NUCLEAR ENERGY INSTITUTE

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November 9, 2000

Dr. Susan F. Shankman
Director, Licensing and Inspection
Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Project Number: 689

Subject: Request Review and Comment on NEI 96-07, Appendix B: Guidelines for 10 CFR 72.48 Implementation

Dear Dr. Shankman:

NEI 96-07, Appendix B: Guidelines for 10 CFR 72.48 Implementation was forwarded to you for review and comment June 15, 2000. The staff provided their recommendations for document improvement August 18, 2000. A meeting was held on September 7, 2000, between the NEI 72.48 Issue Task Force and the Spent Fuel Project Office to review and clarify dispositioning of the staff's recommendations. NEI 96-07, Appendix B: Guidelines for 10 CFR 72.48 Implementation (draft) was revised and forwarded on September 26, 2000.

Enclosed for your review for eventual endorsement in a regulatory guide is the revised NEI 96-07, Appendix B: Guidelines for 10 CFR 72.48 Implementation, (draft) November 6, 2000, based on further staff and industry review. Also enclosed is a summary of the proposed follow up changes for ease of review.

NEI and the industry are committed to providing complete guidance for NRC endorsement. We anticipate the need for continuing dialogue with the NRC to ensure readiness for the April 5, 2001, rule implementation date. If you have any questions or would like to set up a meeting, please contact me at (202) 739-8109 or by e-mail (lxh@nei.org), or Alan Nelson at (202) 739-8110 or by e-mail (apn@nei.org).

Sincerely,

Lynnette Hendricks

Lynnette Hendricks

Enclosures

NF04
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Add: NMSS/Ginny Tharpe
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NEI 96-07, Appendix B: Guidelines for 10 CFR 72.48 Evaluations
November 6, 2000
Proposed Changes

B1.2.1

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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, **general** licensees **must** also control changes to **their 10 CFR 72.212 evaluations** using the 10 CFR **72.48** process **in accordance with 10 CFR 72.212(b)(2)(ii).**

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**, ensures 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 issuance of a spent fuel storage cask CoC, or implementation of 10 CFR 72.212 evaluations**.

Subpart G also addresses corrective action. The application of 10 CFR **72.48** to compensatory measures that address degraded and non-conforming conditions is described in Section **B**4.4.

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.

ISFSI design events have been divided into categories based upon a qualitative assessment of frequency. **The design events, as discussed in NUREG-1567 and ANSI/ANS-57.9, are**:

- **<u>Design Event I - Normal Operations</u>: Events that are expected to occur regularly or frequently in the course of normal operation of the ISFSI.**

- **<u>Design Event II - Anticipated Occurrences (Off-normal Events)</u>: Events that can be expected to occur with moderate frequency or on the order of once during per calendar year of ISFSI operation.**

- **<u>Design Events III and IV - Accident Events</u>: Events considered to occur infrequently, if ever, during the lifetime of the ISFSI.**

During initial **ISFSI facility** licensing **or spent fuel storage cask certification, design events** were assessed in relative frequencies, as described above. Minimal increases in **the** frequency **of occurrence of an accident** 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.

...

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 **important to safety (ITS) SSCs and not-important to safety (NITS) SSCs when the failure of the NITS SSCs to perform their design functions could affect the ability of the ITS SSCs to perform their design functions**. 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.

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B4.3.3

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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 on a site-specific basis, the record of the 72.48 evaluation containing the updated calculated offsite dose value would be retained and the revised value used as the bounding value for the next 72.48 evaluation. 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(c)(2) requirementthat a general licensee shall request that the CoC holder obtain a CoC amendment. An exemption request should describe the proposed change and include justification for why the CoC holder is not requesting a CoC amendment for the change, and justification for the change itself.

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 "consequences" means dose. 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, 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 to mitigate the consequences of 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., **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 **and anticipated occurrences**, 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 **affecting normal operations** governed by 10 CFR Part 20 and **10 CFR 72.104** requirements. **An ISFSI must not exceed the limits of 10 CFR 20 and 10 CFR 72.104 as a result of a proposed activity.**

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 **the dose limits for ISFSI design bases accidents.The** calculated dose values for **a given** accident would be identified in the UFSAR. **If a general licensee has calculated a lower offsite dose consequence, 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 **accident** 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 **limit** (10 CFR **72.106**, as applicable). The current calculated dose values are those documented in the most up-to-date analyses of record.

10 CFR 72.104 establishes the annual dose limits for ISFSI anticipated occurrences (off-normal events) combined with normal ISFSI operations and other site operations (e.g., 25 mrem whole body to any real individual beyond the controlled area). In order to comply with 10 CFR 72.104, no activity would be allowed to result in the ISFSI exceeding the 10 CFR 72.104 limits. For anticipated occurrences, a *minimal increase* would include any increase up to the 10 CFR 72.104 limits. Any increase in consequences of an anticipated occurrence previously evaluated in the UFSAR that is still within the 10 CFR 72.104 limits would always be less than a minimal increase in consequences.

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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(c)(2) requirement that a general licensee shall request that the CoC holder obtain a CoC amendment. An exemption request should describe the proposed change and include justification for why the CoC holder is not requesting a CoC amendment for the change, and justification for the change itself.** 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**.

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NEI 96-07, Appendix B [Draft]

Nuclear Energy Institute

GUIDELINES FOR 10 CFR 72.48 IMPLEMENTATION

DRAFT – November 6, 2000

ACKNOWLEDGMENTS

10 CFR 72.48 was revised by the NRC to conform to the revised 10 CFR 50.59 to provide consistent implementation of these two analogous regulations. This Appendix was developed by starting with the NRC endorsed Guidance of NEI 99-06 Revision 1, Guidelines for 10 CFR 50.59 Implementation.
Recognition should be given to the NEI 10 CFR 50.59 Task Force and the Regulatory Process Working Group for their efforts in influencing regulatory change and development of the 50.59 guidelines.

This guidance was developed with the valuable assistance of the NEI Dry Storage 10 CFR 72.48 Issue Task Force. We appreciate the direct participation of the utilities, and vendors who contributed to the development and modification of the guideline. The dedicated and timely effort of the many task force participants, including management support of the effort, is greatly appreciated.

NOTICE

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FOREWORD

In 1999, the NRC revised 10 CFR 72.48 to be consistent with the changes being made to 10 CFR 50.59. NEI 97-06, Revision 1 was developed to provide guidance for the revised 10 CFR 50.59 regulation. Because of the intended consistency between 10 CFR 50.59 and 10 CFR 72.48, this Appendix B to NEI 96-07 was developed by utilizing the NEI 96-07, Revision 1 guidance to the maximum extent possible.

Please see the Foreword to NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," for background information regarding the development of NEI 96-07, Revision 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.

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.

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NEI 96-07, APPENDIX B:

Guidelines for 10 CFR 72.48 Evaluations

(Draft November 6, 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 applicable regulations**), 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, **general** licensees **must** also control changes to **their 10 CFR 72.212 evaluations** using the 10 CFR **72.48** process **in accordance with 10 CFR 72.212(b)(2)(ii).**

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

Prior NRC issuing an ISFSI license **or spent fuel storage cask CoC**, 10 CFR Part **72, Subpart G**, ensures 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 issuance of a spent fuel storage cask CoC, or implementation of 10 CFR 72.212 evaluations**.

Subpart G also addresses corrective action. The application of 10 CFR **72.48** to compensatory measures that address degraded and non-conforming conditions is described in Section **B**4.4.

B1.2.3 Relationship of 10 CFR 72.48 to the UFSAR

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. NEI 98-03, Revision 1 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 keep up-to-date the UFSAR for the cask designs 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 useful 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 and 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 addressing degraded and nonconforming conditions and on dispositioning 10 CFR **72.48** evaluations.

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 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 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**. 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 utilized to provide functions that would normally be served by the fuel clad, such as retrievabilty and criticality prevention (configuration of the fuel).** The **barriers** are designed to reliably fulfill their operational function by meeting all criteria and standards applicable to mechanical components **and** pressure components. 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**. **Analyses in the UFSAR also demonstrate that offsite doses during normal operations and anticipated occurrences will not exceed the limits of 10 CFR 72.104. 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 **and minimize doses to the public**. 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 identify** the accidents or malfunctions **to be evaluated in the UFSAR**. **Accident events are considered to occur infrequently, if ever, during the lifetime of the facility/cask.** Consequences resulting from accidents and malfunctions are analyzed and documented in the UFSAR and are evaluated against dose acceptance limits of **10 CFR 72.106. In addition, the SRP identifies anticipated occurrences (also known as off-normal events) to be evaluated in the UFSAR that are expected to occur with moderate frequency or once per calendar year. Doses from anticipated occurrences and normal operations must be within the limits of 10 CFR 72.104.**

The design effort and the operational controls necessary to ensure the required performance of the physical barriers during **normal operations, anticipated occurrences, 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.

The following are considered the basic nuclear safety criteria for the design of an ISFSI installation:

> **(1) maintain subcriticality;**
>
> **(2) prevent the release of radioactive material above acceptable amounts;**
>
> **(3) ensure radiation rates and doses do not exceed acceptable levels; and**
>
> **(4) 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 reflect performance of equipment 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 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

B 3.1	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). Section B4.3 provides guidance for performing 10 CFR **72.48** evaluations 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 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 **ISFSI facility 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 systems, structures and components (SSCs) that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, **CoC conditions,** orders or technical specifications, or (2) credited in licensee **or CoC holder** 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 bases 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-**important-to-safety** SSCs may perform design functions.

Method of performing or controlling a function means how a design function is accomplished as credited in the safety analyses,

[1] Definition of *design bases function* from revised Appendix B to NEI 97-04 (endorsed by Regulatory Guide **DG 1093**).

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 **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 **B**3.10. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR **72.48**(c)(2)(viii) is provided in Section **B**4.3.8.

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 **B**4.3.8.2.

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. The NRC wrote SECY-00-0047, dated February 23, 2000, to propose a draft regulatory guide (DG-1093) to endorse Appendix B to NEI 97-04. **As described in SECY-00-0047, the NEI general guidance is as follows:**

> **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 may 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 **B**4.2.1.1.

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 particular 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 **may be** controlled by **other more specific regulations**.

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 **B**3.10) are evaluated under criterion 10 CFR **72.48**(c)(2)(viii), whereas changes to input parameters described in the **U**FSAR 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	■ **Tipover and end drop analysis**
■ 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	■ **Benchmarking and correlation ranges**
■ 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.

- **Methods of evaluation used in UFSAR analyses that demonstrate that radioactive doses from normal**

operations and anticipated occurrences will be within the limits of 10 CFR 72.104.

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 procedures specifically identified in the UFSAR (e.g., operating 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, 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**. Sections **B**4.1.4 identifies examples of procedures that are not subject to 10 CFR **72.48.**

10 CFR 72.48 screening of procedures is discussed in Section B4.2.1.2.

B3.12 SAFETY ANALYSES

Definition:

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:

(1) The margins of safety during normal operations and expected operational occurrences during the life of the ISFSI or MRS; and

(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.

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; and
- **UFSAR analyses that demonstrate the design and performance of structures, systems, and components important to safety during normal operations and expected operational occurrences.**

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 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 storage conditions) or that could affect the capability of SSCs to perform their intended design functions (e.g., high stresses, high temperatures) are evaluated before they are conducted to determine if prior NRC approval is required.

B4 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 **B**4.1 and **B**4.2, 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 method of transfer that is identified in the UFSAR, and also would affect a specific transfer method requirement 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 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, maintenance-related testing, identical replacements, housekeeping and similar activities that do not permanently alter the design, performance requirements, operation, or control 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 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 98-03, Revision 1 may also be useful to Part 72 licensees and CoC holders 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:

- Administrative controls for creating or modifying procedures
- Training programs
- **ISFSI/cask design** 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 and/or 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 under 10 CFR **72.48**. Activities that are screened out from further evaluation under 10 CFR **72.48** should be documented as discussed in Section B4.2.3.

Each element of a proposed activity must be screened except in instances where linking elements of an activity is appropriate, in which case the linked elements can be considered together. A test for linking elements of proposed changes is interdependence.

It is appropriate for discrete elements to be considered 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.

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

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 **B**4.4.

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 activity 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 proposed activity is essential. A given activity 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 activity:

- 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 ativity 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** of the SSC **or cask**?

- Does the activity adversely affect other **casks that are in use at the ISFSI**?

- 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 **B**3.3, 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

[2] Note that as discussed in Section **B**4.2.1.1, any change that alters a design basis limit for a fission product barrier—positively or negatively—is considered adverse and must be screened in.

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 would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and 10 CFR **72.48**. 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 should 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 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.

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 adversely 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, a**n 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 adversely 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 adversely 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 non-**important-to-safety** 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** non-**important-to-safety** equipment **near the ISFSI** could compromise the **cask** cooling system's ability to **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** 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 **B**4.2.1, 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. In addition, any change to a design bases limit for a fission product barrier must be considered adverse and 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** and with no other design function affected 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 a 72.48 evaluation of the change is needed. Alternatively, 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 are "screened in" (i.e., require a 10 CFR **72.48** evaluation) if they adversely affect how SSC **or cask** design functions are performed or controlled (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), changes to the man-machine interface, 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 changes affecting how SSC design functions are performed or controlled :

- **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. 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 under10 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.

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 **B**3.14, 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 a 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.**

- Information gathering that is nonintrusive to the operation or design function of the associated SSC.

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.

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. Evaluations should consider the effects of the proposed activity on operator actions.

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.

ISFSI design events have been divided into categories based upon a qualitative assessment of frequency. **The design events, as discussed in NUREG-1567 and ANSI/ANS-57.9, are**:

- **Design Event I - Normal Operations: Events that are expected to occur regularly or frequently in the course of normal operation of the ISFSI.**

- **Design Event II - Anticipated Occurrences (Off-normal Events): Events that can be expected to occur with moderate frequency or on the order of once during per calendar year of ISFSI operation.**

- **Design Events III and IV - Accident Events: Events considered to occur infrequently, if ever, during the lifetime of the ISFSI.**

During initial **ISFSI facility** licensing **or spent fuel storage cask certification, design events** were assessed in relative frequencies, as described above. Minimal increases in **the** frequency **of occurrence of an accident** 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 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 occurence 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 occurance 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 occurance 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 occurance of an accident.

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

1. The proposed activity has a negligible effect on the frequency of occurance of an accident. A negligible effect on the frequency of occurance 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 occurance 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. or

   - The resultant frequency of occurrence remains below 1E-6 per year or applicable **ISFSI site**-specific threshold.

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

<u>Example</u>

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 **important to safety (ITS) SSCs and not-important to safety (NITS) SSCs when the failure of the NITS SSCs to perform their design functions could affect the ability of the ITS SSCs to perform their design functions**. 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 occurance 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. 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, it also needs to consider the nature of the proposed activity.

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.

Examples 1-4, below, illustrate cases where there would not be more than a minimal increase in the likelihood of occurance of a malfunction of a SSC important to safety:

Example 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.

Example 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.

Example 3

The change satisfies applicable design bases requirements (e.g., seismic and wind loadings, separation criteria, environmental qualification, etc.).

Example 4

The change involves a new or modified **fuel handling** action that supports a design function credited in safety analyses, provided:

- The action (including required completion time) is reflected in procedures and 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 and cask design functions**

Examples 5-8 are cases that would require prior NRC approval because they would result in more than a minimal increase in the likelihood of occurance of a malfunction of a SSC important to safety:

Example 5

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.

Example 6

The change would reduce system/equipment redundancy, diversity, separation, or independence.

Example 7

The change would (permanently) substitute manual action for automatic action for performing UFSAR-described design functions. (Guidance for temporary substitution of manual action for automatic action to compensate for a degraded/nonconforming condition is provided in NRC Generic Letter 91-18, Revision 1, **which was written for reactor licensees and may also be useful to ISFSI licensees and cask CoC holders.)**

Example 8

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. Note: The factor of two should be applied at the component level. Certain changes 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 frequency under criterion 10 CFR **72.48**(c)(2)(i).

Example 9

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 "consequences" means dose. 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 **B**4.3.7, concerning 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 to mitigate the consequences of 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., **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 **and anticipated occurrences**, 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 **affecting normal operations** governed by 10 CFR Part 20 and **10 CFR 72.104** requirements. **An ISFSI must not exceed the limits of 10 CFR 20 and 10 CFR 72.104 as a result of a proposed activity.**

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 **the dose limits for ISFSI design bases accidents.The** calculated dose values for **a given** accident would be identified in the UFSAR. **If a general licensee has calculated a lower offsite dose consequence, 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 **accident** 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 **limit** (10 CFR **72.106**, as applicable). The current calculated dose values are those documented in the most up-to-date analyses of record.

10 CFR 72.104 establishes the annual dose limits for ISFSI anticipated occurrences (off-normal events) combined with normal ISFSI operations and other site operations (e.g., 25 mrem whole body to any real individual beyond the controlled area). In order to comply with 10 CFR 72.104, no activity would be allowed to result in the ISFSI exceeding the 10 CFR 72.104 limits. For anticipated occurrences, a *minimal increase* would include any increase up to the 10 CFR 72.104 limits. Any increase in consequences of an anticipated occurrence previously evaluated in the UFSAR that is still within the 10 CFR 72.104 limits would always be less than a minimal 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.

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 on a site-specific basis, the record of the 72.48 evaluation containing the updated calculated offsite dose value would be retained and the revised value used as the bounding value for the next 72.48 evaluation. 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(c)(2) requirementthat a general licensee shall request that the CoC holder obtain a CoC amendment. An exemption request should describe the proposed change and include justification for why the CoC holder is not requesting a CoC amendment for the change, and justification for the change itself.

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.

<u>Example 3</u>

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. 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 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 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 **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 example illustrates 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 a 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.

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. Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or the overall **ISFSI facility** level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting 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 cladding integrity would continue to be important to maintain retrievability and sub-criticality (fuel configuration).

Preservation of the confinement boundary is required to ensure against the uncontrolled release of radioactive materials. 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 **B**4.1, 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. Any effects to the heat transfer analyses would be compared to the design basis limits and the effects on cladding stresses.

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 **(such as the requirements governing normal operations and anticipated occurrences), and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents**. 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 **B**4.2.1.3.

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 <u>not</u> 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 **B**4.2.1.3);

- 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.

- **Use of a methodology which is described in the UFSAR, but which has not been specifically approved by the NRC either through a Topical Report review or through endorsement in the storage system SER. The following are examples:**

  The UFSAR describes the methodology used for the heat transfer evaluations of the storage system. The methodology was never submitted to the NRC for approval in a Topical Report, and the storage system SER does not indicate whether the NRC has endorsed or approved the methodology. In this case, use of the methodology described in the UFSAR to support a change would NOT "result in a departure from a method of evaluation described in the UFSAR."

  The UFSAR describes the methodology used to evaluate the cask drop onto the storage pad. The SER specifically states that the "NRC does not endorse" the methodology described in the UFSAR and that the NRC used a different methodology to confirm acceptability of the applicant's results. In this case, use of the methodology described in the UFSAR would NOT "result in a departure from a method of evaluation described in the UFSAR."

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 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 **would** typically follow one of two paths. **Some** utilities **and spent fuel storage cask vendors will** prepare and obtain 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** approve the use of the methodologies for a given class of **ISFSIs or spent fuel storage casks**. In some cases, the NRC **would** accord "generic" approval of analysis methodologies. Terms, conditions and limitations relating to the application of the methodologies **would** 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, the NRC's approval **would** typically be part of an **ISFSI or cask design's licensing basis and** 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** 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 or **CoC holders** should consult various sources, as appropriate. These include SERs, topical reports, licensee correspondence with the NRC and licensee or **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."

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, has established a method by which **reactor** licensees can demonstrate they are generally qualified to perform safety analyses. **Reactor** licensees 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. 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 May be Considered "Approved by the NRC 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** 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 the basis

documented for concluding that the differences are not relevant to determining that the new application is technically appropriate.

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 condition, 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, or to change the **ISFSI** facility, **cask design,** or procedures, 10 CFR **72.48** should be applied to the corrective action, unless another regulation applies. In these cases, the final corrective action 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 accidently 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(c)(2) requirement that a general licensee shall request that the CoC holder obtain a CoC amendment. An exemption request should describe the proposed change and include justification for why the CoC holder is not requesting a CoC amendment for the change, and justification for the change itself.** 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 activity.

(2) Redesign the proposed activity so that 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.

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 **ISFSI licensee or cask CoC holder** to ensure 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 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 Section **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 **72.48** is not required for activities that are canceled or that 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 prior NRC approval pursuant to paragraph 10 CFR 72.48(c)(2).

The records required to be reported by the CoC holders to the cask users are only those records created by the CoC holders. These would include the records of 72.48 evaluations created by the CoC holders as a result of adopting changes that were reported to the CoC holders by the cask users. Records of changes reported to a CoC holder by a user but not adopted by the CoC holder do not need to be provided to other cask users.

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.

Due to the nature of the spent fuel storage casks, cask users are limited in their ability to incorporate changes to the cask design after the cask is loaded with spent fuel and placed in storage. Accordingly, the 60-day report of cask design changes evaluated in accordance with the provisions of 10 CFR 72.48 provided to the cask users (specific and general licensees) by the CoC holders are provided for information only and do not require specific action by the cask user. Cask users are required to report defects in any spent fuel storage structure, system, or component which is important to safety or results in a significant reduction in the effectiveness of any spent fuel storage confinement system during use to the NRC (10 CFR 72.75 for site specific and general licensees; 10 CFR 72.216 for general licensees). Additionally, cask certificate holders are required to provide written reports to the NRC within 30 days of discovery of a design or fabrication deficiency for any spent fuel storage cask which has been delivered to a licensee when the design or fabrication deficiency affects the ability of systems, structures, or components important to safety to perform their intended safety function. Accordingly, safety significant information related to a specific spent fuel cask design will be provided to the NRC in a timely manner and any safety significant concerns communicated to the cask users via NRC generic correspondence for disposition.

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.

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

ATTACHMENTS

1. **Figure B-1 10 CFR 72.48 Process Site Specific Licensee, General Licensee, Certificate Holder**

2. **Figure B-2 General or Specific Licensee (Cask User) 60-Day reports to CoC Holder**

3. **Figure B-3 CoC Holder 60-Day Reports to Cask Users**

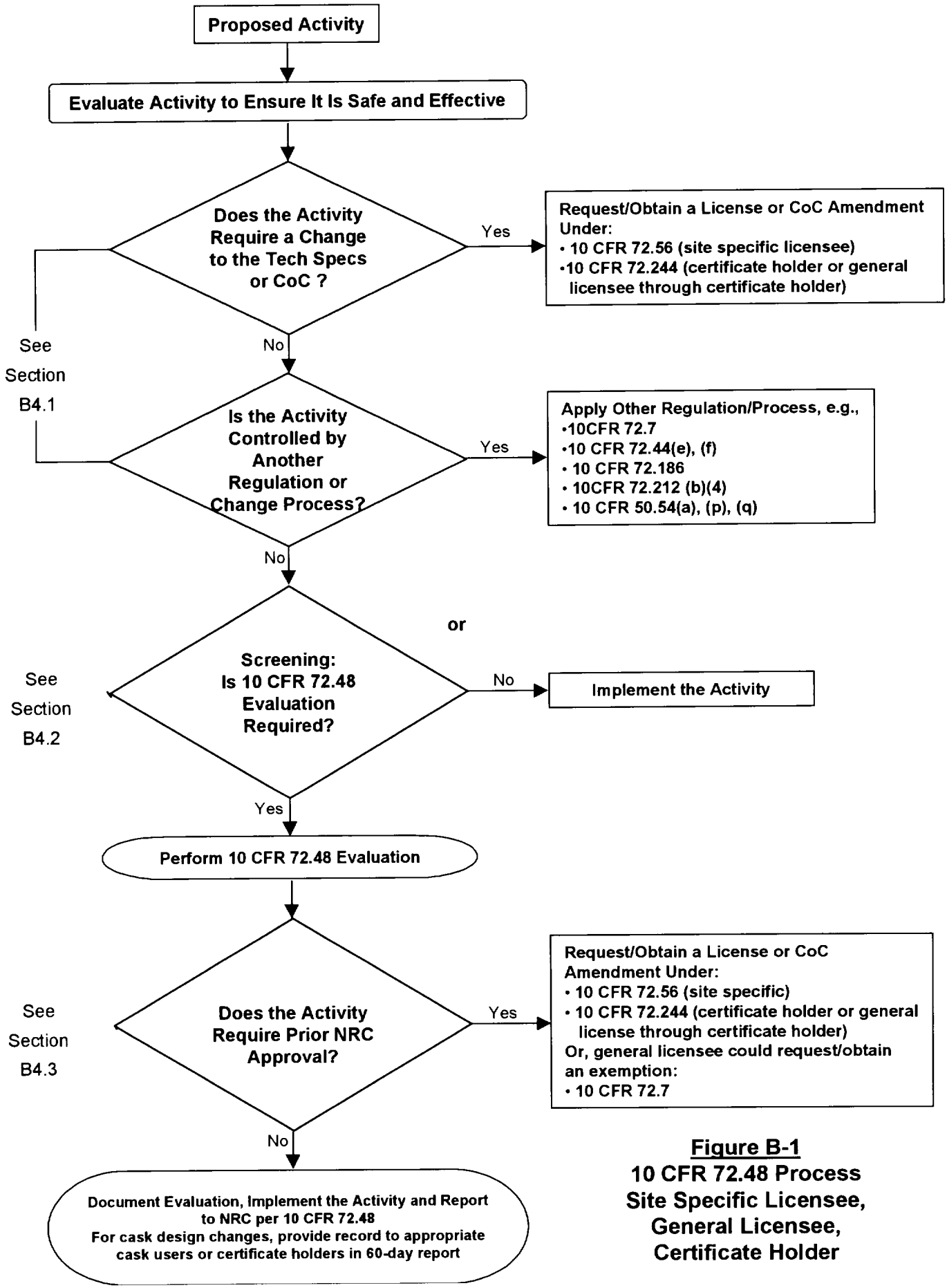

Figure B-1
10 CFR 72.48 Process
Site Specific Licensee, General Licensee, Certificate Holder

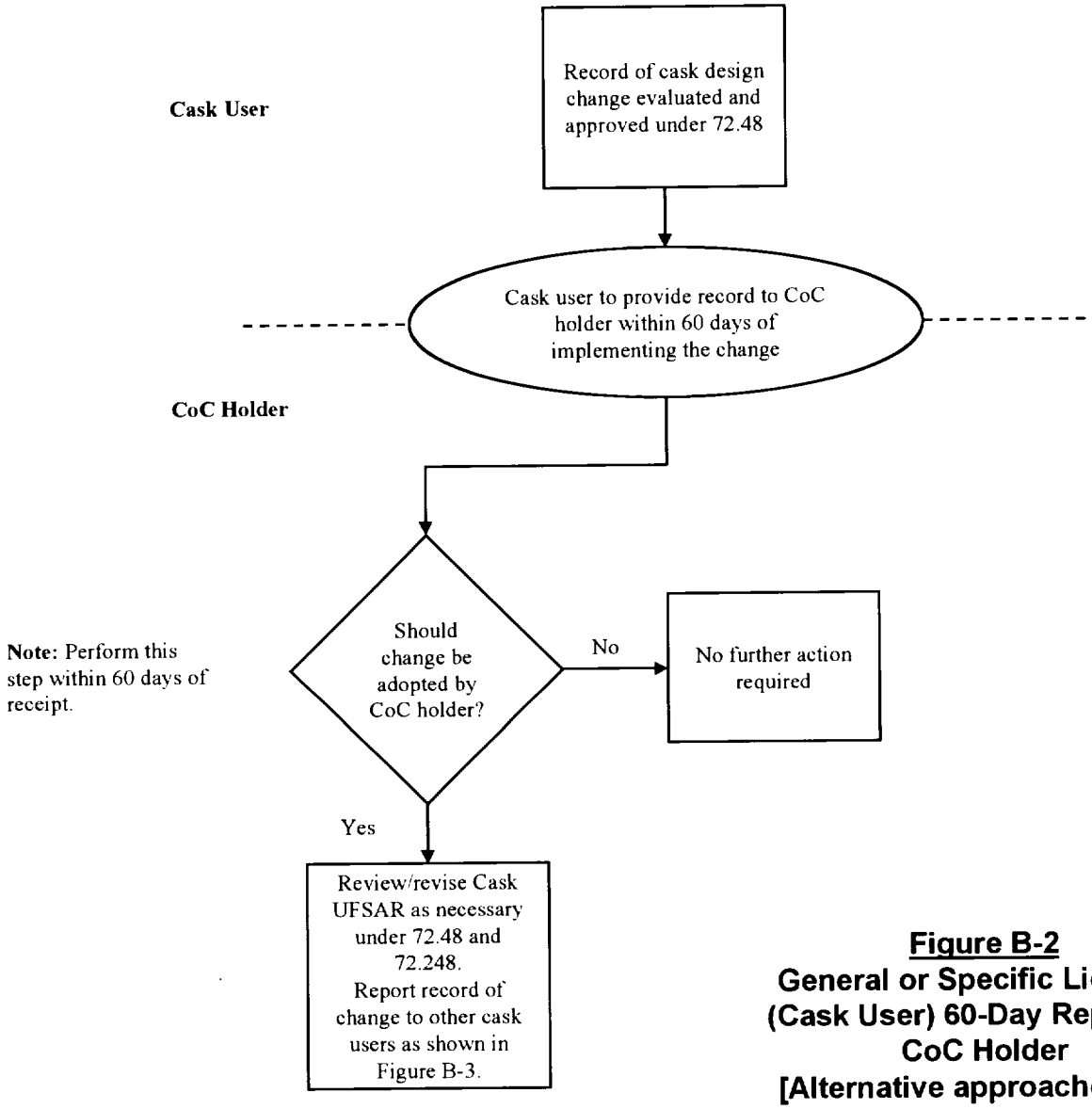

Figure B-2
General or Specific Licensee (Cask User) 60-Day Reports to CoC Holder
[Alternative approaches may be acceptable]

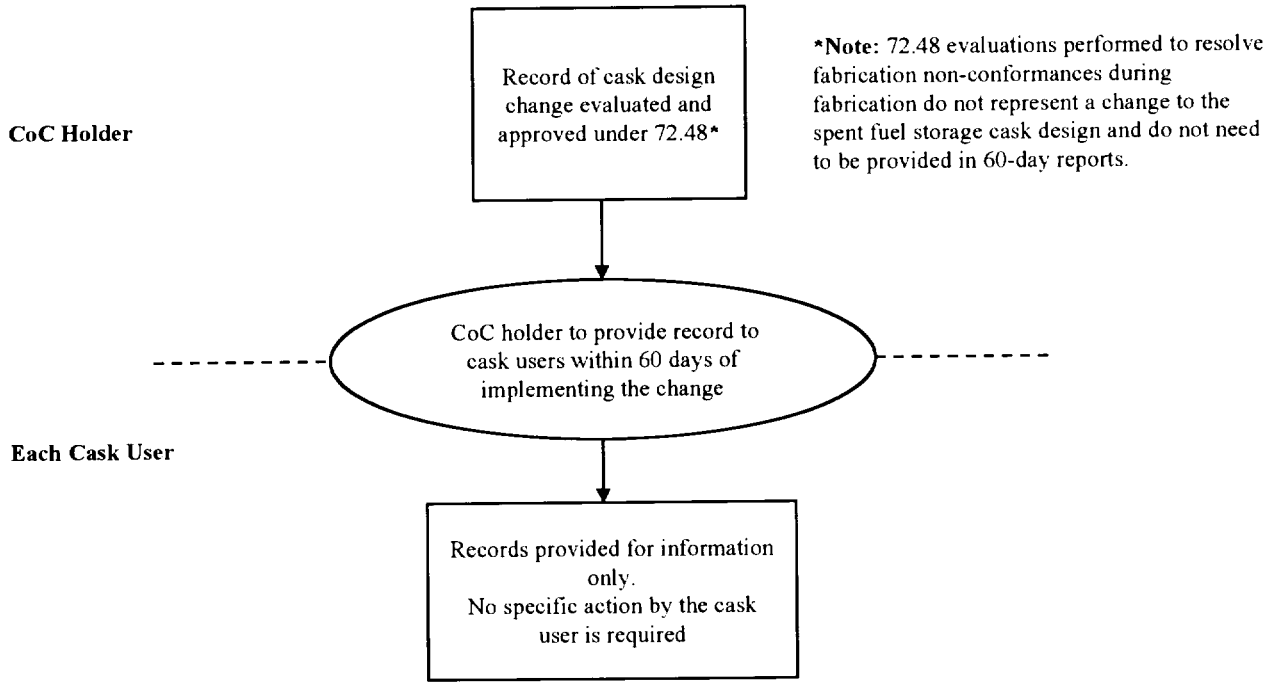

Figure B-3
CoC Holder 60-Day Reports to Cask Users [Alternative approaches may be acceptable]

ATTACHMENT

4. 10 CFR 72.48 Changes, Tests, and Experiments

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

ATTACHMENT 4

Text of 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

(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 an accident previously evaluated in the FSAR (as updated);

(ii) Result in more than a minimal increase in the likelihood 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.