discussion deals with accidents and accident mitigation. This needs to be modified or clarified.	Clarified various sections, including B2.0 and B4.3.1.
5. Use the term "important to safety" classification instead of "safety related."	Revised as suggested.
6. The terms "Facility" and "ISFSI facility" are used throughout the document. Choose one or the other for consistency.	Revised to "ISFSI Facility."
7. Identify reactor-related references as such, and describe how the references may apply to an ISFSI or cask design.	Revised to specify that these documents were provided as guidance for Part 50 reactor licensees, but may also be useful to ISFSI licensees and cask CoC holders.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<p>8. Replace or remove a number of reactor terms, e.g., plant, train, pump motor change, control rooms, random single failure, loss of offsite power, steam generator tube rupture, failure modes and effects analysis, Class 1E, Seismic Category I, mode changes, ATWS, etc.</p>	<p>Revised as suggested.</p>
<p>9. The guidance states that in evaluating the requirements of 72.48(c)(2)(iii) and (iv) regarding offsite dose consequences, the 72.104 requirements will not be used. The staff believes that there is merit in not applying the minimal standard (e.g., 10% of the margin) to the 72.104 dose limits because the limits are so low (25 mrem). However, the guidance is not clear as to which dose limits should be applied when performing a 72.48 evaluation for an activity that affects an accident that was previously evaluated in the FSAR against the 72.104 dose limits. It is essential that the guidance be clear as to how the offsite consequences need to be evaluated under 72.48(c)(2)(iii) and (iv) for off-normal events; for example, those events in Section 15.2.1 of NUREG-1567, "Standard Review Plan for Spent Fuel Dry Storage Facilities," described in the FSAR.</p> <p>One alternative would be to state in the 72.48 guidance that the acceptance criteria presented in the FSAR be used as the limits for the 72.48(c)(2)(iii) and (iv) evaluations, instead of referring to 72.104 or 106 specifically. We are willing to discuss alternative approaches.</p>	<p>Discussion item.</p>

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<p>10. The definition of "safety analysis" excludes the analysis used to demonstrate compliance with 72.104, excludes normal operation, and is too narrow in scope. The staff recommends deriving the definition of safety analysis from 72.24(d). We propose the following definition:</p> <p style="padding-left: 40px;">Safety analyses are analyses performed pursuant to NRC requirements to demonstrate the design and performance of structures, systems, and components important to safety, with the objective of assessing the impact on public health and safety, resulting from operation of the ISFSI or MRS and including determination of:</p> <p style="padding-left: 80px;">(1) The margins of safety during normal operations and expected operational occurrences during the life of the ISFSI or MRS; and</p> <p style="padding-left: 80px;">(2) The adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents, including natural and manmade phenomena and events.</p>	<p>Discussion item.</p>
<p>11. The document would benefit from adding a table of contents and list of references.</p>	<p>Table of contents will be added.</p>
<p>12. The use and definition of "NRC approved" needs clarification and examples in the document. In addition, the guidance pertaining to NRC approved evaluation methodologies is very broad and could lead to significant uncertainty in the application of the guidance. The staff is particularly concerned that methodologies that have not been approved by NRC may be considered approved by a licensee or vendor using the guidance. This needs</p>	<p>Section B4.3.8.2, which has been updated with the latest NEI 96-07, Rev 1 changes, provides details regarding "NRC approved." In addition, Section B4.3.8.2 points out that licenses/CoC holders must have an adequate understanding of the method and the basis for determining it is approved for use in its intended application, and refers to resources to be used for determining this basis.</p>

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

further discussion and clarification.	
13. The guidance document should include additional examples of application of the 72.48 screening and evaluation process if possible and a reasonable number of examples should include proposed changes that result in requiring NRC approval.	Examples needed.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

Detailed Comments

NRC Comment (Note: Bold type identifies suggested text additions)	NEI Disposition
<u>Page 1 (7)</u>	
Second paragraph: Add as the last sentence: Guidance for implementation of the regulation by a wet ISFSI licensee is not specifically included in this document.	Revised as suggested.
<u>Page 2 (8)</u>	
1. B1.2: Add a discussion of the relationship of 72.48 to 72.104, Subpart F of Part 72, and Part 21.	72.104 is discussed in Section B4.3.3. Subpart F of Part 72 (GDC) is discussed in Section B2.0. Part 21 contains reporting requirements which are outside the scope of this guidance document. Discussing Part 21 in this document would be a deviation from NEI 96-07, Revision 1, and therefore is not recommended.
2. Third Bullet: Suggest that "Quality Assurance" be deleted in third bullet since it has no change process under Part 72.	Revised as suggested.
3. Last Bullet: Suggest mentioning that NEI 99-04 is directed toward reactor licensees but has guidance that is applicable to a CoC holder and Part 72 licensee.	Revised as suggested.
<u>Page 3 (9)</u>	
Second Bullet: Suggest attaching GL 83-11 or noting that the document is available on the NRC website.	Added a paragraph to the "Foreword" stating that: "[t]he NRC documents referenced in this document can be found on the NRC Internet Web site (www.nrc.gov) or may be obtained directly from the NRC. The NEI documents referenced in this document may be found on the NRC Internet Web site (linked from the NRC document that endorses the NEI document), or may be

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

	obtained directly from NEI."
<u>Page 4 (10)</u>	
1. B1.2.3: Clarify how the 50.59 reference applies to casks or ISFSIs.	Revised as suggested.
2. Bottom paragraph: Add the sentence General licensees should adopt and maintain the current FSAR as of the date of first use of the cask at the ISFSI.	<p>Section B3.7 was modified to address this comment by specifying that "[f]or general licensees, the FSAR (as updated) means the FSAR for the cask design used at the ISFSI, as amended (updated) by the CoC holder in accordance with 10 CFR 72.248 (including changes since the last update), and as supplemented by changes made by the general licensee from the cask FSAR under 72.48."</p> <p>The recommended words "adopt ... the current FSAR as of the date of the first use of the cask at the ISFSI" may not capture the licensing bases for the cask design and fabrication that was done prior to use at the ISFSI.</p>
<u>Page 6 (13)</u>	
Section B 1.5, line 6: "allows an ISFSI licensee..."	Revised as suggested.
<u>Page 7 (14)</u>	
1. B2.0, line 4: "design stage for a spent fuel storage cask,"	Revised as suggested.
<p>2. B2.0, line 5: "through the robust design of physical barriers . . . and through the use of shielding to minimize radiation dose to the public for both normal and off-normal conditions of operation . . ."</p> <p>Suggest adding a discussion of the design preventing criticality, ability to withstand postulated accidents and natural phenomena, ensuring fuel retrievability, and heat removal capability.</p>	Revised as suggested.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<p>The discussion of two barriers should be qualified for non-failed fuel and that for failed fuel stored in cans. In the case of a cask with failed fuel, only one fission product barrier, the confinement, will be relied upon.</p>	
<p>3. Last paragraph: Delete reference to engineered safety features, add normal, off-normal, and accident discussion.</p>	<p>Revised as suggested.</p>
<p>4. Last sentence: "the integrity of the barrier(s) will be maintained, and limits established in 10 CFR 72.104 and 72.106 will not be exceeded..."</p>	<p>Discussion item.</p>
<p>5. Last paragraph, line 4: Remove "civil structures" as they are generally not part of the barriers in the context of cladding and confinement.</p>	<p>Revised as suggested.</p>
<p>Page 8 (15)</p>	
<p>1. First sentence: Add a reference to 72.236.</p>	<p>Revised as suggested.</p>
<p>2. Second paragraph, second sentence: "to contain radioactivity and to minimize doses to the public during normal, off normal, and accident conditions."</p>	<p>Discussion item.</p>
<p>3. Next to last paragraph: Add references to SRPs and NUREGs-1567 and -1536.</p>	<p>Revised as suggested.</p>
<p>4. Next to last paragraph: Second and third sentences are incorrect. Discuss normal, off-normal, and accident conditions and the basis for each. <u>See NUREG-1567, page xxx.</u></p>	<p>Discussion item.</p>
<p>5. Last paragraph, line 2: "of the physical barriers during normal, off-normal, and accident conditions..."</p>	<p>Discussion item.</p>

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 9 (16)</u>	
1. First paragraph, line 6: "control rooms, if present,"	Revised as suggested.
2. Add the following at the beginning of the second paragraph: As stated in NUREG-1567, the following are considered the basic nuclear safety criteria for the design of an ISFSI installation: maintain subcriticality, prevent the release of radioactive material above acceptable amounts, ensure radiation rates and doses do not exceed acceptable levels, and maintain retrievability of the stored radioactive materials. At the end of the first sentence of the second paragraph, add and the maintenance of long-term integrity.	Revised as suggested. However, does NUREG-1567 apply to all ISFSI licensees and cask CoC holders?
3. Last paragraph, next to last sentence: "and to impact the ability to meet the design criteria discussed above."	Revised as suggested.
<u>Page 10 (17)</u>	
Suggest adding a definition of normal, off-normal, and accident conditions.	These definitions are already included in Section 4.3.1. Duplicating them in this section would be inconsistent with NEI 96-07, Revision 1.
<u>Page 12 (19)</u>	
Second line: replace "plant" with facility or cask design.	Revised as suggested.
<u>Page 13 (20/21)</u>	
First line: delete "transient".	Unnecessary - the latest NEI 96-07, Rev 1 update changed this paragraph.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 14 (22)</u>	
1. The paragraph under the <u>Conservative vs. Non-Conservative Evaluation Results</u> section discusses a one point evaluation which might not be an acceptable means of verifying that a revised method was acceptable. This should be clarified.	"Conservative vs. Non-conservative evaluation results" is discussed in Section B4.3.8.1.
2. Suggest adding a criticality methodology example to discuss an improper application of a revised method.	Discussion item.
3. Suggest that the guidance include the following example in this section. A licensee makes a change to a methodology and finds it acceptable because the results of current analysis are similar to the original analysis results. He then makes a change to a cask design and uses the revised methodology to determine that the change does not require NRC approval following the guidance in Appendix B. However, he applies the methodology to an unacceptable range and this should be approved by NRC via an amendment. The guidance should address how the 72.48 process would address this situation.	Discussion item.
<u>Page 15 (23)</u>	
Section B3.5: Add discussion of normal, off-normal, and accident conditions.	These conditions are already discussed in Section 4.3.1. Duplicating them in this section would be inconsistent with NEI 96-07, Revision 1.
<u>Page 19 (27)</u>	
Second full paragraph: Delete "Quality Assurance" as there are no change processes for a QA program under Part 72.	Revised as suggested.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 22 (30)</u>	
1. Third bullet right column: Suggest adding benchmarking and correlation ranges.	Revised as suggested.
2. Second bullet in mid page: Add reference to 72.104 and discussion of normal, off-normal, etc.	Discussion item.
<u>Page 23 (32 - top)</u>	
1. Bottom paragraph, line 2: "integrity of the spent fuel cask" or ISFSI...	Revised as suggested.
2. Bottom paragraph: Delete "mitigate" or clarify its use for the cask design since Part 72 does include a reference to the design being able to mitigate the results of an accident, and add reference to 72.104.	Would a berm be an example of something that could "mitigate the consequences of an accident?"
<u>Page 24 (32)</u>	
1. Discussion paragraph, line 2: "cask design's capability to perform its intended functions during normal and off-normal conditions..."	Discussion item.
2. Discussion paragraph: Add as second sentence: "Cask analysis for normal and off-normal conditions are discussed in the applicable sections of the FSAR and . . . These analyses for normal, off-normal, and accident conditions clearly fall within the meaning of "safety analysis" . . ."	Discussion item.
<u>Page 25 (33)</u>	
1. Discussion paragraph: "unanalyzed storage conditions..."	Revised as suggested.
2. Discussion paragraph: Replace "high flow rates" with	Revised as suggested.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<p>high stresses.</p>	
<p><u>Page 27 (35)</u></p>	
<p>1. First paragraph: Replace "technical specifications" with technical specifications/CoC.</p>	<p>Revised as suggested, except changed it to "license/CoC amendment."</p>
<p>2. Second paragraph, line 1: Replace "Another" with A second...</p>	<p>Revised as suggested.</p>
<p>3. Add a third paragraph before B4.1.2 that would begin as: A third situation that would involve 72.48 and another regulation is when a change is proposed for a dual-purpose cask that will affect the Part 71 license. This needs to be discussed further here and in other sections of the guidance.</p>	<p>Revised as suggested.</p>
<p><u>Page 29 (37)</u></p>	
<p>Set of bullets: Suggest that these are too reactor-oriented and should reflect procedures used at an ISFSI.</p>	<p>Revised as suggested.</p>
<p><u>Page 32 (40)</u></p>	
<p>1. Second bullet: "design function or passive design characteristics..."</p>	<p>Revised as suggested.</p>
<p>2. Sixth bullet: "degrade the seismic, structural, heat removal, shielding, or criticality control capability of the SSC or cask?"</p>	<p>Revised as suggested.</p>
<p>3. Seventh bullet: What is the meaning of multiple cask site?</p>	<p>Revised to clarify.</p>

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 33 (44)</u>	
1. Second paragraph: Change "non safety related" to not important to safety (two times plus in third paragraph).	Revised as suggested.
2. Second paragraph, last sentence: Change "cool" to remove heat from.	Revised as suggested.
3. Last paragraph, bullet: Suggest using a more practical example than the valve changeout.	Revised to clarify that the valve is used during loading operations..
<u>Page 34 (46)</u>	
1. First bullet: "material with similar properties including load capacity..."	Revised as suggested.
2. Second bullet: Suggest using an alternative example or adding more detail to the discussion.	Revised as suggested by adding more detail.
<u>Page 35 (47)</u>	
First paragraph: Change "an evaluation" to a 72.48 evaluation.	Revised as suggested.
<u>Page 36 (48/49)</u>	
1. Fourth full paragraph: "in an NRC-approved topical report and its associated SER."	This would be a deviation from NEI 96-07, Revision 1, and therefore is not recommended.
2. Bullet at bottom: "in the applicable NRC-approved topical report and its associated SER."	This would be a deviation from NEI 96-07, Revision 1, and therefore is not recommended.
<u>Page 40 (54)</u>	
Second bullet: Change "plant-specific" to site-specific.	Revised as suggested, but added "ISFSI site-specific."

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 41</u>	
1. B4.3.2, first paragraph: Change "safety related" to important to safety.	Revised as suggested.
2. B4.3.2, third paragraph: Provide a better example than "a motor change on a pump".	Revised by deleting this example.
<u>Page 42 (56)</u>	
Middle paragraph: Discussion of trains and analog to digital upgrade should be modified to better reflect cask designs.	Revised by deleting this discussion.
<u>Page 43 (57)</u>	
Section 3, fourth bullet: Change "plant systems" to cask design functions.	Revised as suggested
<u>Page 44 (57/58)</u>	
1. Top two lines: Provide better example instead of "pump casings".	Revised by deleting this example.
2. Third paragraph: Rewrite to be more cask design specific.	Revised by deleting this example
3. Example: Rewrite to remove discussion of elapsed time as it may not be appropriate in certain climates.	Revised to clarify the example. Note: Not all examples in this guidance document will apply to all licensees and CoC holders because of the large variety of ISFSIs and cask designs. The examples are provided to demonstrate the concepts in a way to help understanding.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 45 (58/59)</u>	
1. Second paragraph: Delete "inside or outside the control room" and replace "reactor accidents" with accidents involving an ISFSI or a cask.	Revised as suggested
2. Third paragraph: Suggest listing cask-related accidents instead of "turbine missiles and flooding".	Revised by changing "turbine missiles" to "tornado missiles."
3. Fourth paragraph: It is not clear why the proposed activities governed by 72.104 are being proposed to be exempt from 72.48 screening and evaluations. This needs clarification or an alternative treatment. See general comment above.	Discussion item.
<u>Page 47 (61)</u>	
Example 1: This example should also address the 72.104 requirements. Suggest adding a qualifier for minimal, <10% of the difference between 1 rem and 5 rem.	Revised this example by adding clarification.
<u>Page 48 (61)</u>	
First paragraph: Delete underlined text and replace with: This would become the 72.212 (b)(2)(i)(A) analysis of record for the modified facility or cask design. Alternatively, the licensee could instead choose to request that the CoC holder obtain NRC approval for the proposed change.	Revised this example by deleting the reference to the 72.212 evaluation, and instead stated that the new dose value would be retained in the record of the 72.48 evaluation. Also added: "If prior NRC approval is required under 72.48, the general licensee could either request that the CoC holder for their cask system submit a CoC amendment request to the NRC under 10 CFR 72.244, if appropriate, or could submit, under 10 CFR 72.7, a request for an exemption to the 72.48(2) provision requiring that a general licensee shall request that the CoC holder obtain a CoC amendment."

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 50 (64)</u>	
Second full paragraph: "random single failure, loss of offsite power, and steam generator tube scenarios" needs to be replaced by cask related discussions.	Revised by deleting this example
<u>Page 51 ((64/65)</u>	
1. First paragraph: Replace "plant" with facility or cask design.	Revised as suggested.
2. First bullet: Add a sentence at the end. Thus, this would require approval by NRC.	Revised as suggested.
3. Second bullet: The use of a pump replacement example should be qualified for ISFSI applicability or replaced by another example.	Revised by deleting this example
<u>Page 52 (66)</u>	
1. Second paragraph: Delete FMEA discussion, replace "system" with facility, delete "event initiators".	Revised as suggested.
2. B4.3.7: Add a discussion of non-failed fuel versus failed fuel and effect on the number of fission product barriers.	Revised by adding: "Even if the cladding is not explicitly credited in the UFSAR as a fission product boundary, such as when damaged fuel is stored in a cask, effects of a proposed activity on cladding should still be considered when answering this 72.48(c)(2)(vii) criteria because the undamaged cladding integrity would continue to be important to maintain retrievability and sub-criticality."
<u>Page 55 (69)</u>	
Table, right column: Clarify the basis for the basis limit list for criticality.	Discussion item.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 56 (70)</u>	
Second paragraph, last sentence: "allowables" and pressure	Revised as suggested.
<u>Page 57 (71)</u>	
Suggest adding a criticality example to this section.	Need example.
<u>Page 58 (72)</u>	
B4.3.8, first paragraph: "design basis" normal, off-normal, and	Discussion item.
<u>Page 59 (73)</u>	
Second line: Suggest defining what "approved by the NRC" means regarding methods and analyses.	Section B4.3.8.2, which has been updated with the latest NEI 96-07, Rev 1 changes, provides details regarding "NRC approved." In addition, Section B4.3.8.2 points out that licenses/CoC holders must have an adequate understanding of the method and the basis for determining it is approved for use in its intended application, and refers to resources to be used for determining this basis.
<u>Page 62 (76)</u>	
1. First paragraph: Second sentence is not true for cask vendors. Vendors have not generally provided topicals to the NRC for methodologies.	Revised to present this in future tense.
2. Third paragraph: Change "plant" to facility or cask design.	Revised as suggested.
<u>Page 63 (77)</u>	
Title: Define what "Technically Appropriate" means.	Unnecessary - the latest NEI 96-07, Rev 1 update changed this paragraph.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 64 (78)</u>	
1. First sub-bullet on bottom: Replace "Class 1E, Seismic Category I" with seismic design basis.	Unnecessary - the latest NEI 96-07, Rev 1 update changed this paragraph.
2. Second sub-bullet on bottom: "specific components" or contents...	Unnecessary - the latest NEI 96-07, Rev 1 update changed this paragraph.
<u>Page 67 (83)</u>	
1. First full paragraph: Delete the underlined section and replace with the following: For those cases where the need for an amendment is identified by a general licensee, the licensee should provide sufficient information to the CoC holder to support a request for amendment to the NRC. The CoC holder, rather than the general licensee, will need to officially request the amendment.	Revised to say: " If prior NRC approval is required under 72.48 for a general licensee, the licensee could either request that the CoC holder for their cask system submit a CoC amendment request to the NRC under 10 CFR 72.244, if appropriate, or, if the change would only apply to their site, could submit, under 10 CFR 72.7, a request for an exemption to the 72.48(2) provision requiring that a general licensee shall request that the CoC holder obtain a CoC amendment."
2. Next to last paragraph: Replace "make mode changes" with continue normal operations of the ISFSI.	Unnecessary - the latest NEI 96-07, Rev 1 update changed this paragraph.
<u>Page 70 (86)</u>	
Fifth paragraph: The last sentence 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." Although this is true, the guidance should recommend that such records be maintained for future review and audits. Such data would be useful for internal evaluations of how well the change process was working.	This paragraph and the referenced paragraph B4.2.3 already say that the documentation for screenings that screen out should be maintained.

DRAFT September 6, 2000
Disposition of NRC's August 18, 2000 comments on NEI 96-07 Appendix B.

<u>Page 72 (88)</u>	
<p>Top of page: Suggest adding: Although not required by regulations, it would be advisable if a general or specific licensee determines that no further action is required after evaluating a 72.48 change developed by another user or the CoC holder, that this determination be documented and maintained for future reference.</p>	<p>Revised by adding at the end of this section: "Documentation of the reviews of the 60-day reports by the recipients should be maintained, but is not required by 10 CFR 72.48."</p>

Attachment 3
Revised Redline/Strikeout Version of
Appendix B

NEI 96-07, Appendix B [Draft]

Nuclear Energy Institute

GUIDELINES FOR 10 CFR
72.48 IMPLEMENTATION

DRAFT - September 1, 2000

ACKNOWLEDGMENTS

To be added

NOTICE

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FOREWORD

To be added

1. References in this document to "site specific licensee" include both ISFSI site specific licensees and applicants for an ISFSI site specific license. References to "CoC holder" include both spent fuel storage cask Certificate of Compliance holders and applicants for a Certificate of Compliance.

2. The NRC documents referenced in this document can be found on the NRC Internet Web site (www.nrc.gov) or may be obtained directly from the NRC. The NEI documents referenced in this document may be found on the NRC Internet Web site (linked from the NRC document that endorses the NEI document), or may be obtained directly from NEI.

TABLE OF CONTENTS

<u>FOREWORD.....</u>	<u>i</u>
<u>1 INTRODUCTION.....</u>	
<u>1.1 PURPOSE.....</u>	
<u>1.2 RELATIONSHIP OF 10 CFR 50.59 TO OTHER REGULATORY</u> <u>REQUIREMENTS AND CONTROLS</u>	
<u>1.2.1 Relationship of 10 CFR 50.59 to Other Processes That</u> <u>Control Licensing Basis Activities</u>	
<u>1.2.2 Relationship of 10 CFR 50.59 to 10 CFR Part 50,</u> <u>Appendix B.....</u>	
<u>1.2.3 Relationship of 10 CFR 50.59 to the UFSAR.....</u>	
<u>1.2.4 Relationship of 10 CFR 50.59 to 10 CFR 50.2 Design</u> <u>Bases.....</u>	
<u>1.2.5 Relationship of 10 CFR 72.48 to the 10 CFR Part 71.....</u>	
<u>1.3 10 CFR 50.59 PROCESS SUMMARY:.....</u>	
<u>1.4 APPLICABILITY TO 10 CFR 72.48.....</u>	
<u>1.5 CONTENT OF THIS GUIDANCE DOCUMENT.....</u>	
<u>2.0 DEFENSE IN DEPTH DESIGN PHILOSOPHY AND 10 CFR 50.59</u>	
<u>3.0 DEFINITIONS AND APPLICABILITY OF TERMS</u>	
<u>3.1 10 CFR 50.59 EVALUATION</u>	
<u>3.2 ACCIDENT PREVIOUSLY EVALUATED IN THE FSAR (AS UPDATED).....</u>	
<u>3.3 CHANGE</u>	
<u>3.4 DEPARTURE FROM A METHOD OF EVALUATION DESCRIBED IN THE</u> <u>FSAR (AS UPDATED).....</u>	
<u>3.5 DESIGN BASES (DESIGN BASIS).....</u>	

3.6 FACILITY AS DESCRIBED IN THE FSAR (AS UPDATED)	
3.7 FINAL SAFETY ANALYSIS REPORT (AS UPDATED)	
3.8 INPUT PARAMETERS	
3.9 MALFUNCTION OF AN SSC IMPORTANT TO SAFETY	
3.10 METHODS OF EVALUATION	
3.11 PROCEDURES AS DESCRIBED IN THE FSAR (AS UPDATED)	
3.12 SAFETY ANALYSES	
3.13 SCREENING	
3.14 TESTS OR EXPERIMENTS NOT DESCRIBED IN THE FSAR (AS UPDATED)	
4 IMPLEMENTATION GUIDANCE	
4.1 APPLICABILITY	
4.1.1 Applicability to Licensee Activities	
4.1.2 Maintenance Activities	
4.1.3 UFSAR Modifications	
4.1.4 Changes to Procedures Governing the Conduct of Operations	
4.1.5 Changes to Approved Fire Protection Programs	
4.2 SCREENING	
4.2.1 Is the Activity a Change to the Facility or Procedures as Described in the UFSAR?	
4.2.3 Screening Documentation	
4.3 EVALUATION PROCESS	50

- 4.3.1 Does the Activity Result in More Than a Minimal Increase in the Frequency of Occurrence of an Accident?.....
- 4.3.2 Does the Activity Result in More Than a Minimal Increase in the Likelihood of Occurrence of a Malfunction of an SSC Important to Safety?
- 4.3.3 Does the Activity Result in More Than a Minimal Increase in the Consequences of an Accident?.....
- 4.3.4 Does the Activity Result in More Than a Minimal Increase in the Consequences of a Malfunction?.....
- 4.3.5 Does the Activity Create a Possibility for an Accident of a Different Type?
- 4.3.6 Does the Activity Create a Possibility for a Malfunction of an SSC Important to Safety with a Different Result?
- 4.3.7 Does the Activity Result in a Design Basis Limit for a Fission Product Barrier Being Exceeded or Altered?.....
- 4.3.8 Does the Activity Result in a Departure from a Method of Evaluation Described in the UFSAR Used in Establishing the Design Bases or in the Safety Analyses?
- 4.3.8.1 Guidance for Changing One or More Elements of a Method of Evaluation
- 4.3.8.2 Guidance for Changing from One Method of Evaluation to Another
- 4.3.8.3 EXAMPLES
- 4.4 APPLYING 10 CFR 50.59 TO COMPENSATORY ACTIONS TO ADDRESS NONCONFORMIN
- 4.5 DISPOSITION OF 10 CFR 50.59 EVALUATIONS.....

5.0 DOCUMENTATION AND REPORTING.....

ATTACHMENTS

- 1. 10 CFR 72.48—CHANGES, TESTS, AND EXPERIMENTS.....

NEI 96-07, Appendix B:
Guidelines for 10 CFR 72.48 Evaluations
(Draft ~~September 1~~ June 9, 2000)

B1 INTRODUCTION

B1.1 PURPOSE

10 CFR 72.48 establishes the conditions under which an independent spent fuel storage installation (ISFSI) licensee, a monitored retrievable storage installation (MRS) licensee, or a spent fuel storage cask certificate holder may make changes in the ISFSI facility, spent fuel storage cask design, or procedures, and conduct tests or experiments without prior NRC approval. Proposed changes, tests and experiments (hereafter referred to collectively as activities) that satisfy the definitions and one or more of the criteria in the rule must be reviewed and approved by the NRC before implementation. Thus 10 CFR 72.48 provides a threshold for regulatory review—not the final determination of safety—for proposed activities.

The purpose of this Appendix B to NEI 96-07 is to provide guidance for developing effective and consistent 10 CFR 72.48 implementation processes. This guidance document addresses the implementation of 10 CFR 72.48 by ISFSI licensees and CoC holders for spent fuel dry cask storage. Guidance for implementation of 10 CFR 72.48 by a wet ISFSI licensee is not specifically included in this document.

10 CFR 72.48 was revised by the NRC to conform with the revised 10 CFR 50.59 to provide for consistent implementation of these two analogous regulations. Therefore, as stated in the foreword and in Section 1.4 of NEI 96-07, the guidance of NEI 96-07 may be applied to support the implementation of 10 CFR 72.48. This Appendix was developed by starting with the guidance of NEI 96-07 for 50.59 and modifying wording only as needed to apply to 72.48. The modifications from NEI 96-07 are identified in bold lettering.

B1.2 RELATIONSHIP OF 10 CFR 72.48 TO OTHER REGULATORY REQUIREMENTS AND CONTROLS

As the process for controlling most changes to ISFSI and spent fuel storage cask design activities, implementation of 10 CFR 72.48 interfaces with many other regulatory requirements and controls. To optimize the use of 10 CFR 72.48, the rule and this guidance should be understood in the context of the proper relationship with these other regulatory processes. These relationships are described below:

B1.2.1 Relationship of 10 CFR 72.48 to Other Processes that Control Licensing Basis Activities

10 CFR 72.48 focuses on the effects of proposed activities on the safety analyses that are contained in the updated FSAR (UFSAR) for the ISFSI or spent fuel storage cask and are a cornerstone of each ISFSI's or spent fuel storage cask's licensing basis. In addition to 10 CFR 72.48 control of changes affecting the safety analyses, there are several other complementary processes for controlling activities that affect other aspects of the licensing basis:

- Amendments to a specific ISFSI License (including the technical specifications) are sought and obtained under 10 CFR 72.56.
- Amendments to a cask certificate of compliance (CoC) (including terms, conditions, and specifications) are sought and obtained by the certificate holder under 72.244 (for the certificate holder and for general licensees).
- Where changes to the ISFSI facility, cask design, or procedures are controlled by more specific regulations (e.g., ~~quality assurance~~, security and emergency preparedness program changes controlled under other Part 72 provisions), 10 CFR 72.48(c)(4) states that the more specific regulation applies.
- Changes that require an exemption from a 10 CFR Part 72 regulation are processed in accordance with 10 CFR 72.7.
- Guidance for controlling changes to licensee commitments is provided by NEI 99-04, *Guideline for Managing NRC Commitment Changes*. (Note: Although this guidance was developed for power reactor licensees, and endorsed for

those licensees by the NRC in SECY-00-045 and Office Letter 900, Revision 0, it may also provide useful guidance to Part 72 licensees and CoC holders.

- **The Maintenance Rule, 10 CFR 50.65; does not apply to an ISFSI or spent fuel storage cask licensed or certified under 10 CFR Part 72. Therefore, the guidance in NEI 96-07 concerning the application of the maintenance rule for temporary changes associated with maintenance does not apply to the ISFSI or spent fuel storage cask activities under Part 72.**
- **Guidance for licensee qualification to use generically approved analysis methods is provided in NRC Generic Letter (GL) 83-11, Supplement 1. For 10 CFR 50.59 guidance, Section 4.3.8.2 of NEI 96-07 refers licensees to GL 83-11, Supplement 1, to demonstrate they are generally qualified to perform safety analyses in order to change from one method of evaluation to another. The guidance of GL 83-11, Supplement 1, should also be utilized by ISFSI licensees and cask certificate holders when evaluating proposed changes to methods of evaluation. See Section B4.3.8.2 for more detail.**

Together with 10 CFR 72.48, these processes form a framework of complementary regulatory controls over the ISFSI or spent fuel storage cask licensing basis. To optimize the effectiveness of these controls and minimize duplication and undue burden, it is important to understand the scope of each process within the regulatory framework. This guideline discusses the scope of 10 CFR 72.48 in relation to other processes, including circumstances under which different processes, e.g., 10 CFR 72.48 and 10 CFR 72.56/72.244, should be applied to different aspects of an activity.

In addition to controlling changes to the ISFSI facility, spent fuel storage cask design, and procedures described in the UFSAR under 10 CFR 72.48 as required by the rule, some licensees and certificate holders also control changes to other licensing basis information using the 10 CFR 72.48 process. This may be in accordance with a requirement of the license or commitment to the NRC. An example of documentation that may be outside the UFSAR but that is controlled via 10 CFR 72.48 by licensees or CoC holders could be the Technical Specifications Bases.

B1.2.2 Relationship of 10 CFR 72.48 to 10 CFR Part 72, Subpart G

Prior to the ISFSI license or spent fuel storage cask CoC, 10 CFR Part 72, Subpart G, assures that the ISFSI facility and spent fuel storage cask design and construction meet applicable requirements, codes and standards in accordance with the safety classification of systems, structures and components (SSCs). Subpart G design control provisions ensure that all changes continue to meet applicable design and quality requirements. The design and licensing bases evolve in accordance with Subpart G requirements up to the time that an ISFSI license or spent fuel storage cask CoC is received, and 10 CFR 72.48 is not applicable until after that time. Both Subpart G and 10 CFR 72.48 apply following receipt of an ISFSI license or spent fuel storage cask CoC.

Subpart G also addresses corrective action. The application of 10 CFR 72.48 to ~~corrective actions~~ compensatory measures that address degraded and non-conforming conditions is described in Section B4.4.

B1.2.3 Relationship of 10 CFR 72.48 to the UFSAR

The 10 CFR 72.48 is the process that identifies when a license or CoC amendment is required prior to implementing changes to the ISFSI facility, spent fuel storage cask design, or procedures described in the UFSAR or tests and experiments not described in the UFSAR. As such, it is important that the UFSAR be properly maintained and updated in accordance with 10 CFR 72.70 (specific licensees) or 10 CFR 72.248 (cask certificate holders). For Part 50 power reactor licensees, guidance for updating reactor UFSARs to reflect activities implemented under 10 CFR 50.59 is provided by Regulatory Guide 1.181, which endorses NEI 98-03, Revision 1, Guidelines for Updating Final Safety Analysis Reports. The requirements in 10 CFR 72.70 and 72.248 to update the ISFSI and cask FSARs were written by the NRC to closely conform to the reactor FSAR update requirements in 10 CFR 50.71(e). Therefore, the guidance of NEI 98-03, Revision 1 can be generally utilized may also provide useful guidance to ISFSI licensees and cask CoC holders for updating the ISFSI and cask FSARs as required by 10 CFR 72.70 and 72.248. The requirements in 10 CFR 72.70 and 72.248 to update the ISFSI and cask FSARs were written by the NRC to closely conform to the reactor FSAR update requirements in 10 CFR 50.71(e).

Changes made to the UFSAR by a specific licensee would be incorporated into the site-specific ISFSI UFSAR as required by 10 CFR 72.70.

Changes made to the cask UFSAR by the certificate holder would be incorporated into the cask UFSAR as required by 10 CFR 72.248.

General licensees should adopt and maintain the current UFSAR that is used at their ISFSI. Changes made from the applicable cask FSAR by the general licensee would be identified in the required 72.48 screening/evaluation records. Although not required, the general licensee changes from the cask FSAR may be compiled in the on-site 72.212 evaluations document, or may be incorporated in a separate on-site document to assist 72.48 screeners/evaluators. Changes made by the general licensee to the ISFSI 10 CFR 72.212 evaluation would be maintained on site as required by 10 CFR 72.212(b)(2)(iii).

B1.2.4 Relationship of 10 CFR 72.48 to 10 CFR 72.3 Design Bases

10 CFR 72.48 controls changes to both 10 CFR 72.3 design bases and supporting design information contained in the UFSAR. In support of 10 CFR 72.48 implementation, Section B4.3.7 of this guideline defines the design basis limits for fission product barriers that are subject to control under 10 CFR 72.48(c)(2)(vii), and Section B4.3.8 provides guidance on the scope of methods of evaluation used in establishing design bases or in the safety analyses that are subject to control under 10 CFR 72.48(c)(2)(viii). Additional guidance for identifying 10 CFR 50.2 design bases is provided in NEI 97-04, Appendix B. Since the NRC authored 10 CFR 72.48 to conform to 10 CFR 50.59, and the definition of design bases in 10 CFR 72.3 is very similar to that in 10 CFR 50.2, the guidance of Appendix B of NEI 97-04, Revision 1, for Part 50 design bases may also be used for 10 CFR 72.48. See Section B3.5 for more details.

As discussed in Section B3.3, "design bases functions" (defined in NEI 97-04, Appendix B) are a subset of "design functions" for purposes of 10 CFR 72.48 screening.

B1.2.5 Relationship of 10 CFR 72.48 to 10 CFR Part 71

Some spent fuel dry cask storage systems are designed as "multipurpose" cask systems, which are issued a CoC under 10 CFR Part 72 for storage and a CoC under 10 CFR Part 71 for transportation. These systems also have separate UFSARs for the Part 72 certification and the Part 71 certification. 10 CFR 72.48 controls activities only with respect to the design and licensing bases of the cask storage system certified under Part 72. When activities are proposed for a multipurpose cask system that is certified under both Part 72 and Part 71, the activities may affect the Part 71 transportation design and licensing bases. Activities that affect Part 71 design and licensing bases need to be assessed and controlled under Part 71 requirements, and are outside the scope of this document.

B1.3 10 CFR 72.48 PROCESS SUMMARY:

After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR 72.48 process is applied. This process involves the following basic steps as depicted in Figure B1:

- **Applicability and Screening:** Determine if a 10 CFR 72.48 evaluation is required.
- **Evaluation:** Apply the eight evaluation criteria of 10 CFR 72.48(c)(2) to determine if a license amendment (for specific licensees) or CoC amendment (for general licensees and certificate holders) must be obtained from the NRC.
- **Documentation & reporting:** Document and report to the NRC, and to appropriate licensees or certificate holders, activities implemented under 10 CFR 72.48.

Later sections of this appendix discuss key definitions, provide guidance for determining applicability, screening, and performing 10 CFR 72.48 evaluations, and present examples to illustrate the application of the process.

B1.4 APPLICABILITY TO 10 CFR 50.59

Concurrent with the rulemaking to amend 10 CFR 50.59, the NRC made conforming changes to the analogous provisions in 10 CFR 72.48.

controlling licensee changes, tests and experiments to independent spent fuel storage installations (ISFSIs). The provisions of 10 CFR 72.48 were also extended to holders of Part 72 Certificates of Compliance. As a result, 10 CFR 72.48 establishes criteria identical to those in 10 CFR 50.59 under which both an ISFSI license holder and a certificate holder may make changes to the ISFSI facility or cask design, changes to procedures and conduct tests or experiments without prior NRC approval.

The intent of conforming 10 CFR 72.48 to the terms of 10 CFR 50.59 was to provide for consistent implementation of these two analogous regulations.

B1.5 CONTENT OF THIS GUIDANCE DOCUMENT

The NRC has established requirements for ISFSIs and spent fuel storage cask systems, structures and components to provide reasonable assurance of adequate protection of the public health and safety. Many of these requirements, and descriptions of how they are met, are documented in the ISFSI or spent fuel storage cask updated FSAR (UFSAR). 10 CFR 72.48 allows an ISFSI licensee or spent fuel storage cask certificate holder to make changes in the ISFSI facility, spent fuel storage cask design, or procedures as described in the UFSAR, and to conduct tests or experiments not described in the UFSAR, unless the changes require a change in the technical specifications or spent fuel storage cask CoC or otherwise require prior NRC approval. In order to perform 10 CFR 72.48 screenings and evaluations, an understanding of the design and licensing basis of the ISFSI facility and spent fuel storage cask design and of the specific requirements of the regulations is necessary. Individuals performing 10 CFR 72.48 screenings and evaluations should also understand the rule and concepts discussed in this guidance document.

In Section B2, the relationship between the design criteria established in 10 CFR 72, Subpart F, and 10 CFR 72.48 is discussed as background for applying the rule.

Section B3 presents definitions and discussion of key terms used in 10 CFR 72.48 and this guideline.

Section B4 discusses the application of the definitions and criteria presented in 10 CFR 72.48 to the process of changing the ISFSI facility, spent fuel storage cask design, or procedures and the conduct of tests or experiments. This section includes guidance on the

applicability requirements for the rule, the screening process for determining when a 10 CFR 72.48 evaluation must be performed, and the eight evaluation criteria for determining if prior NRC approval is required. Examples are provided to reinforce the guidance. Guidance is also provided on dispositioning and documenting 10 CFR 72.48 evaluations and reporting to NRC and to the spent fuel storage cask users or the certificate holders.

Section B5 provides guidance on documenting 10 CFR 72.48 evaluations and reporting to NRC and to the other spent fuel storage cask users or certificate holders.

B2.0 DEFENSE IN DEPTH DESIGN PHILOSOPHY AND 10 CFR 72.48

One objective of Title 10 of the Code of Federal Regulations is to establish requirements directed toward protecting the health and safety of the public from the uncontrolled release of radioactivity. At the design stage for a spent fuel storage cask, protection of public health and safety is ensured through the robust design of the engineered protection of physical barriers to guard against the uncontrolled release of radioactivity and through the use of shielding to minimize radiation dose to the public from both normal and off-normal conditions of operation. The defense-in-depth philosophy includes reliable design provisions to (1) prevent criticality, (2) withstand postulated accidents and natural phenomena, (3) ensure fuel retrievability, and (4) provide heat removal capability ~~safely terminate accidents and provisions to mitigate the consequences of accidents~~. The two physical barriers that typically provide defense-in-depth are:

- Fuel Clad
- Spent Fuel Cask Confinement Boundary

These barriers perform a health and safety protection function. For storage of failed fuel, alternative barriers may be used to provide functions served by the fuel clad, such as retrievability and criticality prevention (configuration of the fuel). They barriers are designed to reliably fulfill their operational function by meeting all criteria and standards applicable to mechanical components, and pressure components, ~~and civil structures~~. ~~These barriers are protected extensively by inherent safety features and through the implementation of engineered safety features~~. The public health and safety protection functions are analytically demonstrated

and documented in the UFSAR. Analyses summarized in the UFSAR demonstrate that under the assumed accident conditions, the consequences of accidents challenging the integrity of the barriers will not exceed limits established in 10 CFR 72.106. **In addition, the confinement barriers and systems must meet the criteria established in 10 CFR 72.122(h) for specific and general licensees, and 10 CFR 72.236 for CoC holders.** Thus, the UFSAR analyses provide the final verification of the nuclear safety design phase by documenting **ISFSI facility and/or spent fuel storage cask performance in terms of public protection from uncontrolled releases of radiation.** 10 CFR 72.48 addresses this aspect of design by requiring prior NRC approval of proposed activities which, although safe, require a technical specification or CoC change or meet specific threshold criteria for NRC review.

This protection philosophy pervades the UFSAR accident analyses and Title 10 of the CFR. To understand and apply 10 CFR 72.48, it is necessary to understand this perspective of maintaining the integrity of the physical barriers designed to contain radioactivity. This is because:

- UFSAR accidents and malfunctions are analyzed in terms of their effect on the physical barriers. There is a relationship between barrier integrity and dose.
- The principal "consequences" that the physical barriers are designed to preclude is the uncontrolled release of radioactivity. Thus for purposes of 10 CFR 72.48, the term "consequences" means dose.

For many ISFSI licensees and spent fuel storage cask CoC holders, NRC Standard Review Plan (SRP, including NUREG-1536 or NUREG-1567) guidelines define categories of accidents or malfunctions. The categories are (1) off-normal events (also known as anticipated occurrences), expected to occur with moderate frequency or once per calendar year, and (2) accident events, considered to occur infrequently, if ever, during the lifetime of the facility/cask. For each category a probability (frequency) and a corresponding acceptable consequence is given in terms of barrier loss and radioactivity release. Consequences resulting from accidents and malfunctions are analyzed and documented in the UFSAR and are evaluated against dose acceptance limits that vary depending on the event frequency.

The design effort and the operational controls necessary to ensure the required performance of the physical barriers during postulated accidents off-normal and accident conditions are extensive. Because 10 CFR 72.48 provides a mechanism for determining if NRC approval is needed for activities affecting ISFSI facility and spent fuel storage cask design and operation, it is helpful to review briefly the requirements and the objectives imposed by the CFR on ISFSI facility and spent fuel storage cask design, construction and operation. The review will define more clearly the extent of applicability of 10 CFR 72.48.

Subpart F to 10 CFR Part 72 provides General Design Criteria for ISFSI and spent fuel storage cask designs. 10 CFR 72.122(h) of Subpart F includes criteria for protection by the confinement barriers and systems. The criteria establish requirements for inherent protection, instrumentation and control, confinement barriers and systems, control rooms (if present), electric power systems, and related inspection and testing. All of these requirements concentrate on protecting fission product barriers either through inherent or mitigative means.

As stated in NUREG-1567, the following are considered the basic nuclear safety criteria for the design of an ISFSI installation, maintain subcriticality, prevent the release of radioactive material above acceptable amounts, ensure radiation rates and doses do not exceed acceptable levels, and maintain retrievability of the stored radioactive materials. 10 CFR 72.124 of Subpart F establishes extensive requirements on ISFSI and spent fuel storage cask criticality safety, the objectives again being the protection of fission product barriers and the maintenance of long-term integrity. With similar intent, other Sections of Subpart F to Part 72 provide extensive design, inspection, testing, and operational requirements for the quality of the ISFSI and spent fuel storage cask. These requirements ensure inherent and engineered protection of the fission product barriers. 10 CFR 72.122(a) of Subpart F imposes requirements on the quality of implemented protection and the conditions under which these systems must function without loss of capability to perform their safety functions. These conditions include natural phenomena, fire, operational and accident generated environmental conditions.

The implementation of this design philosophy requires extensive accident analyses to define the correct relationship among nominal operating conditions, functional and operating limits, and limiting conditions for operations in order to protect the integrity of the

stored fuel or waste container, to protect employees against occupational exposures and to guard against the uncontrolled release of radioactive materials. The specific license UFSAR, the spent fuel storage cask UFSAR, and the general license 10 CFR 72.212 evaluations present the set of limiting analyses required by NRC. The limiting analyses are utilized to confirm the systems and equipment design, to identify critical setpoints and operator actions, and to support the establishment of technical specifications. Therefore, the results of the UFSAR accident analyses assume functioning of all the equipment (and under the conditions) specified by NRC regulations or requirements. Changes to an ISFSI facility, spent fuel storage cask design and operation or general license 10 CFR 72.212 evaluation, and to conduct of new tests and experiments have the potential to affect the probability and consequences of accidents, to create new accidents and to impact the integrity of fission product barriers. Therefore, these activities are subject to 10 CFR 72.48.

B3.0 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

- B3.1 10 CFR 72.48 Evaluation
- B 3.2 Accident Previously Evaluated in the FSAR (as updated)
- B 3.3 Change
- B 3.4 Departure from a Method of Evaluation Described in the FSAR (as updated) Used in Establishing the Design Bases or in the Safety Analyses
- B 3.5 Design Bases (Design Basis)
- B 3.6A Facility
- B 3.6B Facility or Spent Fuel Storage Cask Design as Described in the FSAR (as updated)
- B 3.7 Final Safety Analysis Report (as updated)
- B 3.8 Input Parameters
- B 3.9 Malfunction of an SSC Important to Safety
- B 3.10 Methods of Evaluation

- B 3.11** Procedures as described in the FSAR (as updated)
- B 3.12** Safety Analyses
- B 3.13** Screening
- B 3.14** Tests or experiments not described in the FSAR (as updated)

B3.1 10 CFR 72.48 EVALUATION

Definition:

A 10 CFR 72.48 evaluation is the documented evaluation against the eight criteria in 10 CFR 72.48(c)(2) to determine if a proposed change, test or experiment requires prior NRC approval via license amendment under 10 CFR 72.56 (specific licensee) or CoC amendment under 72.244 (cask certificate holder, for itself or for a general licensee).

Discussion:

It is important to establish common terminology for use relative to the 10 CFR 72.48 process. The definitions of *10 CFR 72.48 Evaluation* and *Screening* are intended to clearly distinguish between the process and documentation of licensee screenings and the further evaluation that may be required of proposed activities against the eight criteria in 10 CFR 72.48(c)(2). ~~While many ISFSI or cask activities are subject to a screening, only changes to the ISFSI facility or spent fuel storage cask design or procedures described in the UFSAR, and tests or experiments not described in the UFSAR, require evaluation and reporting to NRC under 10 CFR 72.48. Section B4.3 provides guidance for performing 10 CFR 72.48 evaluations. See also Section B3.13 on the definition of "screening."~~ The screening process is discussed in Section B4.2

The phrase "change made under 10 CFR 72.48" (or equivalent) refers to changes subject to the rule (see Section B4.1) that either screened out of the 10 CFR 72.48 process or did not require prior NRC approval based on the results of a 10 CFR 72.48 evaluation. Similarly, the phrases "10 CFR 72.48 applies [to an activity]" or "[an activity] is subject to 10 CFR 72.48" mean that screening, and if necessary, evaluation is required for the activity. The "10 CFR 72.48 process" includes screening, evaluation, documentation and reporting to NRC of activities subject to the rule.

B3.2 ACCIDENT PREVIOUSLY EVALUATED IN THE FSAR (AS UPDATED)**Definition:**

Accident previously evaluated in the FSAR (as updated) means a design basis accident or event described in the **ISFSI or spent fuel storage cask UFSAR** including accidents, such as those typically analyzed in the **accident analyses section(s)** of the UFSAR, and events the **ISFSI facility or cask design** is required to withstand such as floods, fires, earthquakes, and other external hazards.

Discussion:

The term "accidents" refers to the ~~anticipated (or abnormal) operational transients and postulated design basis accidents~~ that are analyzed to demonstrate that the **ISFSI facility and spent fuel storage casks** can be operated without undue risk to the health and safety of the public. For purposes of 10 CFR 72.48, ~~the term~~ "accidents" encompasses other events for which the ~~plant~~ **ISFSI or cask design** is required to cope and which are described in the UFSAR (e.g., tornado missiles, fire, earthquakes and flooding).

Accidents also include new transients or postulated events added to the licensing basis based on new NRC requirements and reflected in the UFSAR pursuant to 10 CFR 72.70 (specific licensee) or 72.248 (certificate holder and general licensee).

B3.3 CHANGE**Definition:**

Change means 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.

Discussion:

Additions and removals to the **ISFSI facility or spent fuel storage cask design** or procedures can adversely impact the performance of SSCs and the bases for the acceptability of their design and operation. Thus the definition of change includes modifications of an existing provision (e.g., SSC design requirement, analysis method or parameter), additions or removals (physical removals, abandonment,

or non-reliance on a system to meet a requirement) to the ISFSI facility or spent fuel storage cask design or procedures.

The definitions of "change...", "facility or spent fuel storage cask design ..." (see Section B3.6b), and "procedures..." (see Section B3.11) make clear that 10 CFR 72.48 applies to changes to underlying analytical bases for the ISFSI facility or cask design and operation as well as for changes to SSCs and procedures. Thus 10 CFR 72.48 should be applied to a change being made to an evaluation for demonstrating adequacy of the ISFSI facility or cask design even if no physical change to the ISFSI facility or cask design is involved. Further discussion of the terms in this definition is provided as follows:

Design functions are UFSAR-described design bases functions and other SSC functions described in the UFSAR that support or impact design bases functions. Implicitly included within the meaning of design function are the conditions under which intended functions are required to be performed, such as equipment response times, process conditions, equipment qualification and single failure.

Design bases functions are functions performed by SSCs that are (1) required to meet regulations, license conditions, orders or technical specifications, or (2) credited in safety analyses to meet NRC requirements.¹

UFSAR description of design functions may identify what SSCs are intended to do, when and how design functions are to be performed, and under what conditions. Design functions may be performed by important-to-safety SSCs or non-important-to-safety SSCs and include functions that, if not performed, would initiate an accident that the ISFSI or cask design is required to withstand.

As used above, "credited in the safety analyses" means that, if the SSC were not to perform its design function in the manner described, the assumed initial conditions, mitigative actions or other information in the analyses would no longer be within the range evaluated (i.e., the analysis results would be called into question). The phrase "support or impact design bases functions" refers both to those SSCs needed to support design bases functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design bases functions (for instance, control systems and physical arrangements). Thus, both important-to-safety and non-

¹ Definition of design bases function from NEI 97-04, Appendix B (endorsed by DG-1093).

important-to-safety SSCs may perform design functions. ~~Design function means an SSC function that is credited in safety analyses or that supports or impacts an SSC function credited in safety analyses. This may include (1) functions performed by safety-related SSCs or non-safety related SSCs, and (2) functions of non-safety related SSCs that, if not performed, would initiate a transient or accident. Design functions include the conditions under which intended functions are required to be performed, such as equipment response times, environmental and process conditions, equipment qualification, and single failure.~~

Method of performing or controlling a function means how a design function is accomplished as credited in the safety analyses, including specific operator actions, procedural step or sequence, or whether a specific function is to be initiated by manual versus automatic means. For example, substituting a manual actuation for automatic would constitute a change to the method of performing or controlling the function.

Evaluation that demonstrates that intended functions will be accomplished means the method(s) used to perform the evaluation (as discussed in Section B3.10). For example, a thermodynamic calculation that demonstrates the storage cask design has sufficient heat removal capacity for responding to a postulated accident.

Temporary Changes

Temporary changes to the ISFSI facility or spent fuel storage cask design or procedures, such as placing temporary lead shielding on equipment, removal of barriers and use of temporary scaffolding and supports, are made to facilitate a range of plant ISFSI or cask activities and are subject to 10 CFR 72.48 as follows:

- 10 CFR 72.48 should be applied to temporary changes proposed as compensatory measures to address degraded or non-conforming conditions as discussed in Section B4.4.
- Other temporary changes to the ISFSI facility or spent fuel storage cask design or procedures are subject to 10 CFR 72.48 in the same manner as permanent changes, to determine if prior NRC approval is required. Screening and, as necessary, evaluation of such temporary changes may be considered as part of the screening/evaluation of the proposed permanent change.

The Maintenance Rule, 10 CFR 50.65, does not apply to an ISFSI or to a spent fuel storage cask licensed or certified under 10 CFR Part 72. The guidance of NEI 96-07 in the context of 10 CFR 50.59 for assessing and managing temporary changes associated with maintenance activities in accordance with 10 CFR 50.65(a)(4) would not apply to ISFSI/cask changes.

B3.4 DEPARTURE FROM A METHOD OF EVALUATION DESCRIBED IN THE FSAR (AS UPDATED) USED IN ESTABLISHING THE DESIGN BASES OR IN THE SAFETY ANALYSES

Definition:

Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses means (i) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Discussion:

The 10 CFR 72.48 definition of "departure ..." provides licensees with flexibility to make changes in methods of evaluation that are "conservative" or that are not important with respect to demonstrating that SSCs can perform their intended design functions. See also the definition and discussion of "methods of evaluation" in Section B3.10. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR 72.48(c)(2)(viii) is provided in Section B4.3.8.

Conservative vs. Non-Conservative Evaluation Results

Gaining margin by revising an element of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR 72.48. Such departures require prior NRC approval of the revised method. In other words, analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change in an element of a method of evaluation that changes the result of a cask peak pressure analysis from 45 psig to 48 psig (with design basis limit of 50 psig) would be considered a conservative change for purposes of 10 CFR 72.48(c)(2)(viii). This is because results closer to limiting values are considered conservative in the sense that the new analysis result

provides less margin to applicable limits for making future physical or procedure changes without a license amendment.

If use of a modified method of evaluation resulted in a change in calculated cask peak pressure from 45 psig to 40 psig, this would be non-conservative. This is because the change would result in more margin being available (to the design basis limit of 50 psig) for a licensee to make more significant future changes to the physical cask or procedures.

“Essentially the Same”

Licensees may change one or more elements of a method of evaluation such that results move in the non-conservative direction without prior NRC approval, provided the results are “essentially the same” as the previous result. Results are “essentially the same” if they are within the margin of error for the type of analysis being performed. Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) would typically be within the analysis margin of error and thus considered “essentially the same.”

“Approved by the NRC for the Intended Application”

Rather than make a minor change to an existing method of evaluation, a licensee may also adopt completely new methodology without prior NRC approval provided the new method is approved by the NRC for the intended application. A new method is “approved by the NRC for the intended application” if it is approved for the type of analysis being conducted and the licensee or CoC holder satisfies applicable terms and conditions for its use. Specific guidance for making this determination is provided in Section B4.3.8.2.

B3.5 DESIGN BASES (DESIGN BASIS)

Definition:

(10 CFR 72.3) Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of an ISFSI facility or of a spent fuel storage cask and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted state-of-the-art practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under

which a structure, system, or component must meet its functional goals. The values for controlling parameters for external events include--

- **Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and**
- **Estimates of severe external man-induced events to be used for deriving design bases that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.**

Discussion:

The definition of design bases in 10 CFR 72.3 is analogous to the definition of design bases in 10 CFR 50.2. Guidance and examples for identifying 10 CFR 50.2 design bases are provided in Appendix B of NEI 97-04, *Design Bases Program Guidelines*, Revision 1, [Month] 2000. As described in SECY-00-0047, dated February 23, 2000, the NEI general guidance is:

10 CFR 50.2 design bases consist of the following:

- **Design bases functions: Functions performed by SSCs that are (1) required to meet regulations, license conditions, orders or technical specifications, or (2) credited in safety analyses to meet NRC requirements.**
- **Design bases values: Values or ranges of values of controlling parameters established by NRC requirement, established or confirmed by safety analyses, or chosen by the licensee from an applicable code, standard or guidance document as reference bounds for design to meet design bases functional requirements.**

SECY-00-0047 discusses how the implementation of the proposed NEI guidance would affect a number of Part 50 sections. Regarding 50.59, SECY-00-0047 states that "[t]he staff believes that the clarification of the definition of design bases may help licensees determine which methods are included in

the scope of the [50.59(c)(2)(viii) 'departure from a method of evaluation'] criterion. The Staff also believes that, because most methods currently described in the UFSAR establish design values that are consistent with the NEI guidance for design bases values, few UFSAR methods will be excluded by this clarification.”

The requirements of 10 CFR 72.48 are analogous to the requirements of 10 CFR 50.59, and the definition of design bases in 10 CFR 72.3 is analogous to the definition of design bases in 10 CFR 50.2. Therefore, the guidance of Appendix B to NEI 97-04, Revision 1, for 10 CFR Part 50 design bases should also be used for 10 CFR Part 72 design bases.

B3.6A FACILITY

Definition:

Facility means either an independent spent fuel storage installation (ISFSI) or a Monitored Retrievable Storage facility (MRS).

Discussion:

In this guidance, references to ISFSI facility include both ISFSI facility and MRS facility.

B3.6B FACILITY OR SPENT FUEL STORAGE CASK DESIGN AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

Facility or spent fuel storage cask design as described in the final safety analysis report (FSAR) (as updated) means:

- The structures, systems, and components (SSC) that are described in the FSAR (as updated),
- The design and performance requirements for such SSCs described in the FSAR (as updated), and
- The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

Discussion:

For specific licensees, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the ISFSI facility and spent fuel storage cask design submitted and updated per the requirements of 10 CFR 72.70. For cask certificate holders, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design submitted and updated per the requirements of 10 CFR 72.248. For general licensees, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design, as amended and supplemented, as well as the written evaluations for the ISFSI facility required by 10 CFR 72.212.

10 CFR 72.48 screening of ISFSI facility or spent fuel storage cask design changes is discussed in Section B4.2.1.1.

B3.7 FINAL SAFETY ANALYSIS REPORT (AS UPDATED)**Definition:**

Final Safety Analysis Report (as updated) means:

- For specific licensees, the Safety Analysis Report for a facility submitted and updated in accordance with 10 CFR 72.70;
- For general licensees, the Safety Analysis Report for a spent fuel storage cask design, as amended and supplemented; and
- For certificate holders, the Safety Analysis Report for a spent fuel storage cask design submitted and updated in accordance with 10 CFR 72.248.

Discussion:

As used throughout this guidance document, UFSAR is synonymous with "FSAR (as updated)." The scope of the UFSAR includes its text, tables, diagrams, etc., as well as supplemental information explicitly incorporated by reference. References that are merely listed in the UFSAR and documents that are not explicitly incorporated by

reference are not considered part of the UFSAR and therefore are not subject to control under 10 CFR 72.48.

For general licensees, the FSAR (as updated) means the FSAR for the cask design used at the ISFSI, as amended (updated) by the CoC holder in accordance with 10 CFR 72.248 (including changes since the last update), and as supplemented by changes made by the general licensee from the cask FSAR under 72.48. The changes made by the general licensee from the cask FSAR would be identified in the required 72.48 screening/evaluation records. Although not required, the general licensee changes from the cask FSAR may be compiled in the on-site 72.212 evaluations document, or may be incorporated in a separate on-site document to assist 72.48 screeners/evaluators.

Per 10 CFR 72.48(c)(4), licensees are not required to apply 10 CFR 72.48 to UFSAR information that is subject to other specific change control regulations. For example, licensee ~~Quality Assurance Programs, Emergency Plans and Security Plans~~ are controlled by other provisions in Part 72.

Per 10 CFR 72.48(c)(3), the "FSAR (as updated)," for purposes of 10 CFR 72.48, also includes UFSAR update pages approved by the specific licensee or certificate holder for incorporation in the UFSAR since the last required update was submitted per 10 CFR 72.70 or 72.248. The intent of this requirement is to ensure that decisions about proposed activities are made with the most complete and accurate information available. Pending UFSAR revisions may be relevant to a future activity that involves that part of the UFSAR. Therefore, pending UFSAR revisions to reflect completed activities that have received final approval for incorporation in the next required update should be considered as part of the UFSAR for purposes of 10 CFR 72.48 screenings and evaluations, as appropriate. Appropriate configuration management mechanisms should be in place to identify and assess interactions between concurrent changes affecting the same SSCs or the same portion of the UFSAR. **The configuration management mechanisms for general licensees (and specific licensees, as applicable) should ensure that they are notified in a timely manner of pending UFSAR changes by the certificate holders of the casks they are using, so that these pending changes will be considered in subsequent 72.48 screenings/evaluations.**

Specific guidance on the required content of ISFSI and cask UFSAR updates may be provided in the future.

B3.8 INPUT PARAMETERS

Definition:

Input parameters are those values derived directly from the physical characteristics of SSC or processes in the ISFSI facility or cask design, including flow rates, temperatures, pressures, dimensions or measurements (e.g., volume, weight, size, etc), and system response times.

Discussion:

The principal intent of this definition is to distinguish methods of evaluation from evaluation input parameters. Changes to methods of evaluation described in the UFSAR (see Section B3.10) are evaluated under criterion 10 CFR 72.48(c)(2)(viii), whereas changes to input parameters described in the UFSAR are considered changes to the ISFSI facility or cask design that would be evaluated under the other seven criteria of 10 CFR 72.48(c)(2), but not criterion (c)(2)(viii).

If a methodology permits the licensee or cask certificate holder to establish the value of an input parameter on the basis of ISFSI facility- or cask design-specific considerations, then that value is an input to the methodology, not part of the methodology. On the other hand, an input parameter is considered to be an element of the methodology if:

- The method of evaluation includes a methodology describing how to select the value of an input parameter to yield adequately conservative results. However, if a licensee or cask certificate holder opts to use a value more conservative than that required by the selection method, reduction in that conservatism should be evaluated as an input parameter change, not a change in methodology.
- The development or approval of a methodology was predicated on the degree of conservatism in a particular input parameter or set of input parameters. In other words, if certain elements of a methodology or model were accepted on the basis of the conservatism of a selected input value, then that input value is considered an element of the methodology.

Examples illustrating the treatment of input parameters are provided in Section B4.2.1.3.

Section B4.3.8 provides guidance and examples to describe the specific elements of evaluation methodology that would require evaluation under 10 CFR 72.48(c)(2)(viii) and to clearly distinguish these from specific types of input parameters that are controlled by the other seven criteria of 10 CFR 72.48(c)(2).

B3.9 MALFUNCTION OF AN SSC IMPORTANT TO SAFETY

Definition:

Malfunction of SSCs important to safety means the failure of SSCs to perform their intended design functions described in the UFSAR.

Discussion:

Guidance and examples for applying this definition is provided in Section B4.3.

B3.10 METHODS OF EVALUATION

Definition:

Methods of evaluation means the calculational framework used for evaluating behavior or response of the ISFSI facility, cask design, or an SSC.

Discussion:

Examples of methods of evaluation are presented below. Changes to such methods of evaluation require evaluation under 10 CFR 72.48(c)(2)(viii) only for evaluations used either in UFSAR safety analyses or in establishing the design bases, and only if the methods are described, outlined or summarized in the UFSAR. Methodology changes that are subject to 10 CFR 72.48 include changes to elements of existing methods described in the UFSAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies.

Elements of Methodology

Example

- | | |
|--|--|
| ■ Data correlations | ■ ?? |
| ■ Means of data reduction | ■ ASME methods for evaluating cask parameters |
| ■ Physical constants or coefficients | ■ Heat transfer coefficients |
| ■ Mathematical models | ■ Decay heat models |
| ■ Specific limitations of a computer program | ■ ?? <u>Benchmarking and correlation ranges</u> |
| ■ Specified factors to account for uncertainty in measurements or data | ■ Criticality calculations; fuel characterization |
| ■ Statistical treatment of results | ■ Vendor-specific thermal design procedure |
| ■ Dose conversion factors and assumed source term(s) | ■ ICRP factors |

Methods of evaluation described in the UFSAR subject to criterion 10 CFR 72.48(c)(2)(viii) are:

- Methods of evaluation used in analyses that demonstrate that design basis limits of fission product barriers are met (i.e., for the parameters subject to criterion 10 CFR 72.48(c)(2)(vii))
- Methods of evaluation used in UFSAR safety analyses, including cask and accident analyses typically presented in the accident analyses section(s) of the UFSAR, to demonstrate that consequences of accidents do not exceed 10 CFR 72.106 dose limits
- Methods of evaluation used in supporting UFSAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the ISFSI facility and cask design are required to withstand, including natural phenomena, environmental conditions, and dynamic effects.

B3.11 PROCEDURES AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

Procedures as described in the final safety analysis report (as updated) means those procedures that contain information described in the FSAR (as updated) such as how SSCs are operated and controlled (including assumed operator actions and response times).

Discussion:

For specific licensees, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the ISFSI facility submitted and updated per the requirements of 10 CFR 72.70. For cask certificate holders, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design submitted and updated per the requirements of 10 CFR 72.248. For general licensees, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design, as amended and supplemented (see section B3.7).

For purposes of 10 CFR 72.48, "procedures" are not limited to plant procedures specifically identified in the UFSAR (e.g., operating, chemistry, system, test, surveillance, and emergency procedures). Procedures include UFSAR descriptions of how actions related to system operation are to be performed and controls over the performance of design functions. This includes UFSAR descriptions of operator action sequencing or response times, certain descriptions (text or figure) of SSC operation and operating modes, operational and radiological controls, ~~inspection and testing frequency, and similar information.~~ If changes to these activities or controls are made, such changes are considered changes to procedures described in the UFSAR, and the changes are subject to 10 CFR 72.48.

Even if described in the UFSAR, ~~procedures that do not contain information on how SSCs are operated or controlled do not meet the definition of "procedures as described in the UFSAR" and are not subject to 10 CFR 72.48 for performing maintenance, work control, and administrative activities are normally outside the definition of "procedures as described in the UFSAR" because they do not typically contain information on how SSCs are operated or controlled.~~ Sections B4.1.2 and B4.1.4 ~~identifies~~ identify examples of procedures that are not subject to 10 CFR 72.48.

10 CFR 72.48 ~~s~~Screening of procedures is discussed in Section B4.2.1.2.

B3.12 SAFETY ANALYSES

Definition:

Safety analyses are analyses performed pursuant to NRC requirement to demonstrate the integrity of the **spent fuel cask or ISFSI** or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guidelines in 10 CFR 72.106. The safety analyses presented in the UFSAR include, but are not limited to, the accident analyses typically presented in the **accident analyses section(s)** of the UFSAR.

Discussion:

Safety analyses are those analyses or evaluations that demonstrate that acceptance criteria for the **ISFSI facility's or cask design's** capability to withstand or respond to postulated events are met. **Cask accident analyses typically presented in the accident analyses section(s)** of the UFSAR clearly fall within the meaning of "safety analyses" as defined above. Also within the meaning of this definition for purposes of 72.48 are:

- Supporting UFSAR analyses that demonstrate that SSC design functions will be accomplished as credited in the accident analyses
- UFSAR analyses of events that the **ISFSI facility or cask design** is required to withstand such as tornado missiles, fires, floods, and earthquakes.

B3.13 SCREENING

Definition:

Screening is the process for determining whether a proposed activity requires a 10 CFR 72.48 evaluation to be performed.

Discussion:

Screening is that part of the 10 CFR 72.48 process that determines whether a 10 CFR 72.48 evaluation is required prior to implementing a proposed activity.

The definitions of "change," "facility or spent fuel storage cask design as described...," "procedures as described...," and "test or experiment not described..." constitute criteria for the 10 CFR 72.48 screening process. Activities that do not meet these criteria are said

to "screen out" from further review under 10 CFR 72.48, i.e., may be implemented without a 10 CFR 72.48 evaluation.

Engineering and technical information concerning a proposed activity may be used along with other information as basis for determining if the activity screens out or requires a 10 CFR 72.48 evaluation.

Further discussion and guidance on screening is provided in Section B4.2.

B3.14 TESTS OR EXPERIMENTS NOT DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

Tests or experiments not described in the final safety analysis report (as updated) means any activity where any SSC is utilized or controlled in a manner which is either:

- Outside the reference bounds of the design bases as described in the UFSAR, or
- Inconsistent with the analyses or descriptions in the UFSAR.

Discussion:

10 CFR 72.48 ~~is must be~~ applied to tests or experiments not described in the UFSAR. The intent of the definition is to ensure that tests or experiments that put the ISFSI facility or cask design in a situation that has not previously been evaluated (e.g., unanalyzed system alignments, storage conditions) or that could affect the capability of SSCs to perform their intended design functions (e.g., high flow rates, stresses, high temperatures) are evaluated before they are conducted to determine if prior NRC approval is required.

~~Post modification testing should be evaluated as a test under 10 CFR 72.48 only if an abnormal mode of operation is proposed that is not described in the UFSAR. Post modification testing may be considered as part of the 10 CFR 72.48 evaluation for the modification itself.~~

~~10 CFR 72.48 screening of tests and experiments is discussed in Section B4.2.2.~~

4 IMPLEMENTATION GUIDANCE

ISFSI Licensees and Cask CoC holders may determine applicability and screen activities to determine if 10 CFR 72.48 evaluations are required as described in Sections B4.1 and B4.2, or equivalent manner.

B4.1 APPLICABILITY

As stated in Section (b) of 10 CFR 72.48, the rule applies to:

- **Each holder of a general or specific license issued under Part 72, and**
- **Each holder of a Certificate of Compliance (CoC) issued under Part 72.**

B4.1.1 Applicability to Licensee and Cask CoC holder Activities

10 CFR 72.48 is applicable to tests or experiments not described in the UFSAR and to changes to the ISFSI facility, **spent fuel storage cask design**, or procedures as described in the UFSAR, including changes made in response to new requirements or generic communications, except as noted below:

- **Per 10 CFR 72.48(c)(1)(i) and (ii), proposed activities that require a change to the technical specifications or CoC must be made via the license amendment or CoC amendment process, 10 CFR 72.56 or 72.244. Aspects of proposed activities that are not directly related to the required technical specification or CoC change are subject to 10 CFR 72.48.**
- **To reduce duplication of effort, 10 CFR 72.48(c)(4) specifically excludes from the scope of 10 CFR 72.48 changes to the ISFSI facility, **spent fuel storage cask design**, or procedures that are controlled by other more specific requirements and criteria established by regulation. For example, 10 CFR 72.44(e) and (f) specifies criteria and reporting requirements for changing physical security and emergency plans for ISFSI specific licensees.**

Activities controlled and implemented under other regulations may require related information in the UFSAR to be updated. To the extent the UFSAR changes are directly related to the activity implemented via another regulation, applying 10 CFR 72.48 is not

required. UFSAR changes should be identified to the NRC as part of the required UFSAR update, per 10 CFR 72.70 (specific licensee) or 72.248 (cask CoC holder). However, there may be certain activities for which a licensee or cask CoC holder would need to apply both the requirements of 10 CFR 72.48 and that of another regulation. For example, a modification to an ISFSI facility or cask design involves revising the method of ~~transfer~~ of a loaded spent fuel storage cask from the power plant to the ISFSI. The change would affect the ~~requirements for method of transfer~~ that are identified in the UFSAR, and also would affect a specific transfer method requirement for the limit of fuel in the cask handling equipment contained in the cask technical specifications. Thus, a license/CoC amendment to revise the technical specifications under 10 CFR 72.56 (specific licensee) or 72.244 (cask CoC holder for itself and the general licensee) would be required to implement the revised ~~transfer requirements that are in the technical specifications~~. 10 CFR 72.48 should be applied to the balance of the change.

A ~~second~~ other situation that could require a licensee to apply both 72.48 and another regulation is when proposed changes could affect both the 10 CFR Part 50 reactor facility described in the reactor UFSAR and the 10 CFR Part 72 ISFSI facility or cask design described in the ISFSI/cask UFSAR. An example could be a change to a cask loading activity in the reactor spent fuel building. In this case, both a 50.59 and 72.48 screening/evaluation may need to be performed.

A third situation that could involve 72.48 and another regulation would be when a change is proposed for a dual-purpose cask system that is certified under both 10 CFR Part 71 and 10 CFR Part 72. See Section B1.2.5.

B4.1.2 Maintenance Activities

Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities are subject to 10 CFR 72.48.

Maintenance activities include troubleshooting, calibration, refurbishment, ~~post-maintenance-related~~ testing, identical replacements, housekeeping, ~~associated temporary changes, and~~

similar activities that do not permanently alter the design or design function of SSCs, and are thus not subject to 10 CFR 72.48. Maintenance activities include troubleshooting, calibration, refurbishment, maintenance-related testing, identical replacements, housekeeping and similar activities that do not permanently alter the design or design function of SSCs. Maintenance activities also include temporary alterations to the ISFSI facility, cask design, or procedures that directly relate to and are necessary to support the maintenance. Examples of temporary alterations that support maintenance include jumpering terminals, lifting leads, placing temporary lead shielding on pipes and equipment, removal of barriers, and use of temporary blocks, bypasses, scaffolding and supports.

The Maintenance Rule, 10 CFR 50.65, does not apply to an ISFSI or to a spent fuel storage cask licensed or certified under 10 CFR Part 72. The guidance of NEI 96-07, Revision 1, for assessing and managing the risk impact of maintenance activities in accordance with 10 CFR 50.65(a)(4) would not apply to ISFSI/cask changes.

~~10 CFR 72.48 should be applied to maintenance activities in the following cases:~~

- ~~• The design is not restored to its original condition as a result of the maintenance activity (e.g., if SSCs are removed or the design, design function or operation is altered. In this case, 10 CFR 72.48 would be applied to the change in design.~~
- ~~• A temporary change in support of the maintenance is expected to be in effect for more than 90 days. In this case, 10 CFR 72.48 would be applied to the temporary change prior to implementation in the same manner as a permanent change.~~

10 CFR 72.48 should be applied to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section B4.4.

B4.1.3 UFSAR Modifications

For Part 50 reactor licensees, per NEI 98-03 (Revision 1, June 1999), as endorsed by Regulatory Guide 1.181 (September 1999), modifications to the UFSAR that are not the result of activities

performed under 10 CFR 50.59 are not subject to control under 10 CFR 50.59. Such modifications include reformatting and simplification of UFSAR information and removal of obsolete or redundant information and excessive detail. **As discussed in Section B1.2.3, the guidance of NEI 986-037, Revision 1 may also be useful to Part 72 licensees and CoC holdersean be generally utilized for updating the ISFSI and cask UFSARs required by 10 CFR 72.70 and 72.248.**

Therefore, 10 CFR 72.48 need not be applied to the following types of activities:

- Editorial changes to the UFSAR (including referenced procedures, topical reports, etc.)
- Clarifications to improve reader understanding
- Correction of inconsistencies within the UFSAR (e.g., between sections)
- Minor corrections to drawings, e.g., correcting mislabeled valves
- Similar changes to UFSAR information that do not change the meaning or substance of information presented

B4.1.4 Changes to Procedures Governing the Conduct of Operations

Even if described in the ISFSI or cask UFSAR, changes to managerial and administrative procedures governing the conduct of ISFSI facility operations are controlled under 10 CFR 72, Subpart G (quality assurance), programs and are not subject to control under 10 CFR 72.48. These include, but are not limited to, procedures in the following areas:

- ISFSI Operations and maintenance activities procedures such as control of equipment status (tag-outs)
- ~~Shift staffing and personnel qualifications~~
- ~~Changes to position titles when no UFSAR described organizational responsibilities or relationships are changed~~
- ~~Control of plant procedures~~
- ~~Training programs~~
- ~~On-site/off-site safety review committees~~
- ISFSI/cask design Plant modification process
- Calculation process

B4.1.5 Changes to Approved Fire Protection Programs

The guidance of NEI 96-07, Revision 1 for this section in the context of 10 CFR 50.59 is not applicable to implementation of 10 CFR 72.48, because the standard fire protection license condition focuses on the capability of a reactor to achieve and maintain safe shutdown, and does not consider ISFSI or spent fuel storage cask considerations.

B4.1.6 Changes to Written Evaluations Required by 10 CFR 72.212

10 CFR 72.212((b)(2)(ii) requires that a general licensee evaluate any changes to the written evaluations required by 10 CFR 72.212 using the requirements of 10 CFR 72.48(c).

B4.1.7 Cask Design Changes Made by a CoC Holder and Adopted by a General Licensee

The Federal Register notice issuing the current 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.”

As discussed in detail in this guidance document, per 10 CFR 72.48, a general licensee may make changes in the spent fuel storage cask design as described in the FSAR (as updated) without obtaining prior NRC approval if a change in the terms, conditions, or specifications incorporated in the CoC is not required, and the change does not meet any of the eight evaluation criteria in 10 CFR 72.48(c)(2). 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. 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 answers/justification used in the 72.48 screening/evaluation may be taken from the CoC holder's 72.48 screening/evaluation if they could also apply to the general licensee screening/evaluation.

B4.2 SCREENING

Once it has been determined that 10 CFR 72.48 is applicable to a proposed activity, screening is performed to determine if the activity should be evaluated against the evaluation criteria of 10 CFR 72.48(c)(2).

Engineering, design and other technical information concerning the activity and affected SSCs should be used to assess whether the activity is a test or experiment not described in the UFSAR or a modification, addition or removal (i.e., change) that affects:

- A design function of an SSC or cask design
- A method of performing or controlling the design function, or
- An evaluation for demonstrating that intended design functions will be accomplished

Sections B4.2.1 and B4.2.2 provide guidance and examples for determining whether an activity is (1) a change to the ISFSI facility, spent fuel storage cask design, or procedures as described in the UFSAR or (2) a test or experiment not described in the UFSAR. If an activity is determined to be neither, then it screens out and may be implemented without further evaluation. Activities that are screened out from further evaluation under 10 CFR 72.48 should be documented as discussed in Section B4.2.3.

Activities that screen out may nonetheless require UFSAR information to be updated. Updated UFSAR information must be provided to the NRC by specific licensees in accordance with 10 CFR 72.70, and by cask CoC holders in accordance with 10 CFR 72.248. CoC holders should also provide a record of changes that screen-out but result in needed UFSAR updates to cask users within 60 days of implementing the change.

Specific guidance for applying 10 CFR 72.48 to temporary changes proposed as compensatory measures for degraded or non-conforming conditions is provided in Section B4.4.

B4.2.1 Is the Activity a Change to the ISFSI Facility, Spent Fuel Storage Cask Design, or Procedures as Described in the UFSAR?

To determine whether or not a proposed change affects a design function, method of performing or controlling a design function or an evaluation that demonstrates that design functions will be accomplished, a thorough understanding of the affected SSCs and the proposed change is essential. A given change may have both direct and indirect effects that the screening review must consider. The following questions illustrate a range of effects that may stem from a proposed change: ~~Only proposed changes that would, based on supporting engineering and technical information, have adverse effects on SSC or cask design functions require evaluation under 10 CFR 72.48. A determination of whether adverse effects exist should consider both direct and indirect effects of the activity. Examples of questions that could be considered include the following:~~

- Does the activity decrease the reliability of the SSC or cask design function, including functions that are relied upon for prevention of a radioactivity release?
- Does the activity reduce existing redundancy, diversity or defense-in-depth?
- Does the activity add or delete an automatic or manual design function or passive design characteristics of the SSC or cask?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system interaction?
- Does the activity adversely affect the ability or response time to perform required actions, e.g., alter equipment access or add steps necessary for performing tasks?
- Does the activity degrade the seismic, structural, heat removal, shielding, or criticality control capability ~~or environmental qualification of the SSC or cask?~~

- Does the activity adversely affect other casks that are in use at the ISFSI at a multiple-cask site?
- ~~Does the activity use equipment/tools that interface either directly or indirectly with an operable SSC?~~
- Does the activity introduce intrusive test equipment into the SSC or cask such that an SSC or cask design function is affected?
- Does the activity affect a method of evaluation used in establishing the design bases or in the safety analyses?
- For activities affecting SSCs, procedures, or methods of evaluation that are not described in the UFSAR, does the change have an indirect effect on structural integrity, environmental conditions or other UFSAR-described design functions?

Per the definition of "change" discussed in Section B3.3, 10 CFR 72.48 is applicable to additions as well as to changes to and removals from the ISFSI facility, cask design, or procedures. Additions should be screened for their effects on the existing facility, cask design, and procedures as described in the UFSAR and, if required, a 10 CFR 72.48 evaluation should be performed. NEI 98-03 can provide guidance for determining whether additions to the ISFSI facility and procedures should be reflected in the UFSAR per 10 CFR 72.70 (specific licensee) or 72.248 (cask CoC holder).

Consistent with historical practice, changes affecting SSCs or functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions. A 10 CFR 72.48 evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.

Screening for Adverse Effects

A 10 CFR 72.48 evaluation is required for 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., "adverse changes"). Changes that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new accidents or otherwise.

meet the 10 CFR 72.48 evaluation criteria.²

Per the definition of "design function," SSCs may have preventive, as well as mitigative, design functions. Adverse changes to either must be screened in. Thus a change that decreases the reliability of a function whose failure could initiate an accident would be considered to adversely affect a design function and would screen in. In this regard, changes that would relax the manner in which Code requirements are met for certain SSCs should be screened for adverse effects on design function. Similarly, changes that would introduce a new type of accident or malfunction with a different result would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 72.48 evaluation. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

If a change has both positive and adverse effects, the change should be screened in. The 10 CFR 72.48 evaluation may focus on the adverse effects.

The screening process is not concerned with the magnitude of adverse effects that are identified. Any change that adversely affects a UFSAR-described design function, method of performing or controlling design functions, or evaluation that demonstrates that intended design functions will be accomplished is screened in. The magnitude of the adverse effect (e.g., is the minimal increase standard met?) is the focus of the 10 CFR 72.48 evaluation process.

Screening determinations are made based on the engineering/technical information supporting the change. The screening focus on design functions, etc., ensures the essential distinction between (1) 10 CFR 72.48 screenings, and (2) 10 CFR 72.48 evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR 72.48(c)(2). Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse effect on UFSAR-described design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished may be used as basis for screening out the change. If the effect of a change is such that existing safety analyses would no longer be bounding and therefore UFSAR safety analyses must be re-run to demonstrate that all required safety functions and design requirements

²Note that as discussed in Section B4.2.1.1, any change that alters a design basis limit for a fission product barrier—positively or negatively—is considered adverse and must be screened in.

are met, the change is considered to be adverse and must be screened in. The revised safety analyses may be used in support of the required 10 CFR 72.48 evaluation of such changes.

Changes that entail update of safety analyses to reflect improved performance, capacity, timing, etc., resulting from a change (beneficial effects on design functions) are not considered adverse and need not be screened in, even though the change calls for safety analyses to be updated. For example, ... a change that improves the closure time of main control room isolation dampers reduces the calculated dose to operators, and UFSAR dose consequence analyses are to be updated as a result. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of the dampers (post accident isolation of the main control room) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used in support of the 10 CFR 50.59 evaluation to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 72.48 screening and evaluation, consider the example ... of a change to a diesel generator starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR described design function credited in the ECCS analyses is for the diesel to start within 12 seconds. This change would screen out because it is apparent that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's start time to 13 seconds would screen in because the change adversely effects the design function (to start in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in support of the 10 CFR 50.59 evaluation to determine whether any of the evaluation criteria are met such that prior NRC approval is required for the change.

Additional specific guidance for identifying adverse effects due to a procedure or methodology change is provided in subsections B4.2.1.2 and B4.2.1.3, respectively.

B4.2.1.1 Screening of Changes to the ISFSI Facility or Spent Fuel Storage Cask Design as Described in the UFSAR

Screening to determine that a 10 CFR 72.48 evaluation is required is straightforward when a change affects an SSC or cask design function, method of performing or controlling a design function, or evaluation that demonstrates intended design functions will be accomplished as described in the UFSAR.

However, an ISFSI facility or cask design may also contain SSCs not described in the UFSAR. These can be components, subcomponents of larger components or even entire systems. Changes to SSCs that are not explicitly described in the UFSAR can have the potential to affect SSC or cask design functions that are described and thus may require a 10 CFR 72.48 evaluation. In such cases, the approach for determining whether a change involves a change to the ISFSI facility or spent fuel storage cask design as described in the UFSAR, is to consider the larger, UFSAR-described SSC of which the SSC being modified is a part. If for the larger SSC, the change affects a UFSAR-described design function, method of performing or controlling the design function, or an evaluation demonstrating that intended design functions will be accomplished, then a 10 CFR 72.48 evaluation is required.

Another important consideration is that a change to ~~not a~~ important-to-safety ~~safety-related~~ SSCs not described in the UFSAR can indirectly affect the capability of SSCs or a cask to perform their UFSAR-described design function(s). For example, increasing the heat generation from ~~not a~~ important-to-safety ~~safety-related~~ equipment near the ISFSI could compromise the cask cooling system's ability to ~~cool~~ remove heat from the spent fuel.

Seismic qualification, missile protection, flooding protection, and fire protection are some of the areas where changes to ~~non-~~ important-to-safety ~~safety-related~~ SSCs, whether or not described in the UFSAR, can affect the UFSAR-described design function of SSCs or casks through indirect or secondary effects.

Equivalent replacement is a type of change to the ISFSI facility or spent fuel storage cask design that does not alter the design functions of SSCs. Licensee/certificate holder equivalence assessments, e.g., consideration of performance/operating characteristics and other factors, may thus form the basis for screening determinations that no 10 CFR 72.48 evaluation is required.

As discussed in Section B4.2.1, only proposed changes to SSCs that would, based on supporting engineering and technical information, have adverse effects on design functions require evaluation under 10 CFR 72.48. Changes that have positive or no effect on design functions may generally be screened out. The exception to this is that any change to a design bases limit for a fission product barrier—adverse or beneficial—must be screened in. This is because 10 CFR 72.48(c)(2)(vii) requires prior NRC approval any time a proposed change would “exceed or alter” a design bases limit for a fission product barrier.

The following examples illustrate the 10 CFR 72.48 screening process as applied to proposed ISFSI facility or cask design changes:

Example 1

▲A licensee/certificate holder proposes to replace a globe valve with a ball valve in a vent/drain application that is used in the loading process to reduce the propensity of this valve to leak. The UFSAR-described design function of this valve is to allow the cask to be filled, drained, and vented in the loading process. The vent/drain function of the valve does not relate to design functions credited in the safety analyses, and the licensee has determined that a ball valve is adequate to support the vent/drain function and is superior to the globe valve in terms of its isolation function. Thus the proposed change affects the design of the existing vent/drain valve—not the design function that supports system performance credited in the safety analyses—and evaluation/reporting to NRC under 10 CFR 72.48 is not required. The screening determination should be documented, and the UFSAR should be updated per 10 CFR 72.70 (specific licensee) or 10 CFR 72.248 (cask CoC holder) to reflect the change. If this change were being made by a general licensee for a site-specific implementation, the general licensee should consider updating their 10 CFR 72.212 evaluation to reflect this deviation from the cask UFSAR.

Example 2

▲The bolts for retaining the outside lid of the outer concrete cask are being replaced with bolts of a different material with similar properties including load capacity and strength, but equivalent load capacity and strength, such that the lid will still be secured with the same strength as before the change. Because the replacement bolts are equivalent in function to the original bolts and the outer lid of the concrete cask continues to meet the same functional requirements, this activity may be screened out as an equivalent change. If the replacement bolts have a reduced load capacity or strength, the activity would screen in and would require a full 10 CFR 72.48 evaluation.

Example 3

▲A licensee/certificate holder would like to change the brand of coating used on the cask. The current coating brand is identified in the cask UFSAR. The licensee/certificate holder has determined that the new brand of coating is equivalent to the current brand, based on a demonstrated laboratory qualification process (i.e., meets the performance and operating characteristics, functional requirements, corrosion resistance, heat transfer characteristics, adherence properties, etc.). This change may be screened out as an equivalent change, and an evaluation is not required. The UFSAR should be updated per 10 CFR 72.70 (specific licensee) or 10 CFR 72.248 (cask CoC holder) to reflect the change. If this change were being made by a general licensee for a site-specific implementation, the general licensee should consider updating their 10 CFR 72.212 evaluation to reflect this deviation from the cask UFSAR.

Example 4

▲A licensee plans to place a motor vehicle fuel storage tank in close proximity to the cask transfer route from the fuel building to the ISFSI. A 72.48 screening identifies that a fire or explosion of the tank could impact the UFSAR described design capability of a cask to withstand a fire or explosion. The screening would conclude that an 72.48 evaluation of the change is needed. If the screening identifies that the tank

would be far enough away from the cask transfer route that the cask could not be affected by a tank fire or explosion, the screening would conclude that no 72.48 evaluation is needed.

B4.2.1.2 Screening of Changes to Procedures as Described in the UFSAR

Changes to procedures are "screened in" (i.e., require a 10 CFR 72.48 evaluation) if they adversely affect the change affects how SSC or cask design functions are performed or controlled, as described in the UFSAR (including changes to UFSAR-described procedures, assumed operator actions and response times). Changes to a procedure that does not affect how SSC or cask design functions described in the UFSAR are performed or controlled would screen out. Proposed changes that are determined to have positive or no effect on how SSC design functions are performed or controlled may be screened out.

For purposes of 10 CFR 72.48 screening, changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in. Such changes include replacement of automatic action by manual action (or vice versa), analog to digital upgrades, changing a valve from "locked closed" to "administratively closed" and similar changes.

The following examples illustrate the 10 CFR 72.48 screening process as applied to proposed proposed changes affecting how SSC design functions are performed or controlled procedure changes:

- **Operating Procedures include operator actions for transport and placement of the filled cask, which are described in the UFSAR, but also address operator actions for maintenance of the transport equipment that are outside the cask and ISFSI design basis and not described in the UFSAR. A change would screen out at this step if the change was to those procedures or parts of procedures dealing with maintenance of the transport equipment.**
- **If the UFSAR description of the cask loading procedure contains eight fundamental sequences, the licensee's or CoC holder's decision to eliminate one of the sequences would screen in. On the other hand, if the licensee or CoC holder consolidated the eight**

fundamental sequences and did not affect the method of controlling or performing cask loading, the change would screen out.

- The UFSAR describes that a dry lubricant will be used in the dry shielded canister insertion process. A procedure change to delete the use of the lubricant or use a wet lubricant would screen in as a change in the procedures as described in the UFSAR and require an evaluation. If a licensee/CoC holder wishes to utilize a different brand of dry lubricant that is equivalent to the current brand (justified in the screening), the change would screen out and no evaluation would be required.

B4.2.1.3 Screening Changes to UFSAR Methods of Evaluation

As discussed in Section B3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC or cask design functions will be accomplished are considered part of the "facility or spent fuel storage cask design as described in the UFSAR." Thus use of new or revised methods of evaluation (as defined in Section B3.10) is considered to be a change that is controlled by 10 CFR 72.48 and needs to be considered as part of this screening step. ~~Changing Adverse changes to~~ elements of a method of evaluation included in the UFSAR, or use of an alternative method, must be evaluated under 10 CFR 72.48(c)(2)(viii) to determine if prior NRC approval is required (see Section B4.3.8). Changes to methods of evaluation (only) do not require evaluation against the first seven criteria.

Changes to methods of evaluation not included in the UFSAR or to methodologies included in the UFSAR that are not used in the safety analyses or to establish design bases would screen out at this step.

Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not subject to control under 10 CFR 72.48 unless the UFSAR states they were used for specific analyses within the scope of 10 CFR 72.48(c)(2)(viii).

Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation under 10 CFR 72.48 if the changes are outside the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or

SER. If the changes are within constraints and limitations associated with use of the method, the change is not considered adverse and may be screened out, do not require evaluation under 10 CFR 72.48 if the changes are within the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or SER.

Proposed use of an alternative method is considered an adverse change that must be evaluated under 10 CFR 72.48(c)(2)(viii).

The following examples illustrate the screening of changes to methods of evaluation:

- The UFSAR identifies the name of the computer code used for performing cask containment performance analyses, with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated topical report and SER. A change that goes beyond restrictions on the use of the method should be evaluated under 10 CFR 72.48(c)(2)(viii) to determine if prior NRC approval is required.

B4.2.2 Is the Activity a Test or Experiment Not Described in the UFSAR?

As discussed in Section B3.14, tests or experiments not described in the UFSAR are activities where an SSC or cask is utilized or controlled in a manner that is outside the reference bounds of the design for that SSC or cask or inconsistent with analyses or description in the UFSAR.

Tests and experiments that are described in the UFSAR may be screened out at this step. Tests and experiments that are not described in the UFSAR may be screened out provided the test or experiment is bounded by tests and experiments that are described. Similarly, tests and experiments not described in the UFSAR may be screened out provided that affected SSCs will be appropriately isolated from the ISFSI facility and cask.

Examples of tests that would "screen in" at this step (assuming they were not described in the UFSAR) would be:

- Testing the heat transfer capabilities of a loaded spent fuel storage cask by blocking the air vents.

- Drawing gas from a loaded canister by penetrating the canister after it has been sealed.
- Testing a pressure switch on loaded cask by raising the internal pressure beyond that described in the UFSAR

Examples of tests that would "screen out" would be:

- Performing a radiography check of a concrete overpack prior to loading spent fuel.

B4.2.3 Screening Documentation

10 CFR 72.48 recordkeeping requirements apply to 10 CFR 72.48 evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with procedures of screenings that conclude a proposed activity may be screened out (i.e., that a 10 CFR 72.48 evaluation was not required). The basis for the conclusion should be documented to a degree commensurate with the safety significance of the change. For changes, the documentation should include the basis for determining that there would be no adverse effect on design functions, etc. -Typically, the screening documentation is retained as part of the change package. This documentation does not constitute the record of changes required by 10 CFR 72.48, and thus is not subject to 10 CFR 72.48 documentation and reporting requirements. Screening records need not be retained for activities for which a 10 CFR 72.48 evaluation was performed or for activities that were never implemented.

B4.3 EVALUATION PROCESS

Once it has been determined that a given activity requires a 10 CFR 72.48 evaluation, the written evaluation must address the applicable criteria of 10 CFR 72.48 (c)(2). These eight criteria are used to evaluate the effects of proposed activities on accidents and malfunctions previously evaluated in the UFSAR and their potential to cause accidents or malfunctions whose effects are not bounded by previous analyses.

Criteria (c)(2)(i—vii) are applicable to activities other than changes in methods of evaluation. Criterion (c)(2)(viii) is applicable to changes in

methods of evaluation. Each activity must be evaluated against each applicable criterion. If any of the criteria are met, a specific licensee must apply for and obtain a license amendment per 10 CFR 72.56, and a CoC holder must apply for and obtain a CoC amendment per 10 CFR 72.244 (for itself or for a general licensee) before implementing the activity. The evaluation against each criterion should be appropriately documented as discussed in Section B4.5. Subsections B4.3.1 through B4.3.8 provide guidance and examples for evaluating proposed activities against the eight criteria.

Each element of a proposed activity must undergo a 10 CFR 72.48 evaluation, except in instances where linking elements of an activity is appropriate, in which case the linked elements can be evaluated together. A test for linking elements of proposed changes is interdependence.

It is appropriate for discrete elements to be evaluated together if (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures; or (2) they are performed collectively to address a design or operational issue. For example, a pump upgrade modification may also necessitate a change to a support system, such as cooling water.

If concurrent changes are being made that are not linked, each must be evaluated separately and independently of each other.

The effects of a proposed activity being evaluated under 10 CFR 72.48 should be assessed against each of the evaluation criteria separately. For example, an increase in frequency/likelihood of occurrence cannot be compensated for by additional mitigation of consequences.

Specific guidance for applying 10 CFR 72.48 to temporary changes proposed as compensatory measures for degraded or nonconforming conditions is provided in Section B4.4.

B4.3.1 Does the Activity Result in More than a Minimal Increase in the Frequency of Occurrence of an Accident?

In answering this question, the first step is to identify the accidents that have been evaluated in the UFSAR that are affected by the proposed activity. Then a determination should be made as to whether the frequency of these accidents occurring would be more than minimally increased.

Accidents and transients have been divided into categories based upon a qualitative assessment of frequency. For example, SRP

guidance defines the following categories for plant conditions for most cask designs as follows:

Normal - Expected frequently or regularly

Anticipated Occurrences/(Off-Normal Events) - Expected to occur with moderate frequency or once per calendar year

Accidents and Events Associated with Natural Phenomena - Expected to occur infrequently, if ever, during the lifetime of the ISFSI facility or cask

During initial ISFSI facility licensing or spent fuel storage cask certification, accidents were assessed in relative frequencies, as described above. Minimal increases in frequency resulting from subsequent licensee or cask certificate holder activities do not significantly change the licensing basis of the ISFSI facility or cask and do not impact the conclusions reached about acceptability of the ISFSI facility or cask design.

Since accident and transient frequencies were considered in a broad sense as described above, a change from one frequency category to a more frequent category is clearly an example of a change that results in more than a minimal increase in the frequency of occurrence of an accident.

Changes within a frequency category could also result in more than a minimal increase in the frequency of occurrence of an accident. Normally, the determination of a frequency increase is based upon a qualitative assessment using engineering evaluations consistent with the UFSAR analysis assumptions. However, a spent fuel storage cask-specific accident frequency calculation or PRA may be used to evaluate a proposed activity in a quantitative sense. It should be emphasized that PRAs are just one of the tools for evaluating the effect of proposed activities, and their use is not required to perform 10 CFR 72.48 evaluations.

Reasonable engineering practices, engineering judgment, and PRA techniques, as appropriate, should be used in determining whether the frequency of occurrence of an accident would more than minimally increase as a result of implementing a proposed activity. A large body of knowledge has been developed in the area of accident frequency and risk significant sequences through reactor plant-specific and generic studies. Additional studies are being conducted for spent fuel storage cask PRA. This knowledge,

where applicable, should be used in determining what constitutes more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR. The effect of a proposed activity on the frequency of an accident must be discernable and attributable to the proposed activity in order to exceed the more than minimal increase standard.

Although this criterion allows minimal increases, licensees and CoC holders must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in Regulatory Guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE standards). Further, departures from the design, fabrication, construction, testing, and performance standards as outlined in the General Design Criteria (Subpart F to Part 72) are not compatible with a "no more than minimal increase" standard.

Because frequencies of occurrence of natural phenomena were established as part of initial licensing or certification and are not expected to change, changes in design requirements for earthquakes, tornadoes and other natural phenomena should be treated as potentially affecting the likelihood of a malfunction rather than the frequency of occurrence of an accident.

The following are examples where there is not more than a minimal increase in the frequency of occurrence of an accident:

1. The proposed activity has a negligible effect on the frequency of occurrence of an accident. A negligible effect on the frequency of occurrence of an accident exists when the change in frequency is so small or the uncertainties in determining whether a change in frequency has occurred are such that it cannot be reasonably concluded that the frequency has actually changed (i.e., there is no clear trend towards increasing the frequency).
2. The proposed activity meets applicable NRC requirements as well as the design, material, and construction standards applicable to the SSC being modified. If the proposed activity would not meet applicable requirements and standards, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.
3. The change in frequency of occurrence of an accident is calculated to support the evaluation of the proposed activity, and one of the following criteria are met:

- The increase in the pre-change accident ~~or transient~~ frequency does not exceed 10 percent.³ or
- The resultant frequency of occurrence remains below 1E-6 per year or applicable ~~plant~~ ISFSI site-specific threshold.

If the proposed activity would not meet ~~one~~ either of the above criteria, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.

Example

A change is made to the ISFSI such that electrical power must be interrupted for a short time to allow connection of the pressure monitoring system to each cask as it is placed on the storage pad. Such interruptions would occur several times each year, since more than one cask is loaded at this ISFSI each year. While this power interruption does not affect the safety or confinement capability of the previously stored casks, the ability to monitor confinement integrity is lost for a short period of time. While such interruptions would be permitted under the Technical Specifications for the cask, the UFSAR evaluates loss of power to the ISFSI pressure monitoring system as an Off-normal event assumed to occur once per year.

In this case, prior NRC approval would be required, since the loss of power to the pressure monitoring system would occur more than once per year and would become a normal event.

B4.3.2 Does the Activity Result in More than a Minimal Increase in the Likelihood of Occurrence of a Malfunction of an SSC Important to Safety?

The term "malfunction of an SSC important to safety" refers to the failure of structures, systems and components (SSCs) to perform their intended design functions—including both ~~nonnot -~~ important-to-safety safety-related and important-to-

³ The proposed 10 percent increase threshold is consistent with the NRC report, "Options for Incorporating Risk Insights into 10 CFR 50.59 Process," December 17, 1998, Section 6.4.1.

~~safety~~safety-related SSCs. The cause and mode of a malfunction should be considered in determining whether there is a change in the likelihood of a malfunction. The effect or result of a malfunction should be considered in determining whether a malfunction with a different result is involved per Section B4.3.6.

In determining whether there is more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC to perform its design function as described in the UFSAR, the first step is to determine what SSCs are affected by the proposed activity. Next, the effects of the proposed activity on the affected SSCs should be determined. This evaluation should include both direct and indirect effects.

Direct effects are those where the proposed activity affects the SSCs (e.g., a motor change on a pump). Indirect effects are those where the proposed activity affects one SSC and this SSC affects the capability of another SSC to perform its UFSAR described design function. Indirect effects also include the effects of proposed activities on the design functions of SSCs credited in the safety analyses. The safety analysis assumes certain design functions of SSCs in demonstrating the adequacy of design. Thus, certain design functions, while not specifically identified in the safety analysis, are credited in an indirect sense.

After determining the effect of the proposed activity on the important to safety SSCs, a determination is made of whether the likelihood of a malfunction of the important to safety SSCs has increased more than minimally. Qualitative engineering judgment and/or an industry precedent is typically used to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense, if available and practical. The effect of a proposed activity on the likelihood of malfunction must be discernable and attributable to the proposed activity in order to exceed the more than minimal increase standard. A proposed activity is considered to have a negligible effect on the likelihood of a malfunction when a change in likelihood is so small or the uncertainties in determining whether a change in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed (i.e., there is no clear trend towards increasing the likelihood). A proposed activity that has a negligible effect satisfies the minimal increase standard.

Evaluations of a proposed activity for its effect on likelihood of a malfunction would be performed at level of detail that is described in the UFSAR. The determination of whether the likelihood of malfunction is more than minimally increased is made at a level consistent with existing UFSAR-described failure modes and effects analyses. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed activity. ~~Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether the likelihood of malfunction has been increased.~~

Changes in design requirements for earthquakes, tornadoes, and other natural phenomena should be treated as potentially affecting the likelihood of malfunction.

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in Regulatory Guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE standards). Further, departures from the design, fabrication, construction, testing, and performance standards as outlined in the General Design Criteria (Appendix F to Part 72) are not compatible with a "no more than minimal increase" standard.

Below are examples where there is less than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety:

1. The change involves installing additional equipment or devices (e.g., cabling, manual valves, protective features) provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met.
2. The change involves substitution of one type of component for another of similar function, provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met and any new failure modes are bounded by the existing analysis.

3. The change involves a new or modified fuel handling action that supports a design function credited in safety analyses, ~~including manual action that substitutes for automatic action,~~ provided:
 - The action (including required completion time) is reflected in ~~plant procedures and operator training programs~~
 - The licensee has demonstrated that the action can be completed in the time required considering the aggregate affects, such as workload or environmental conditions, expected to exist when the action is required
 - The evaluation of the change considers the ability to recover from credible errors in performance of manual actions and the expected time required to make such a recovery
 - The evaluation considers the effect of the change on ISFSI plant and cask design functions ~~systems~~
4. The change satisfies applicable design bases requirements (e.g., seismic and wind loadings, separation criteria, environmental qualification, etc.)

The following changes would require prior NRC approval because they would result in more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety:

1. The change would cause design stresses to exceed their code allowables or other applicable stress or deformation limit (if any), including vendor-specified stress limits ~~for pump casings that ensure pump functionality.~~
2. The change would reduce system/equipment redundancy, diversity, separation, or independence.
3. The change would substitute manual action for automatic action for performing design functions.
- 3.4. The change in likelihood of occurrence of a malfunction is calculated in support of the evaluation and increases by more than a factor of two.⁴ Note: The factor of two should be applied based on the nature of the activity, e.g., at the component level for component changes. System/functional level Certain changes

⁴ The proposed factor of two threshold is consistent with the NRC report, "Options for Incorporating Risk Insights into 10 CFR 50.59 Process," December 17, 1998, Section 6.4.1.

that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval, e.g., exceed the minimal increase standard for accident/transient frequency under criterion 10 CFR ~~50.59~~72.48(c)(2)(i). For example, a change that increases the likelihood of malfunction of the Emergency AC system or Reactor Protection System by a factor of two would likely cause more than a 10% increase in the frequency of station blackout or ATWS, respectively.

Example

The elapsed time to transfer a loaded spent fuel storage cask from the fuel building to the ISFSI pad is prescribed in the UFSAR (with considerations for ambient temperature) to limit the exposure to potential weather phenomena. If the transfer time is to be extended (adjusting for any ambient temperature considerations), but not doubled, it would not be more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety and NRC approval would not be required. However, if the transfer time were to increase by a factor of two or greater, prior NRC approval would be required.

B4.3.3 Does the Activity Result in More than a Minimal Increase in the Consequences of an Accident?

The UFSAR, based on logic similar to ANSI standards, provides an acceptance criterion and frequency relationship for "conditions for design". When determining which activities represent "more than a minimal increase in consequences" pursuant to 10 CFR 72.48, it must be recognized that the objective of the regulation is the protection of public health and safety. Therefore, an increase in consequences must involve an increase in radiological doses to the public. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological dose to the public are addressed under Section B4.3.7, concerning integrity of fission product barriers, Integrity of Fission Product Barriers, or the other criteria of 10 CFR 72.48(c)(2).

NRC regulates compliance with the provisions of 10 CFR 72 to assure adequate protection of the public health and safety. Activities affecting onsite dose consequences that may require prior NRC approval are those that impede required actions inside or outside the

control room to mitigate the consequences of reactor accidents involving an ISFSI or a cask.

The consequences covered include dose resulting from any accident evaluated in the UFSAR. The accidents include those typically covered in the accident analyses section(s) of the UFSAR and other events with which the cask is designed to cope and are described in the UFSAR (e.g., turbine-tornado missiles and flooding). The consequences referred to in 10 CFR 72.48 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.

10 CFR Part 20 and 10 CFR 72.104 establish requirements for protection against radiation during normal operations, including dose criteria relative to radioactive waste handling and effluents. 10 CFR 72.48 accident dose consequence criteria and evaluation guidance are not applicable to proposed activities governed by 10 CFR Part 20 and 10 CFR 72.104 requirements.

The dose consequences referred to in 10 CFR 72.48 are those calculated by licensees or certificate holders—not the results of independent, confirmatory dose analyses by the NRC that may be documented in Safety Evaluation Reports.

The evaluation should determine the dose that would likely result from accidents associated with the proposed activity. If a proposed activity would result in more than a minimal increase in dose from the existing calculated dose for any accident, then the activity would require prior NRC approval. Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e., there is no clear trend towards increasing the consequences), the change need not be considered an increase in consequences.

10 CFR 72.106 establishes requirements for a controlled area for each ISFSI site so that an individual located on or beyond the nearest boundary of the controlled area may not receive from any design basis accident the more limiting of a total effective dose equivalent of 5 rem, or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 50 rem. The lens dose equivalent shall not exceed 15 rem and the shallow dose equivalent to skin or to any extremity shall not exceed 50 rem.

Therefore, for a given accident, calculated or bounding dose values for that accident would be identified in the UFSAR. **If a general licensee has calculated a lower offsite dose consequence in their on-site 72.212 evaluation, the higher cask UFSAR value would be the bounding value.** These dose values should be within the 10 CFR 72.106 limits, as applicable. An increase in consequences from a proposed activity is defined to be no more than minimal if the increase is less than or equal to 10 percent of the difference between the current bounding calculated dose value and the regulatory guideline value (10 CFR 72.106, as applicable). The current calculated dose values are those documented in the most up-to-date analyses of record.

For some licensees the current calculated dose consequences may already be in excess of the SRP guidelines for some events. In such cases minimal increase is defined as less than or equal to 0.1 rem.

In determining if there is more than a minimal increase in consequences, the first step is to determine which accidents evaluated in the UFSAR may have their radiological consequences affected as a direct result of the proposed activity. Examples of questions that assist in this determination are:

- (1) Will the proposed activity change, prevent or degrade the effectiveness of actions described or assumed in an accident discussed in the UFSAR?
- (2) Will the proposed activity alter assumptions previously made in evaluating the radiological consequences of an accident described in the UFSAR?
- (3) Will the proposed activity play a direct role in mitigating the radiological consequences of an accident described in the UFSAR?

The next step is to determine if the proposed activity does, in fact, increase the radiological consequences of any of the accidents evaluated in the UFSAR. If it is determined that the proposed activity does have an effect on the radiological consequences of any accident analysis described in the UFSAR, then either:

- (1) Demonstrate and document that the radiological consequences of the accident described in the UFSAR are bounding for the proposed activity (e.g., by showing that the results of the UFSAR analysis bound those that would be associated with the proposed activity), or

- (2) Revise and document the analysis taking into account the proposed activity and determine if more than a minimal increase has occurred as described above.

The following examples illustrate the implementation of this criterion. In each example it is assumed that the calculated consequences do not include a change in the methodology for calculating the consequences. Changes in methodology would need to be separately considered under 10 CFR 72.48(c)(2)(viii) as discussed in Section B4.3.8.

Example 1

A cask CoC holder has prepared a calculation showing that the ISFSI boundary fence may be moved closer to the casks than currently described in the UFSAR, and the ISFSI would still meet the 10 CFR 72.106 accident dose limits and all other regulatory requirements, including 10 CFR 72.104 limits. The new calculated offsite accident dose would be 1.1 rem. The calculated accident dose described in the UFSAR is 1.0 rem, and the 10 CFR 72.106 limit is 5 rem. Since 10% of the difference between the UFSAR calculated dose (1.0 rem) and the regulatory limit (5.0 rem) is 0.4 rem, the increase to 1.1 rem would be less than a minimal increase in consequences (less than 10% of the difference between 1.0 rem and 5.0 rem), and prior NRC approval is not required. If the new calculated dose was 1.5 rem, the change would be more than a minimal increase (more than 10% of the difference between the UFSAR value and the regulatory limit) and would require prior NRC approval. In either case, once the change is made, the new value would become the bounding value for the next 72.48 evaluation and would be put in the UFSAR.

If this change were to be made by a general ISFSI licensee for a site-specific application, the record of the 72.48 evaluation containing the updated calculated offsite dose value would be retained put in the on-site 72.212 evaluation and the revised value used as the bounding value for the next 72.48 evaluation. It is not clear at this time how a general licensee would request and obtain prior NRC approval for a site-specific change that requires prior NRC approval per 72.48. The NRC is looking at clarifying the regulations to address this situation. If prior NRC approval is required under 72.48, the general licensee could either request that the CoC holder for their cask system submit a CoC amendment request to the NRC under 10 CFR 72.244, if appropriate, or could submit, under 10 CFR 72.7, a request for

an exemption to the 72.48(2) provision requiring that a general licensee shall request that the CoC holder obtain a CoC amendment.

Example 2

A site-specific licensee has evaluated the consequences of a tornado missile strike to the concrete storage modules which house the spent fuel storage canisters. It is determined that the concrete shield blocks which cover the outlet air vents on the roof could be knocked off, resulting in a temporary reduction in radiological shielding. The offsite consequence of this accident as described in the UFSAR is 30 mrem TEDE (direct and scattered radiation) to a person located 100 meters away from the ISFSI for 8 hours per day during the 7 day recovery period. The onsite consequence of this accident is an increase in occupation exposure of 2.5 person-rem, incurred when replacing the shield blocks.

The licensee wishes to improve fabricability of the concrete storage module by removing the "dog leg" from the pathway of the outlet vents through the concrete, and instead, use a straight-line path. The change results in a negligible increase in dose rates during normal operation. However, in the accident scenario with the loss of the shield block, it is found that the dose consequences would be 200 mrem TEDE, or an increase of 170 mrem. The occupational exposure for recovery operations is calculated to be 15.0 person-rem.

The change would not require prior NRC approval since the increase of 170 mrem is only 3.4 percent of the difference between the current dose consequence and the 10CFR72.106 limit of 5000 mrem [i.e. $(170)/(5000-30) = 0.034$]. The occupational exposure need not be considered under 72.48.

Example 3

Following a gamma scan, it is determined that the effective thickness of the lead in a shield plug is 1/4 inch less than nominal. The fabrication specification and drawings permit only 1/8 inch less than nominal. It is proposed to accept the shield plug "as-is."

The direct effects of a decrease in effective lead thickness would be reviewed to identify potentially affected design basis

parameters. In addition, the indirect effect of increased dose rates would be considered. In this case the review concludes that the offsite accident dose consequences would not increase. Therefore, no prior NRC approval would be required.

Note: For spent fuel storage systems that have Technical Specification limits on shield plug dose rates, the change would be evaluated separately for compliance with the Technical Specification. Further, offsite dose consequences of the change must be evaluated per 10 CFR 72.104. This evaluation would be documented in the general licensee's 10 CFR 72.212 evaluation.

B4.3.4 Does the Activity Result in More than a Minimal Increase in the Consequences of a Malfunction?

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions evaluated in the UFSAR have their radiological consequences affected as a result of the proposed activity. The next step is to determine if the proposed activity does, in fact, increase the radiological consequences and, if so, are they more than minimally increased. The guidance for determining whether a proposed activity results in more than a minimal increase in the consequences of a malfunction is the same as that for accidents. Refer to Section B4.3.3.

B4.3.5 Does the Activity Create a Possibility for an Accident of a Different Type?

The set of accidents that an ISFSI facility or cask design must postulate for purposes of UFSAR safety analyses, typically including explosion, fire, earthquake, flood, etc., are often referred to as "design basis accidents." The terms accidents and off-normal events are often used in regulatory documents (e.g., in the accident analyses section(s) of the Standard Review Plan), where off-normal events are viewed as the more likely, low consequence events and accidents as less likely but more serious. This criterion deals with creating the possibility for accidents of similar frequency and significance to those already included in the licensing basis for the ISFSI facility. Thus, accidents that would require multiple independent failures or other circumstances in order to "be created" would not meet this criterion.

Certain accidents are not discussed in the UFSAR because their effects are bounded by other related events that are analyzed. For example, a postulated cask drop of a certain distance may not be specifically evaluated in the UFSAR because it has been determined to be less limiting than the evaluated cask drop. Therefore, if a proposed design or ISFSI facility change would introduce a cask drop of a distance less than the evaluated cask drop, the postulated cask drop need not be considered an accident of a different type.

The possible accidents of a different type are limited to those that are as likely to happen as those previously evaluated in the UFSAR. The accident must be credible in the sense of having been created within the range of assumptions previously considered in the licensing basis (e.g., random single failure, loss of offsite power, etc.). A new initiator of an accident previously evaluated in the UFSAR is not a different type of accident. Such a change or activity, however, which increases the frequency of an accident previously thought to be incredible to the point where it becomes as likely as the accidents in the UFSAR, could create the possibility of an accident of a different type. For example, there are a number of scenarios, such as multiple steam generator tube ruptures, that have been analyzed extensively. However, these scenarios are of such low probability that they may not have been considered to be part of the design basis. However, if a change or activity is proposed such that a scenario such as a multiple steam generator tube rupture becomes credible, the change or activity could create the possibility of an accident of a different type. In some instances these example accidents could already be discussed in the UFSAR.

In evaluating whether the proposed change or activity creates the possibility of an accident of a different type, the first step is to determine the types of accidents that have been evaluated in the UFSAR. The types of credible accidents that the proposed activity could create that are not bounded by UFSAR-evaluated accidents are accidents of a different type.

4.3.6 Does the Activity Create a Possibility for a Malfunction of an SSC Important to Safety with a Different Result?

Malfunctions of SSCs are generally postulated as potential single failures to evaluate plant ISFSI facility or cask design performance with the focus being on the result of the malfunction rather than the cause or type of malfunction. A malfunction that involves an initiator

or failure whose effects are not bounded by those explicitly described in the UFSAR is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or effect is the same as, or is bounded by, that previously evaluated in the UFSAR. The following examples illustrate this point:

- **A cask CoC holder desires to replace the fuel support breakaway clips used in a particular cask design by an energy absorption device. The breakaway clips are used to mitigate the effects of a cask drop event. This change may introduce a new failure mechanism that could affect the mitigation of a cask drop event. But if this effect (failure of the energy absorption device to mitigate the effects of a cask drop) was bounded by an UFSAR description of the effects of a failure of the breakaway clips to mitigate the effects of a cask drop, then a malfunction with a different result has not been created, and prior NRC approval under the criterion of 72.48(c)(2)(vi) would not be required. If failure of the breakaway clips to mitigate a cask drop event had not been described in the UFSAR, then the replacement of the clips with an energy absorption device would create a possibility for a malfunction of an SSC important to safety with a different result, and prior NRC approval under the criterion of 72.48(c)(2)(vi) would be required.**
- ~~If a pump is replaced with a new design, there may be a new failure mechanism introduced that would cause a failure of the pump to run. But if this effect (failure of the pump to run) was previously evaluated and bounded, then a malfunction with a different result has not been created.~~

Certain malfunctions are not explicitly described in the UFSAR because their effects are bounded by other malfunctions that are described. For example, failure of an air pad carrying a loaded cask and subsequent drop of the pad may not be explicitly described in the UFSAR because the drop would be bounded by the cask drop analysis.

The possible malfunctions with a different result are limited to those that are as likely to happen as those described in the UFSAR. For example, a seismic induced failure of a component that has been designed to the appropriate seismic criteria will not cause a malfunction with a different result. However, a proposed change or activity that increases the likelihood of a malfunction previously

thought to be incredible to the point where it becomes as likely as the malfunctions assumed in the UFSAR, could create a possible malfunction with a different result.

In evaluating a proposed activity against this criterion, the types and results of failure modes of SSCs that have previously been evaluated in the UFSAR and that are affected by the proposed activity should be identified. ~~This evaluation should be performed consistent with any failure modes and effects analysis (FMEA) described in the UFSAR, recognizing that certain proposed activities may require a new FMEA to be performed.~~ Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or the overall ~~system~~ ISFSI facility level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators ~~or mitigation impacts~~, it also needs to consider the nature of the proposed activity. Thus, for instance, ~~if~~ a single failure proof lifting device were to be replaced with a non-single failure proof lifting device, but the lift height is within the cask drop analysis, the consequences should still be evaluated to determine if any new outcomes are introduced.

Once the malfunctions previously evaluated in the UFSAR and the results of these malfunctions have been determined, then the types and results of failure modes that the proposed activity could create are identified. Comparing the two lists can provide the answer to the criterion question.

B4.3.7 Does the Activity Result in A Design Basis Limit for a Fission Product Barrier Being Exceeded or Altered?

For the purposes of 10 CFR 72.48 considerations, the fission product barriers for a spent fuel storage cask system would include the fuel cladding and the confinement boundary for the storage system. Dry spent fuel storage systems are designed in accordance with NRC requirements to preserve both fuel cladding integrity and confinement capability during all credible normal, off-normal, and accident events. Integrity of the fuel cladding is required to maintain retrievability and sub-criticality of the stored spent fuel. Even if the cladding is not explicitly credited in the UFSAR as a fission product boundary, such as when damaged fuel is stored in a cask, effects of a proposed activity on cladding should still be considered when answering this 72.48(c)(2)(vii) criteria

because the undamaged cladding integrity would continue to be important to maintain retrievability and sub-criticality.

Preservation of the confinement boundary is required to ensure against the uncontrolled release of radioactive materials. ~~What actually constitutes~~ The makeup of the confinement boundary depends upon the storage system design as described in the UFSAR.

10 CFR 72.48 evaluation under criterion (c)(2)(vii) focuses on the fission product barriers and on the critical design information that supports their continued integrity. Guidance for applying this criterion is structured around a two-step approach:

- Identification of affected design basis limits for a fission product barrier
- Determination of when those limits are exceeded or altered.

Identification of affected design basis limits for a fission product barrier

The first step is to identify the fission product barrier design basis limits, if any, that are affected by a proposed activity. Design basis limits for a fission product barrier are the controlling numerical values established during the licensing review as presented in the UFSAR for any parameter(s) used to determine the integrity of the fission product barrier. These limits have three key attributes:

- The parameter is fundamental to the barrier's integrity. Design basis limits for fission product barriers establish the reference bounds for design of the barriers, as defined in 10 CFR 72.3. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, design bases limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.

For purposes of this evaluation, design bases parameters that are used to directly determine fission product barrier integrity should be distinguished from subordinate parameters that can indirectly affect fission product barrier performance. Indirect effects of changes to subordinate parameters are evaluated in terms of their effect on the more fundamental design bases parameters/limits that ensure fission product barrier integrity. For example, a heat

transfer pathway is a subordinate parameter for purposes of this evaluation, not a design bases parameter/limit. The acceptability of a reduction in a heat transfer pathway would be determined based on its effect on design bases limits for the fuel clad and the canister (e.g., clad integrity and canister pressure).

- **The limit is expressed numerically. Design basis limits are numerical values used in the overall design process, not descriptions of functional requirements. Design basis limits are typically the numerical event acceptance criteria utilized in the accident analysis methodology. The ISFSI facility's or cask's design and operation associated with these parameters as described in the UFSAR will be at or below (more conservative than) the design basis limit.**
- **The limit is identified in the UFSAR. As required by 10 CFR 72.24(c) or 10 CFR 72.230, design basis limits were presented in the original FSAR and continue to reside in the UFSAR. They may be located in a vendor topical report that is incorporated by reference in the UFSAR.**

Consistent with the discussion of 10 CFR 72.48 applicability in Section B4.1, any design basis limit for a fission product barrier that is controlled by another, more specific regulation or Technical Specification would not require evaluation under Criterion (c)(2)vii. The effect of the proposed activity on those parameters would be evaluated in accordance with the more specific regulation. Effects (either direct or indirect—see discussion below) on design basis parameters covered by another regulation or Technical Specification need not be considered as part of evaluations under this criterion.

Examples of typical fission product barrier design basis limits are identified in the following table:

Barrier	Design Bases Parameter	Typical Design Basis Limit
Fuel Cladding	Protection against gross rupture	Clad temperature: consistent with model
		Criticality: K-eff < 0.95, fresh fuel assumed, 95/95 probability/confidence with appropriate consideration of uncertainties/biases
		Decay Heat : Each fuel assembly must meet the specified limit, consistent with heat transfer calculations (e.g. 1 kW max. for each assembly)
Confinement boundary	Preservation of confinement boundary	Pressure: Canister design pressure
		Stresses: Code compliance as described in the UFSAR
		Leak rate: Specified leak rate to be verified by helium leak testing after closure

The list above may vary for a given **ISFSI** facility/cask design and/or cask vendor and may include other parameters for specific accidents. For example, the design of a particular cask system may utilize a methodology for criticality control that credits partial burnup. If a given **ISFSI** facility/cask design has this or other parameters incorporated into the UFSAR as a design basis limit for a fission product barrier, then changes affecting it should be evaluated under this criterion.

Two of the ways that a licensee/certificate holder can evaluate proposed activities against this criterion are as follows. The licensee/certificate holder may identify all design bases parameters for fission product barriers and include them explicitly in the procedure for performing 10 CFR 72.48 evaluations. Alternatively, the effects of a proposed activity could be evaluated first to determine if the change affects design bases parameters for fission product barriers. The results of these two approaches are equivalent provided the guidance for "exceeded or altered" described below is followed. In all cases, the direct and indirect effects of proposed activities must be included in the evaluation.

Exceeded or altered

A specific proposed activity requires a license or cask CoC amendment if the design basis limit for a fission product barrier is "exceeded or altered." The term "exceeded" means that as a result of the proposed activity, the ISFSI facility's or cask's predicted response would be less conservative than the numerical design basis limit identified above. The term "altered" means the design basis limit itself is changed.

The effect of the proposed activity includes both direct and indirect effects. A reduction in the shell thickness (confinement boundary) that increases internal stresses beyond code allowables is a direct effect that would require a license amendment. Indirect effects provide for another parameter or effect to cascade from the proposed activity to the design basis limit. For example, increasing the size of structural components for greater strength in the internal fuel basket, could decrease the free volume within the storage cask. That effect could increase the internal pressure, resulting in an increase in the shell (confinement boundary) stresses. The 10 CFR 72.48(c)(2)(vii) evaluation of this change would focus on whether the design basis ASME code allowables and pressure limits would be exceeded.

Altering a design basis limit for a fission product barrier is not a routine activity, but it can occur. An example of this would be re-evaluating the thermal performance of a storage system while taking credit for reduced decay heat in some of the stored fuel assemblies in order to increase the decay heat in other fuel assemblies. Another example is redesigning portions of the storage canister shell such that they no longer comply with the code of construction. These are infrequent activities affecting key elements of the defense-in-depth philosophy. As such, no distinction has been made between a conservative and non-conservative change in the limit.

Evaluations performed under this criterion may incorporate a number of refinements to simplify the review. For example, if an engineering evaluation demonstrates that no parameters are affected that have design basis limits for fission product barriers associated with them, no 10 CFR 72.48(c)(2)(vii) evaluation is required. Similarly, most parameters that require evaluation under this criterion have calculations or analyses supporting the ISFSI facility's or cask's design. If an engineering evaluation demonstrates that the analysis

presented in the UFSAR remains bounding, then no 10 CFR 72.48(c)(2)(vii) evaluation is required. When using these techniques, both indirect and direct effects must be considered to ensure that important interactions are not overlooked.

Examples illustrating the two-step approach for evaluations under this criterion are provided below:

Example 1

The thickness of the material used for the fuel assembly basket tubes has been found below the minimum specified in the fabrication specifications and drawings. In this example, the basket tubes serve as structural components of the basket. It is proposed to accept the condition "as-is."

Identification of design basis limits

The effects of the reduced material thickness would be reviewed. The direct effect would include the impact on the criticality and heat transfer analyses. The indirect effects would include the impact on fuel cladding integrity caused by the attendant decrease in basket strength. Thus, the proposed activity may impact two design basis limits: criticality and cladding stress.

Exceeded or altered

Any increase in reactivity would be compared to the design basis limit. If the revised reactivity exceeded the design basis limit, then a license amendment would be required.

In this example, the design basis limits are not being "altered." Therefore, this element of the review is not applicable.

Example 2

The as-built interior length of a concrete overpack is found to be less than the minimum length in the fabrication specification and drawings. An analysis shows that thermal expansion of the storage canister when placed in the overpack would result in an interference when the canister is loaded

with design basis fuel assemblies. It is proposed to limit the decay heat of the fuel to be stored in the concrete overpack to 75 percent of the value reflected in the safety analysis.

Identification of Design Basis Limit

The affected parameter is fuel assembly decay heat.

Exceeded or altered

In this case, the design basis limit has not been "exceeded" because the decay heat will be less than the limit. However, the design basis limit itself has been "altered" and thus prior NRC approval is required. The issue of conservative vs. non-conservative is not germane to requiring a submittal. That is, prior NRC approval is required regardless of direction because this is a fundamental change in the ISFSI facility or cask design.

B4.3.8 Does the Activity Result in a Departure from a Method of Evaluation Described in the UFSAR Used in Establishing the Design Bases or in the Safety Analyses?

The UFSAR contains design and licensing basis information for an ISFSI facility or spent fuel storage cask design, including description on how regulatory requirements for design are met and how the ISFSI facility or cask responds to various design basis accidents and events. Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and why the ISFSI facility's or cask's response to accidents and events is acceptable. As such, in cases where the analytical methodology was considered to be an important part of the conclusion that the ISFSI facility or cask met the required design bases, these analytical methods were described in the UFSAR and received varying levels of NRC review and approval during licensing.

Because 10 CFR 72.48 provides a process for determining if prior NRC approval is required before making changes to the ISFSI facility or spent fuel storage cask design as described in the UFSAR, changes to the methodologies described in the UFSAR also fall under the provisions of the 10 CFR 72.48 process, specifically criterion (c)(2)(viii). In general, licensees or cask certificate holders can make changes to elements of a methodology without first obtaining a license amendment or cask CoC amendment if the results are essentially the same as, or more conservative than, previous results. Similarly, licensees or cask certificate holders can also use different methods

without first obtaining a license or cask CoC amendment if those methods have been approved by the NRC for the intended application.

If the proposed activity does not involve a change to a method of evaluation, then the 10 CFR 72.48 evaluation should reflect that this criterion is not applicable. If the activity involves only a change to a method of evaluation, then the 10 CFR 72.48 evaluation should reflect that criteria 10 CFR 72.48(c)(2)(i—vii) are not applicable.

The first step in applying this criterion is to identify the methods of evaluation that are affected by the change. This is accomplished during application of the screening criteria in Section B4.2.1.3.

Next, the licensee or cask CoC holder must determine whether the change constitutes a departure from a method of evaluation that would require prior NRC approval. As discussed further below, for purposes of evaluations under this criterion, the following changes are considered a departure from a method of evaluation described in the UFSAR:

- Changes to any element of analysis methodology that yield results that are non-conservative or not essentially the same as the results from the analyses of record.
- Use of new or different methods of evaluation that are not approved by NRC for the intended application.

By way of contrast, the following changes are not considered departures from a method of evaluation described in the UFSAR:

- Departures from methods of evaluation that are not described, outlined or summarized in the UFSAR (such changes may have been screened out as discussed in Section B4.2.1.3);
- Use of a new NRC-approved methodology (e.g., new or upgraded computer code) to reduce uncertainty, provide more precise results, or other reason, provided such use is (a) based on sound engineering practice, (b) appropriate for the intended application, and (c) within the limitations of the applicable SER. The basis for this determination should be documented in the licensee or cask CoC holder evaluation.
- Use of a methodology revision that is documented as providing results that are essentially the same as or more

conservative than either the previous revision of the same methodology or with another methodology previously accepted by NRC through issuance of an SER.

Subsection B4.3.8.1 provides guidance for making changes to one or more elements of an existing method of evaluation used to establish the design bases or in the safety analyses. Subsection B4.3.8.2 provides guidance for adopting an entirely new method of evaluation to replace an existing one. Examples illustrating the implementation of this criterion are provided in Section B4.3.8.3.

B4.3.8.1 Guidance for Changing One or More Elements of a Method of Evaluation

The definition of "departure ..." provides licensees with the flexibility to make changes under 10 CFR 72.48 to methods of evaluation whose results are "conservative" or that are not important with respect to the demonstrations of performance that the analyses provide. Changes to elements of analysis methods that yield conservative results, or results that are essentially the same would not be departures from approved methods.

Conservative vs. Non-Conservative Results

Gaining margin by changing one or more elements of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR 72.48. Such departures require prior NRC approval of the revised method. Analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change from 45 psig to 48 psig in the result of a cask peak pressure analysis (with design basis limit of 50 psig) using a revised method of evaluation would be considered a conservative change when applying this criterion. In other words, the revised method is more conservative if it predicts more severe conditions given the same set of inputs. This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making potential physical or procedure changes without a license amendment.

In contrast, if the use of a modified method of evaluation resulted in a change in calculated cask peak pressure from 45 psig to 40 psig, this

would be a non-conservative change. That is because the change would result in more margin being available (to the design basis limit of 50 psig) for the licensee to make more significant changes to the physical ISFSI facility, cask design, or procedures.

"Essentially the Same"

Licensees or cask CoC holders may change one or more elements of a method of evaluation such that results move in the non-conservative direction without prior NRC approval, provided the revised result is "essentially the same" as the previous result. Results are "essentially the same" if they are within the margin of error for the type of analysis being performed. Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) would typically be within the analysis margin of error and thus considered "essentially the same." For example, when a method is applied using a different computational platform (mainframe vs workstation), results of cases run on the two platforms differed by less than 1%, which is the margin of error for this type of calculation. Thus the results are essentially the same, and do not constitute a departure from a method that requires prior NRC approval.

The determination of whether a new analysis result would be considered "essentially the same" as the previous result can be made through benchmarking the revised method to the existing one, or may be apparent from the nature of the differences between the methods. When benchmarking a revised method to determine how it compares to the previous one, the analyses that are done must be for the same set of plant conditions to ensure that the results are comparable. Comparison of analysis methods should consider both the peak values and time behavior of results, and engineering judgement should be applied in determining whether two methods yield results that are essentially the same.

B4.3.8.2 Guidance for Changing from One Method of Evaluation to Another

The definition of "departure ..." provides licensees with the flexibility to make changes under 10 CFR 72.48 from one method of evaluation to another provided that the new method is approved by the NRC for the intended application. A new method is approved by the NRC for intended application if it is approved for the type of analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied.

NRC approval ~~has~~ would typically followed one of two paths. ~~Most~~ Some reactor or fuel vendors and several utilities and spent fuel storage cask vendors ~~have~~ will prepared and obtained NRC approval of topical reports that describe methodologies for the performance of a given type or class of analysis. Through a Safety Evaluation Report, the NRC ~~would~~ approved the use of the methodologies for a given class of ~~power plants,~~ ISFSIs or spent fuel storage casks. In some cases, the NRC ~~would~~ has accorded "generic" approval of analysis methodologies. Terms, conditions and limitations relating to the application of the methodologies ~~would~~ are usually be documented in the topical reports, the SER, and correspondence between the NRC and the methodology owner that is referenced in the SER or associated transmittal letter.

The second path is the approval of a specific analysis rather than a more generic methodology. In these cases, ~~t~~ The NRC's approval has ~~would~~ typically be part of an ISFSI or cask design's licensing basis and tended to be limited to a given ISFSI or spent fuel storage cask 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 should be ~~are~~ usually documented in the original license or CoC application or license or CoC amendment request, the SER, and any correspondence between the NRC and the analysis owner that is referenced in the SER or associated transmittal letter.

It is incumbent upon the user of a new methodology—even one generically approved by the NRC—to ensure they have a thorough understanding of the methodology in question, the terms of its existing application and conditions/limitations on its use. A range of considerations is identified below that may be applicable to determining whether new methods are technically appropriate for the intended application. The licensee/CoC holder should address these and similar considerations, as applicable, and document in the 10 CFR 72.48 evaluation the basis for determining that a method is appropriate and approved for the intended application. To obtain an adequate understanding of the method and basis for determining it is approved for use in the intended application, licensees/CoC holders should consult various sources, as appropriate. These include SERs, topical reports, licensee correspondence with the NRC and licensee/CoC holder personnel familiar with the existing application of the method. If adequate information cannot be found on which to base the intended application of the methodology, the method should not be considered "approved by the NRC for the intended application." ~~that~~

~~all conditions and limitations under which the method received NRC approval are identified.~~

The applicable terms and conditions for the use of a methodology are not limited to a specific analysis; the qualification of the organization applying the methodology is also a consideration. For Part 50 reactor licensees, the NRC, through Generic Letter 83-11, Supplement 1, the NRC has established a method by which utilities reactor licensees can demonstrate they are generally qualified to perform safety analyses. Reactor licensees Utilities thus qualified can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another plant's licensing basis, without requiring prior NRC approval. The guidance of Generic Letter 83-11, Supplement 1 may also be useful to ISFSI licensees and cask CoC holders as a method to demonstrate that they are generally qualified to perform safety analyses. ISFSI licensees or cask CoC holders thus qualified can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another ISFSI's or cask design's licensing basis, without requiring prior NRC approval. Other ISFSI licensees and Cask CoC holders should also utilize the guidance of GL 83-11, Supplement 1. ISFSI Licensees or cask CoC holders that have not satisfied the guidelines of Generic Letter 83-11, Supplement 1, may, of course, continue to seek ISFSI-specific or cask design-specific approval to use new methods of evaluation.

When considering the application of a methodology, it is necessary to adopt the methodology *en toto* and apply it consistent with applicable terms, conditions and limitations. Mixing attributes of new and existing methodologies is considered a revision to a methodology and must be evaluated as such per the guidance in Section B4.3.8.1.

Considerations for Determining if New Methods are Technically Appropriate for the Intended Application

The following questions highlight important considerations for determining that a particular application of a different method is technically appropriate for the intended application, within the bounds of what has been found acceptable by NRC, and does not require prior NRC approval.

- Is the application of the methodology consistent with the ISFSI facility's or cask design's licensing basis (e.g., NUREG-1536, NUREG-1567, or other ISFSI or cask design-specific commitments)? Will the methodology supersede a methodology

addressed by other regulations or the **ISFSI or cask Technical Specifications**? Is the methodology consistent with relevant industry standards?

If application of the new methodology requires exemptions from regulations or **ISFSI- or cask-specific commitments**, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with an **ISFSI facility's or cask's** licensing basis, then prior NRC approval may be required. The applicable change process must be followed to make the **ISFSI facility's or cask's** licensing basis consistent with the requirements of the new methodology.

- If a computer code is involved, has the code been installed in accordance with applicable software Quality Assurance requirements? Has the **ISFSI- or cask design-specific model** been adequately qualified through benchmark comparisons against test data, ~~empirical plant~~ data, or approved engineering analyses? Is the application consistent with the capabilities and limitations of the computer code? Has industry experience with the computer code been appropriately considered?

The computer code installation and **ISFSI or cask design -specific model qualification** is not directly transferable from one organization to another. The installation and qualification should be in accordance with the licensee's or **cask CoC holder's** Quality Assurance program.

- Is the **ISFSI facility or cask design** for which the methodology has been approved designed and operated in the same manner as the **ISFSI facility or cask design** to which the methodology is to be applied? Is the relevant equipment the same? Does the equipment have the same pedigree? Are the relevant failure modes and effects analyses the same? If the **ISFSI facility or cask design** is designed and operated in a similar, but not identical, manner, the following types of considerations should be addressed to assess the applicability of the methodology:
 - How could those differences affect the methodology?
 - Are additional sensitivity studies required?
 - Should additional single failure scenarios be considered?

- Are analyses of limiting scenarios, effects of equipment failures, etc., applicable for the specific ISFSI or cask design?
- Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?
- Differences in the ISFSI or cask design configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage cask designs may not have been required to consider the same isotopes for offsite dose calculations as those in the licensing basis for more recent vintage cask designs. The existence of these differences does not preclude application of a new methodology to an ISFSI facility or cask design; however, differences must be identified, understood and documented. Slight modifications to the NRC approved methodology to address ISFSI- or cask design-specific features are acceptable provided the analysis results obtained are conservative or essentially the same with respect to the unmodified methodology.

~~Is the ISFSI or cask configuration the same as described in the methodology? If the ISFSI or cask configuration is similar, but not the same, the following types of considerations should be addressed to assess the applicability of the methodology:~~

- ~~• How could these differences affect the methodology?~~
- ~~• Are additional sensitivity studies required?~~
- ~~• Should additional single failure scenarios be considered?~~
- ~~• Are analyses of limiting scenarios, effects of equipment failures, etc., applicable for the specific ISFSI or cask design?~~
- ~~• Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?~~

~~Differences in the ISFSI or spent fuel storage cask design configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage casks may not have been required to consider the same isotopes for offsite dose calculations as those in the licensing basis for more recent vintage casks. The existence of these differences does not preclude application of a new~~

~~methodology to an ISFSI facility or cask design; however, differences must be identified, understood and documented. If evaluation determines the differences to be material to the NRC approval basis for the method, then the method cannot be considered approved for the intended application.~~

- ~~• Is the ISFSI facility or cask design for which the methodology has been approved designed and operated in the same manner as the ISFSI facility or cask design to which the methodology is to be applied? If the ISFSI facilities or cask designs are not designed and operated in the same manner, the following types of considerations should be addressed to assess the applicability of the methodology:~~
 - ~~• Is the equipment the same? Does the equipment have the same pedigree (e.g., Class 1E, Seismic Category I, etc.)? If similar, but not the same, what additional allowances must be made? Are the relevant failure modes and effects analyses the same? If slight modifications to the methodology are required, are these within the terms, conditions, and limitations on which NRC approval of the methodology was based?~~
 - Even if the basic ISFSI facility or cask design configuration is nearly the same between two facilities or cask designs, differences in ISFSI facility or cask specific components may make the application of a methodology to another ISFSI facility or cask design inappropriate. For example, an ISFSI site may have unique soil properties and unique soil liquefaction potential under the ISFSI pad, requiring an application of a methodology that would be inappropriate at another site. The existence of these differences does not preclude application of a new methodology to a ISFSI facility or cask design; however, differences must be identified, understood and documented. If evaluation determines the differences to be material to the NRC approval basis for the method, then the method cannot be considered approved for the intended application.

B4.4 APPLYING 10 CFR 72.48 TO COMPENSATORY ACTIONS TO ADDRESS NONCONFORMING OR DEGRADED CONDITIONS

Three general courses of action are available to licensees to address non-conforming and degraded conditions. Whether or not 10 CFR 72.48 must be applied, and the focus of a 10 CFR 72.48 evaluation if

one is required, depends on the corrective action plan chosen by the licensee or cask CoC holder, as discussed below:

- If the licensee or cask CoC holder intends to restore the SSC back to its as-designed previous condition (as described in the UFSAR), then this corrective action should be performed in accordance with 10 CFR 72, Subpart G (i.e., in a timely manner commensurate with safety). This activity is not subject to 10 CFR 72.48.
- If an interim compensatory action is taken to address the condition and involves a temporary procedure or ISFSI facility or cask design change, 10 CFR 72.48 should be applied to the temporary change. The intent is to determine whether the temporary change/compensatory action itself (not the degraded condition) impacts other aspects of the ISFSI facility, cask design, or procedures described in the UFSAR. In considering whether a temporary change impacts other aspects of the ISFSI facility or cask design, a licensee or cask CoC holder should pay particular attention to ancillary aspects of the temporary change that result from actions taken to directly compensate for the degraded condition.
- If the licensee or cask CoC holder corrective action is either to accept the condition "as-is" resulting in something different than its as-designed condition described in the UFSAR, or to change the ISFSI facility, cask design, or procedures to something different than described in the UFSAR, 10 CFR 72.48 should be applied to the corrective action, unless another regulation applies. In these cases, the final corrective action resolution becomes the proposed change that would be subject to 10 CFR 72.48.

In resolving degraded or nonconforming conditions, the need to obtain NRC approval for a proposed activity does not affect the licensee's authority to operate the ISFSI. The licensee may load or unload casks, etc., provided that necessary SSCs are operable and the degraded condition is not in conflict with the technical specifications, the license, or the CoC.

The following examples illustrate the process for implementing a temporary change as a compensatory action to address a degraded/nonconforming condition:

Example 1

In reviewing cask documentation, a licensee discovers that a loaded cask does not meet the drop analysis and is outside the analyzed space for cask transfer activities. The licensee will perform a new analysis in a timely manner and leave the cask in place until the new analysis is completed. The degraded condition would not be subject to 10 CFR 72.48.

Example 2

While digging a trench outside of the ISFSI, a licensee accidentally cuts some cask temperature monitoring wires. An interim compensatory measure is implemented to connect a temporary temperature monitoring instrument. The cut wires will be repaired in a timely manner. This temporary condition would not be subject to 10 CFR 72.48. The compensatory measure to connect the temporary instrument would be subject to 10 CFR 72.48 to determine if it has any impact on other aspects of the ISFSI facility or cask.

Example 3

A pressure switch on a canister is found to be defective. It is a redundant switch that is described in the UFSAR but not required by the CoC or Technical Specifications. The licensee determines that the switch is not needed for any safety analyses purposes and chooses to leave the failed switch "as is." This would be a change to the ISFSI facility or spent fuel storage cask design and subject to 10 CFR 72.48.

B4.5 DISPOSITION OF 10 CFR 72.48 EVALUATIONS

There are two possible conclusions to a 10 CFR 72.48 evaluation:

- (1) The proposed activity may be implemented without prior NRC approval.
- (2) The proposed activity requires prior NRC approval.

Where an activity requires prior NRC approval, the activity must be approved by the NRC via license amendment in accordance with 10 CFR 72.56 for a specific license, or via cask CoC amendment in accordance with 10 CFR 72.244 for a CoC holder for itself or a

general license, prior to implementation. If prior NRC approval is required under 72.48 for a general licensee, the licensee could either request that the CoC holder for their cask system submit a CoC amendment request to the NRC under 10 CFR 72.244, if appropriate, or, if the change would only apply to their site, could submit, under 10 CFR 72.7, a request for an exemption to the 72.48(2) provision requiring that a general licensee shall request that the CoC holder obtain a CoC amendment. It is not clear at this time how a general licensee would request and obtain prior NRC approval for a site-specific change that requires prior NRC approval per 72.48. The NRC is looking at clarifying the regulations to address this situation. An activity is considered "implemented" when it provides its intended function, that is, when it is placed in service and declared operable. Thus, a licensee or cask CoC holder may design, plan, install, and test a modification prior to receiving the license or CoC amendment to the extent that these preliminary activities do not themselves require prior NRC approval under 10 CFR 72.48.

For proposed activities that are determined to require prior NRC approval, there are three possible options:

- (1) Cancel the planned change activity.
- (2) Redesign the proposed activity so that the it may proceed without prior NRC approval.
- (3) Apply for and obtain a license or cask CoC amendment under 10 CFR 72.56 or 10 CFR 72.244 prior to implementing the activity. Technical and licensing evaluations performed for such activities may be used as part of the basis for license amendment requests.

~~In resolving degraded or nonconforming conditions, the need to obtain NRC approval for a change does not affect the licensee's authority to operate the ISFSI facility or storage cask. The licensee may make mode changes provided that necessary SSCs are operable and the degraded condition is not in conflict with the technical specifications, the license, or cask CoC.~~

It is important to remember that determining that a proposed activity requires prior NRC approval does not determine whether it is safe. In fact, a proposed activity that requires prior NRC approval may significantly enhance overall ISFSI facility or cask safety at the expense of a small adverse impact in a specific area. It is the

responsibility of the licensee or cask CoC holder to assure that proposed activities are safe, and it is the role of the NRC to confirm the safety of those activities that are determined to require prior NRC review.

B5.0 DOCUMENTATION AND REPORTING

10 CFR 72.48(d) requires the following documentation and recordkeeping:

- (1) The licensee and certificate holder shall maintain records of changes in the ISFSI facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.
- (2) The licensee and certificate holder shall submit, as specified in § 72.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months.
- (3) The records of changes in the ISFSI facility or spent fuel storage cask design shall be maintained until (i) spent fuel is no longer stored in the ISFSI facility or the spent fuel storage cask design is no longer being used, or (ii) the Commission terminates the license or CoC issued pursuant to this part..
- (4) Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.
- (5) The holder of a spent fuel storage cask design CoC, who permanently ceases operation, shall provide the records of changes to the new certificate holder or to the Commission, as appropriate, in accordance with Sec. 72.234(d)(3).
- (6) (i) A general licensee shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(ii) A specific licensee using a spent fuel storage cask design, approved pursuant to subpart L of this part, shall

provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(iii) A certificate holder shall 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.

The documentation and reporting requirements of 10 CFR 72.48(d) apply to activities that require evaluation against the eight criteria of 10 CFR 72.48(c)(2) and are determined not to require prior NRC approval. That is, the phrase in 10 CFR 72.48(d)(1), "made pursuant to paragraph (c)," refers to those activities that were evaluated against the eight evaluation criteria (because, for example, they affect the ISFSI facility or cask design as described in the UFSAR), but not to those activities or changes that were screened out. Similarly, documentation and reporting under 10 CFR 50.59 is not required for activities that are canceled or that are determined to require prior NRC approval and are implemented via the license amendment request process.

Documenting 10 CFR 72.48 Evaluations

In performing a 10 CFR 72.48 evaluation of a proposed activity, the evaluator must address the eight criteria in 10 CFR 72.48(c)(2) to determine if prior NRC approval is required. Although the conclusion in each criterion may be simply "yes," "no," or "not applicable," there must be an accompanying explanation providing adequate basis for the conclusion. Consistent with the intent of 10 CFR 72.48, these explanations should be complete in the sense that another knowledgeable reviewer could draw the same conclusion. Restatement of the criteria in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. It is recognized, however, that for certain very simple activities, a statement of the conclusion with identification of references consulted to support the conclusion would be adequate and the 10 CFR 72.48 evaluation could be very brief.

The importance of the documentation is emphasized by the fact that experience and engineering knowledge (other than models and experimental data) are often relied upon in determining whether evaluation criteria are met. Thus the basis for the engineering judgment and the logic used in the determination should be documented to the extent practicable and to a degree commensurate

with the safety significance and complexity of the activity. This type of documentation is of particular importance in areas where no established consensus methods are available, such as for software reliability, or the use of commercial-grade hardware and software where full documentation of the design process is not available.

Since an important goal of the 10 CFR 72.48 evaluation is completeness, the items considered by the evaluator must be clearly stated.

Each 10 CFR 72.48 evaluation is unique. Although each applicable criteria must be addressed, the questions and considerations listed throughout this guidance document to assist evaluating the criteria are not requirements for all evaluations. Some evaluations may require that none of these questions be addressed while others will require additional considerations beyond those addressed in this guidance.

When preparing 10 CFR 72.48 evaluations, licensees may combine responses to individual criteria or reference other portions of the evaluation.

As discussed in Section B4.2.3, licensees may elect to use screening criteria to limit the number of activities for which written 10 CFR 72.48 evaluations are performed. A documentation basis should be maintained for determinations that the changes meet the screening criteria, i.e., screen out. 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.

Reporting to NRC

A summary of 10 CFR 72.48 evaluations for activities implemented under 10 CFR 72.48 must be provided to NRC. Activities that were screened out, canceled or implemented via license or CoC amendment need not be included in this report. The 10 CFR 72.48 reporting requirement (every 24 months) is identical to that for UFSAR updates such that licensees and CoC holders may provide these reports to NRC on the same schedule.

Reporting cask design changes to CoC holders or cask users

10 CFR 72.48(d)(6) requires:

- i) A general licensee shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable**

certificate holder within 60 days of implementing the change.

- ii) A specific licensee using a spent fuel storage cask design, approved pursuant to subpart L of this part, shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.
- iii) A certificate holder shall 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.

The records required to be provided in the 60-day reports would be those for changes to a spent fuel storage cask design that require evaluation against the eight criteria of 10 CFR 72.48(c)(2) and are determined not to require prior NRC approval. These records must include the written evaluation which provides the bases for the determination that the change does not require a license or CoC amendment pursuant to paragraph 10 CFR 72.48(c)(2).

10 CFR 72.48 evaluations performed to resolve fabrication non-conformances for specific storage casks during fabrication do not necessarily represent a change to a "spent fuel storage cask design." When such evaluations do not constitute a change to a cask design, they are not required to be reported in a 60-day report but they would be included in the routine 72.48 report to the NRC.

For the purposes of the 60-day report, licensees and CoC holders should transmit the report for a cask design change within 60 days of final approval of the 10 CFR 72.48 evaluation. Utilizing this milestone to establish the timing of transmitting the report will ensure that potentially affected entities are provided timely notification of the approved change, even if the change may not be actually implemented for some time.

When a general or specific licensee (cask user) receives a copy of the record for a cask design change from the CoC holder (see Figure B.2), they should review the record in a timely manner (within 60 days of receipt) to determine if the change is applicable to their site. If yes, the cask user should then determine if they should adopt the change on site.

If a general licensee determines that a cask design change should be adopted on site, they should review their site-specific 72.212 evaluations to determine if any would be changed by adopting the cask design change. If a 72.212 evaluation is changed, the general licensee would perform a 72.48 screening/evaluation as required by 10 CFR 72.212(b)(2)(ii). The answers/justification used in the 72.48 screenings/evaluations may be taken from the CoC holder's 72.48 screening/evaluation if they could also apply to the general licensee's screening/evaluation. A cask design change that has been reported to the general licensee by the CoC holder and then adopted by the general licensee would not need to be reported back to the CoC holder in a 60-day report because it would not be a change from the CoC holder's design change.

If a specific licensee determines that a cask design change should be adopted on site, they would review their site-specific ISFSI UFSAR to determine if a 72.70 update and 72.48 screening/evaluation would be required. The answers/justification used in the 72.48 screenings/evaluations may be taken from the CoC holder's 72.48 screening/evaluation if they could also apply to the specific licensee's screening/evaluation. . A cask design change that has been reported to the specific licensee by the CoC holder and then adopted by the specific licensee would not need to be reported back to the CoC holder in a 60-day report because it would not be a change from the CoC holder's design change.

When a CoC holder receives a copy of the record for a cask design change from a cask user, they should review the record in a timely manner (within 60 days of receipt) to determine if they should adopt the change (see Figure B.3). If so, the certificate holder would review the cask UFSAR to determine if a 72.48 screening/evaluation and 72.248 update would be required. The answers/justification used in the 72.48 screenings/evaluations may be taken from the cask user's 72.48 screening/evaluation if they could also apply to the CoC holder's screening/evaluation. A cask design change that has been reported to the CoC holder by a general or specific licensee and then adopted by the CoC holder would not need to be reported back to the general or specific licensee in a 60-day report because it would not be a change from the licensee's design change, but it would need to be reported to other cask users in a 60-day report.

Although records of changes to the ISFSI facility, to procedures, and to tests or experiments are not required to be provided in a 60-day report, ISFSI licensees and cask CoC holders may wish to exchange these documents on an agreed-upon schedule. These records may aid the general or specific licensee to comply with the 10 CFR 72.48(c)(3) requirement that, for purposes of implementing 72.48, the FSAR (as updated) is considered to include UFSAR changes resulting from 72.48 evaluations and 72.56/72.244 analyses performed since the last UFSAR update. Other configuration management process may also be used to ensure compliance with this requirement.

Documentation of the reviews of the 60-day reports by the recipients should be maintained, but is not required by 10 CFR 72.48.

ATTACHMENT 1

Text 10 CFR 72.48

§72.48--Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

(1) 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.

(2) Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses means:

(i) Changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

(3) Facility means either an independent spent fuel storage installation (ISFSI) or a Monitored Retrievable Storage facility (MRS).

(4) The facility or spent fuel storage cask design as described in the Final Safety Analysis Report (FSAR) (as updated) means:

(i) The structures, systems, and components (SSC) that are described in the FSAR (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

(5) Final Safety Analysis Report (as updated) means:

(i) For specific licensees, the Safety Analysis Report for a facility submitted and updated in accordance with §72.70;

(ii) For general licensees, the Safety Analysis Report for a spent fuel storage cask design, as amended and supplemented; and

(iii) For certificate holders, the Safety Analysis Report for a spent fuel storage cask design submitted and updated in accordance with §72.248.

(6) Procedures as described in the Final Safety Analysis Report (as updated) means those procedures that contain information described in the FSAR (as updated) such as how SSCs are operated and controlled (including assumed operator actions and response times).

(7) Tests or experiments not described in the Final Safety Analysis Report (as updated) means any activity where any SSC is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the FSAR (as updated) or

(ii) Inconsistent with the analyses or descriptions in the FSAR (as updated).

(b) This section applies to:

(1) Each holder of a general or specific license issued under this part, and

(2) Each holder of a Certificate of Compliance (CoC) issued under this part.

(c) (1) A licensee or certificate holder may 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), without obtaining either:

(i) A license amendment pursuant to §72.56 (for specific licensees) or

(ii) A CoC amendment submitted by the certificate holder pursuant to §72.244 (for general licensees and certificate holders) if:

(A) A change to the technical specifications incorporated in the specific license is not required; or

(B) A change in the terms, conditions, or specifications incorporated in the CoC is not required; and

(C) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

(2) A specific licensee shall obtain a license amendment pursuant to §72.56, a certificate holder shall obtain a CoC amendment pursuant to §72.244, and a general licensee shall request that the certificate holder obtain a CoC amendment pursuant to §72.244, prior to implementing a proposed change, test, or experiment if the change, test, or experiment would:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the FSAR (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a system, structure, or component (SSC) important to safety previously evaluated in the FSAR (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the FSAR;

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the FSAR (as updated);

(v) Create a possibility for an accident of a different type than any previously evaluated in the FSAR (as updated);

(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the FSAR (as updated);

(vii) Result in a design basis limit for a fission product barrier being exceeded or altered as described in the FSAR (as updated);
or

(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses performed pursuant to §72.56 or §72.244 since the last update of the FSAR pursuant to §72.70, or §72.248 of this part.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(d) (1) The licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee and certificate holder shall submit, as specified in §72.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report shall be submitted at intervals not to exceed 24 months.

(3) The records of changes in the facility or spent fuel storage cask design shall be maintained until:

(i) Spent fuel is no longer stored in the facility or the spent fuel storage cask design is no longer being used, or

(ii) The Commission terminates the license or CoC issued pursuant to this part.

(4) The records of changes in procedures and of tests and experiments shall be maintained for a period of 5 years.

(5) The holder of a spent fuel storage cask design CoC, who permanently ceases operation, shall provide the records of changes to the new certificate holder or to the Commission, as appropriate, in accordance with §72.234(d)(3).

(6) (i) A general licensee shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(ii) A specific licensee using a spent fuel storage cask design, approved pursuant to subpart L of this part, shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(iii) A certificate holder shall 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.