

NEI 12-04, Revision 0

**GUIDELINES FOR
10 CFR 72.48
IMPLEMENTATION**

August 2012

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Nuclear Energy Institute

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This guidance was developed by the NEI 10 CFR 72.48 Guidance Update Issue Team with the valuable assistance of the NEI Dry Storage Task Force Steering Group. The NEI Licensing Action Task Force also helped ensure fidelity with 10 CFR 50.59 guidance was maintained, where appropriate. We also recognize the direct participation of the licensees and CoC holders who contributed to the development and modification of the guidance. The dedicated and timely effort of the many participants, including management support of the effort, is greatly appreciated.

NOTICE

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FORWARD

In 1999, the NRC revised 10 CFR 72.48 to be consistent with the changes being made to 10 CFR 50.59 and to give CoC holders the authority to use 10 CFR 72.48 for the first time. NEI 96-07 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, Appendix B to NEI 96-07 was developed to provide guidance specific to the implementation of 10 CFR 72.48 by utilizing the NEI 96-07, Revision 1 guidance to the maximum extent possible. The NRC endorsed NEI 96-07, Appendix B, in Regulatory Guide 3.72.

After over ten years of experience using the revised 10 CFR 72.48 rule, the industry decided to revise the guidance to address lessons learned and relocate the 72.48 guidance in a new document separate from the 50.59 guidance. That decision resulted in this document, NEI 12-04. A fundamental precept used in preparing this guidance document is to retain commonality with the 50.59 guidance where there is commonality in the corresponding rules. The changes to the guidance focus primarily on the aspects of implementing the 10 CFR 72.48 rule by Part 72 specific and general licensees that are necessarily different than 50.59, and the role of the CoC holders, who perform the majority of the activities being authorized under 10 CFR 72.48, but are not licensees.

References in this document to “specific licensee” include both current Part 72 specific licensees and applicants for a Part 72 specific license. References to “CoC holder” include both spent fuel storage cask Certificate of Compliance holders and applicants for a Certificate of Compliance.

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GUIDELINES FOR 10 CFR 72.48 IMPLEMENTATION

1 INTRODUCTION

1.1 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 to the ISFSI facility, MRS, spent fuel storage cask design, or procedures; and conduct tests or experiments, without prior NRC approval. Proposed activities that satisfy the definition of change, test, or experiment included herein and meet 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 document is to:

- Provide for consistent implementation of 10 CFR 72.48 requirements, and
- Assure that relevant aspects of proposed activities are considered.

Recognizing that a diverse population of Part 72 general licensees, specific licensees, and certificate of compliance (CoC) holders all perform activities under 10 CFR 72.48, an effort was also made to provide guidance for developing effective and consistent 10 CFR 72.48 implementation processes while allowing flexibility for appropriate needs or preferences among the parties using the guidance. This guidance document addresses the implementation of 10 CFR 72.48 by ISFSI licensees and storage cask CoC holders. Guidance for implementation of 10 CFR 72.48 by an MRS licensee or a wet pool ISFSI licensee is not specifically included in this document.

In 1999, 10 CFR 72.48 was revised by the NRC to conform to the revised 10 CFR 50.59 to provide for consistent implementation of these two analogous regulations (64FR53582). NEI 96-07 was subsequently developed to provide guidance to licensees in implementing 10 CFR 50.59. Appendix B to that document was issued to provide guidance to those authorized to make changes under 10 CFR 72.48 and retain the connection to the commonalities in the 10 CFR 50.59 rule and its implementation. That appendix was created from the guidance of NEI 96-07 for 10 CFR 50.59 with modifications to the text and figures as needed to apply to 10 CFR 72.48.

This new guidance document, which replaces NEI 96-07, Appendix B, recognizes that 10 CFR 72 has enough unique elements and diverse users (i.e., specific licensees, general licensees, and CoC holders) that a separate guidance document is appropriate. A concerted effort was made in developing this revised guidance to retain information that is applicable to both 10 CFR 50.59 and 10 CFR 72.48 implementation (for licensees)

while recognizing the unique circumstances and issues that arise solely in implementing 10 CFR 72.48 (for licenses and CoC holders).

Throughout this document, the term “review” means the overall process of considering a proposed activity for implementation under 10 CFR 72.48, using either a 10 CFR 72.48 screening, a 10 CFR 72.48 evaluation, or both. Distinctions are made between the two where necessary.

1.2 DEFENSE-IN-DEPTH DESIGN PHILOSOPHY AND 10 CFR 72.48

~~One objective of the NRC requirements in Title 10 of the Code of Federal Regulations is to establish~~ ~~establishes~~ ~~requirements directed toward protecting~~ ensure 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 ~~together~~ ~~generally~~ provide defense-in-depth are:

- Fuel Cladding
- Spent Fuel Cask Confinement Boundary

These barriers perform a health and safety protection function. For storage of damaged fuel, alternative barriers ~~may also need to~~ be utilized to provide functions that would normally be served by the fuel cladding, such as retrievability 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 demonstrated and documented in the CoC holder’s UFSAR for the spent fuel storage cask or the Part 72 specific licensee’s ISFSI 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 ~~and will not lead to a criticality event.~~

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 (i.e., the cask system/ISFSI adequately performs the functions of confinement, criticality safety and~~

Comment [NRC1]: Regarding Section 1.2 as a whole, the NRC notes that portions of the existing guidance (Section B2) have been deleted without explanation. For example, maintaining the retrievability of stored radioactive materials is no longer listed as one of the basic nuclear safety criteria for the design of an ISFSI. Instead, the new proposed NEI guidance states in this regard that “10 CFR Part 72 contains other requirements, such as retrievability, that while not safety functions, must still be performed for regulatory compliance.” Provide justification that these changes are appropriate and consistent with the regulatory requirements contained in Part 72.

shielding). 10 CFR 72.48 addresses this aspect of design by requiring prior NRC approval of proposed activities which, although safe, require a change to the specific license, CoC, or technical specifications, or meet specific threshold criteria for NRC review.

Comment [NRC2]: The staff suggests the text be clarified regarding what "this aspect of design" is intended to refer to.

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, and prevent criticality. 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 "consequence" 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 to members of the public.

Comment [NRC3]: The scope of this statement is incomplete. It needs to address the following three items, consistent with the text at the top and bottom of this page:
1. Loss of confinement (i.e., release of radioactive material)
2. Criticality (i.e., loss of subcriticality)
3. Loss/degradation of shielding capability

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 briefly review the requirements and the objectives imposed by the NRC's regulations 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.

10 CFR 72, Subpart F establishes extensive requirements on ISFSI and spent fuel storage cask 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. Important-to-safety systems, structures, and components must function without loss of capability to perform their safety functions. These conditions include natural phenomena, fire, operational, and accident-generated environmental conditions.

Comment [NRC4]: It is not clear what "These conditions" refers to.

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; and

- (3) Ensure radiation doses do not exceed acceptable levels.

10 CFR Part 72 contains other requirements, such as retrievability, that while not safety functions, must still be performed for regulatory compliance.

The implementation of the defense-in-depth 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, and to guard against the uncontrolled release of radioactive materials. The specific license UFSAR, the spent fuel storage cask UFSAR, and the general licensee's 10 CFR 72.212 evaluations present the set of limiting analyses and evaluations 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. Modifications to an ISFSI facility, spent fuel storage cask design or operation, or general license 10 CFR 72.212 Evaluation Report, and the 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 review under 10 CFR 72.48.

1.3 USE OF THE WORD "CHANGE"

The word "change" has a unique context for use in implementing 10 CFR 72.48, as described 10 CFR 72.48(a)(1) and Definition 3.6. A "change" in this context requires a full evaluation under the applicable criteria of 10 CFR 72.48(c)(2). The 10 CFR 72.48 screening process determines whether a proposed activity involves a change as described in Definition 3.6, or a test or experiment. Thus, throughout this document terms such as "proposed activity," "proposed modification," or "proposed alteration" are used to indicate an activity that has not yet been determined to be a change, test, or experiment in this context. Therefore, all proposed activities determined to be "changes," by definition, have an adverse effect as determined in the 10 CFR 72.48 screening process and require a full 10 CFR 72.48 evaluation (i.e., the phrase "adverse change" is redundant and not used).

2 THE 10 CFR 72.48 PROCESS

2.1 OVERVIEW OF THE GUIDANCE

NEI 12-04 contains six sections and two appendices:

- Section 1 (Introduction) describes the purpose of 10 CFR 72.48 and NEI 12-04.

- Section 2 (The 10 CFR 72.48 Process) provides an overview of the 72.48 process and related regulatory requirements and associated documents.
- Section 3 (Definitions) defines and discusses the key terms used in 10 CFR 72.48 and this guidance document.
- Section 4 (Applicability Determination) describes and provides guidance on how to identify the particular change-control regulation(s) that apply to a proposed activity.
- Section 5 (72.48 Screening) describes and provides guidance for implementing the 10 CFR 72.48 screening process.
- Section 6 (72.48 Evaluation) describes and provides guidance for implementing the 10 CFR 72.48 evaluation process.
- Appendix A provides examples for the guidance in individual subsections of this document.
- Appendix B provides 72.48 reviews for several example proposed activities.

2.1.1 Possible Outcomes

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

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

If prior NRC approval of an activity is required, specific licensees would normally seek a license amendment in accordance with 10 CFR 72.56 and CoC holders would normally request a cask CoC amendment in accordance with 10 CFR 72.244. Alternatively, specific licensees and CoC holders could seek an exemption pursuant to 10 CFR 72.7 to allow implementation of a proposed activity for which the 10 CFR 72.48 review determined prior NRC review and approval is required. If a general licensee determines that prior NRC approval of an activity is required pursuant to 10 CFR 72.48, the licensee would need to request that the CoC holder for their cask system seek a CoC amendment, or the general licensee could request an exemption pursuant to 10 CFR 72.7. General licensees may not request a CoC amendment unless they also happen to be the CoC holder.

The definition of “implemented” varies with respect to 10 CFR 72.48 depending on the entity performing the activity. See Definition 3.14. This unique provision for CoC holders is necessary to provide a starting point for the 60-day requirement to notify licensees of changes and to ensure general licensees have sufficient time to make any site-specific changes necessary to implement the change (i.e., procedures, 212 Report, etc.) if they choose to adopt it as provided in

Definition 3.4. For activities requiring prior NRC approval, a licensee or CoC holder may design, plan, fabricate, install, and test a modification prior to receiving the license or CoC amendment at their own risk but may not make it operational prior to receiving NRC approval.

For proposed activities that are determined to require prior NRC approval based on the 72.48 review, there are four possible options:

- (1) Revise the proposed activity so that it may proceed without prior NRC approval, if possible.
- (2) Apply for and obtain a license or cask CoC amendment under 10 CFR 72.56 or 10 CFR 72.244, as applicable, prior to implementing the activity.
- (3) Apply for an exemption pursuant to 10 CFR 72.7.
- (4) Cancel the activity.

2.1.2 Safety, Compliance and Regulatory Reviews

It is important to remember that determining if a proposed activity requires prior NRC approval pursuant to 10 CFR 72.48 does not include a judgment as to whether the activity is appropriate, safe to do, and otherwise meets all applicable regulatory requirements and commitments. Certainly, all of these questions should be answered in the affirmative for any activity being contemplated, prior to initiating the 10 CFR 72.48 review. It is the responsibility of the ISFSI licensee or cask CoC holder to ensure that proposed activities are safe and compliant with all regulations. These elements of approving and implementing an activity are governed by other programs such as the design control, testing, and inspection portions of the Quality Assurance program; the commitment control program; and the regulatory compliance program.

A proposed activity that significantly enhances overall ISFSI facility or cask safety at the expense of a small adverse impact in a specific area may still need prior NRC approval because it requires a change to the license/CoC or one of the criteria in §72.48(c) is met. Thus the 10 CFR 72.48 review is not a “safety evaluation.” It is a separate, regulatory review to determine if the activity, already determined by the licensee/CoC holder to be safe and compliant with the regulations, requires prior NRC review before field use, ~~notwithstanding the operational or safety enhancements to be gained by implementing the activity.~~

Figure 1 is a flow chart of the 10 CFR 72.48 process. Appendix A provides examples for implementation of the guidance in specific sections of this guidance. Appendix B provides the Applicability Determinations, 10 CFR 72.48 screenings, and 10 CFR 72.48 evaluations for several examples of proposed activities.

2.1.3 Documentation

2.1.3.1 Introduction

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 applicable 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 applicable evaluation criteria. Similarly,

documentation and reporting pursuant to 10 CFR 72.48 are not required for activities that are canceled or that are determined to require prior NRC approval, are implemented via the license/CoC amendment request process, or only required a 72.48 screening but not an evaluation. Notwithstanding the minimum required documentation requirements discussed above, it is recommended that documentation for activities that required only 72.48 screenings be retained as QA records as discussed further in Subsection 2.1.3.2 below.

2.1.3.2 Documenting 10 CFR 72.48 Evaluations

In performing a 10 CFR 72.48 evaluation of a proposed activity, the evaluator must address the applicable 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 overly 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 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. Because 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 question is unique. Although each applicable criterion must be addressed, the questions and considerations listed throughout this guidance are not necessarily applicable for all evaluations. Some evaluations may require that none of these questions be addressed in detail while others will require additional considerations beyond those addressed in this guidance.

Provided that the uniqueness of each 72.48 evaluation question and the topic addressed therein is recognized, licensees may combine responses to individual criteria or reference other portions of the evaluation when preparing 72.48 evaluations, as appropriate. If this “combination” and/or “reference” approach is utilized, it does not absolve the licensee of addressing the topic/intent of each evaluation question.

Comment [NRC5]: The NRC notes that the reference to the “eight” criteria of 72.48(c)(2) has been replaced with the “applicable” criteria, making the revised guidance somewhat vague.

Additionally, this paragraph should clarify the difference between maintaining records and reporting requirements. This paragraph should also clarify that reporting requirements pursuant to 10 CFR 72.48(d)(2) as well as 72.70(b) and 72.248(b) include any changes, tests, and experiments.

As discussed in Section 5.0, licensees may elect to use screening criteria to determine for which activities a full 10 CFR 72.48 evaluation should be performed. A documented 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. However, it is recommended that documentation for activities that required only 72.48 screenings be retained as QA records. This provides the record explaining the logic the reviewer used to determine that an activity did not require a full 72.48 evaluation.

Comment [NRC6]: Explain how this sentence is consistent with the meaning and intent of the 10 CFR 72.48(d) provisions regarding documentation and recordkeeping requirements.

2.1.4 Reporting

A summary of the evaluations for activities implemented under 10 CFR 72.48 must be provided to NRC by both licensees and CoC holders for their respective activities. Duplicate reporting is not required. Activities that were screened out, canceled, implemented via license/CoC amendment, or implemented by exemption 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 specific licensees and CoC holders may provide these reports to NRC on the same schedule as their UFSAR updates.

2.1.4.1 Reporting Changes via 72.48 Evaluations to CoC Holders and Licensees

10 CFR 72.48(d)(6) requires reporting of cask design changes to CoC holders and licensees (see Figures 2 and 3). 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 applicable 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).

Comment [NRC7]: Clarify whether this includes changes that were made or implemented that "screened out."

The records required to be reported by the CoC holders to the licensees are only those records created by the CoC holders. These would include the records of 72.48 evaluations created by the CoC holders directly and as a result of adopting site-specific changes that were reported to the CoC holders by the licensees into the generic licensing basis. 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 licensees. ~~It is recommended that~~ Pursuant to 10 CFR 72.48(d)(6)(iii), CoC holders must provide the documentation for all approved cask UFSAR and design changes to their users within 60 days of implementation, whether or not a full 72.48 evaluation was required for the change. This ensures that all users have a complete UFSAR, including interim changes, between formal UFSAR revisions.

Comment [NRC8]: Clarify whether licensees would also need to provide this information to the CoC holder per 72.48(d)(6)(i) and (ii).

See Definition 3.14 for the definition of "implementation" for CoC holders and licensees as it relates to notifying other entities of changes authorized under 10 CFR 72.48.

2.1.4.2 Fabrication Nonconformances Requiring 72.48 Review

10 CFR 72.48 evaluations performed to resolve fabrication non-conformances for specific storage casks during fabrication also represent a change to a spent fuel storage cask design even though the change may only affect a single cask or group of casks. Such evaluations should be reported to the affected licensee(s) in a 60-day report and included in the routine 72.48 report to the NRC.

2.1.4.3 Activities Approved Without a 72.48 Review

Although records of modifications to the ISFSI facility, cask design, or procedures are not required to be provided in a 60-day report if a full 72.48 evaluation was not required, it is recommended that ISFSI licensees and cask CoC holders exchange these documents on an agreed-upon schedule. These records aid the general or specific licensee in complying with 10 CFR 72.48(c)(3). This requirement states that, for purposes of implementing 10 CFR 72.48, the FSAR (as updated) is considered to include UFSAR changes resulting from 10 CFR 72.48 reviews and license/CoC amendments approved since the last UFSAR update. Other configuration management processes may also be used to ensure compliance with this requirement.

CoC holders should make available to licensees complete documentation, including 10 CFR 72.48 screens/evaluations and changes to licensing basis documents (e.g., licensing drawings and the UFSAR) between the formal UFSAR updates required by 10 CFR 72.248. Sharing this information is recommended in order to ensure all parties maintain configuration control over the licensing basis for the cask system in real time (i.e., a “living” licensing basis). This is required for those performing activities that could affect portions of the licensing basis previously modified under 10 CFR 72.48 but not yet included in an UFSAR update. Furthermore, CoC holders should make available to general licensees the UFSAR changes associated with NRC-approved CoC amendments in a timely manner for the same reason. Because this is a recommendation and not a requirement, any mutually agreeable means to ensure licensees have access to the modified information is acceptable.

2.1.5 Miscellaneous Guidance

2.1.5.1 Licensee Actions Upon Receiving CoC Holder-Authored Changes

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

Comment [NRC9]: Refer to the NRC’s previous interim letter, dated September 26, 2013, and its enclosures for the NRC’s comments and recommendations for Sections 2.1.5.1 through 2.1.5.5. See ML13260A029.

CFR 72.48 program. Guidance for users choosing to adopt generic CoC holder changes is provided in Sections 2.1.5.3 and 2.1.5.4.

Furthermore, due to the nature of spent fuel storage cask use and the general license process, licensees are limited in their ability to incorporate changes to the cask design after the cask is loaded with spent fuel and placed in storage. Accordingly, the 60-day reports to licensees of cask design changes implemented under 10 CFR 72.48 provided by the CoC holder only need to be reviewed for applicability to their plant/ISFSI and for impact on the site-specific evaluations and analyses, the 212 Report, and site programs and procedures. Licensees should process any required changes to site-specific documents in accordance with their own change management programs.

2.1.5.2 Reporting of Defects and Deficiencies

Licensees and CoC holders are required to report certain defects or deficiencies in any spent fuel storage structure, system, or component to the NRC in accordance with the reporting requirements in 10 CFR 72.75 and 10 CFR 21. Accordingly, safety significant information related to a specific spent fuel storage system design will be provided to the NRC in a timely manner and any safety significant concerns communicated to the licensees via NRC generic correspondence for disposition. 10 CFR 72.48 would only apply if compensatory actions are taken to address the defect or deficiency that deviate from the cask or site-specific ISFSI UFSAR (see Section 4.9), or if a procedure or 212 Report revision is required.

2.1.5.3 General Licensee Use of CoC Holder-Generated Modifications

If a general licensee determines that a generic CoC holder design or UFSAR modification is applicable and should be adopted at their site ISFSI, the general licensee would perform an impact evaluation (e.g., procedures, 212 Report, etc.) and perform 10 CFR 72.48 screenings/evaluations as required by their internal change review process for the impacted documents. The answers/justification used in the 10 CFR 72.48 screening/evaluation may be taken from the CoC holder's 10 CFR §72.48 screening/evaluation if they also apply to the general licensee's screening/evaluation. A modification that has been reported to the general licensee by the CoC holder and then used by the general licensee would not need to be reported back to the CoC holder in a 60-day report because the CoC holder initially generated the modification and will have already performed the appropriate regulatory reviews and updated the generic licensing basis documents, as needed.

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

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

may be taken from the CoC holder's §72.48 screening/evaluation if they could also apply to the site-specific licensee's screening/evaluation. A change that has been reported to the site-specific licensee by the CoC holder and then incorporated by the site-specific licensee would not need to be reported back to the CoC holder in a 60-day report because the CoC holder initially generated the modification and will have already performed the appropriate regulatory reviews and updated the generic licensing basis documents, as needed.

2.1.5.5 CoC Holder Actions Upon Receipt of Licensee-Generated Modifications

When a CoC holder receives a copy of the record for a cask design modification from a licensee, they should review the record in a timely manner (e.g., within 60 days of receipt) to determine if they should adopt the change for generic use (see Figure 3). If so, the certificate holder would review the cask UFSAR to determine if a modification to that document and a 10 CFR 72.48 screening/evaluation is required. The answers/justification used in the 10 CFR 72.48 screening/evaluation may be taken from the licensee's 72.48 screening/evaluation if they could also apply to the CoC holder's screening/evaluation. A cask design modification that has been reported to the CoC holder by a general or specific licensee and then adopted by the CoC holder would need to be reported back to all general or specific licensees using that cask design in the 60-day report.

2.2 RELATIONSHIP OF 10 CFR 72.48 TO OTHER REGULATORY REQUIREMENTS AND CONTROLS

2.2.1 Overview of Other Regulatory Control Processes

10 CFR 72.48 focuses on the effects of proposed activities on the safety analyses that are contained in the UFSAR for the ISFSI or spent fuel storage cask, and are the cornerstone of each ISFSI's or spent fuel storage cask's licensing basis. In addition to 10 CFR 72.48 change control for activities affecting the **cask or ISFSI facility and cask design or procedures** as described in the UFSAR, there are several other complementary processes for controlling activities that affect other aspects of the licensing basis. Where activities affecting the ISFSI, cask design, or procedures are controlled by more specific regulations (e.g., quality assurance, security, training, and emergency plan changes), 10 CFR 72.48(c)(4) states that the more specific regulation applies to that portion of the activity. Examples of other more specific regulations and change processes are:

- 10 CFR 72.56, "Application for Amendment of License," is used by specific licensees to request an amendment to a specific ISFSI license (including terms, conditions, and technical specifications).
- 10 CFR 72.244, "Application for Amendment of a Certificate of Compliance," is used by CoC holders to request an amendment to a cask CoC (including terms, conditions, and technical specifications). (Licensees may not

request amendments to a storage cask CoC unless they are also the CoC holder.)

- 10 CFR 72.7, “Specific Exemptions,” is used by licensees and CoC holders to seek an exemption from a regulatory requirement specified elsewhere in 10 CFR 72.
- 10 CFR 50.54, “License Conditions,” is used by general licensees and by specific licensees with a co-located ISFSI that use their Part 50 programs to govern Part 72 activities to make changes to programs governed by this regulation. For example, the Quality Assurance Program, Security Program, and Emergency Plan have change controls processes specified in 10 CFR 50.54.
- NEI 99-04, “Managing NRC Commitment Changes,” is used by licensees to apply the appropriate change process and documentation for changing NRC commitments. (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.)

Together with 10 CFR 72.48, these processes, and others, 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 guidance 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.

It is important to note that the “other regulatory processes” discussed above do not apply equally to general licensees, specific licensees, and CoC holders. Site-specific licensees may have programs controlled pursuant to a Part 72 regulation and a general licensee may have the same program controlled by a Part 50 regulation. CoC holders do not have several of these programs at all. Thus each entity’s 72.48 applicability determination program should be customized appropriately. See Section 4.0 for additional information.

2.2.2 Quality Assurance Program and 72.48

10 CFR Part 72, Subpart G and 10 CFR 50, Appendix B, as applicable, ensure that the ISFSI facility and spent fuel storage cask design, construction, and operation meet applicable regulatory requirements, codes, and standards in accordance with the safety classification of systems, structures and components (SSCs). Both CoC holders and licensees have NRC-approved QA programs. The design control provisions of the QA program ensure that, after initial licensing, all future changes to the ISFSI facility, spent fuel cask design and associated SSCs

continue to meet applicable design and quality requirements. Thus, implementation of the QA program design control process should ensure that the change is safe and in compliance with regulatory requirements. Review of the change pursuant to 10 CFR 72.48 is exclusively a regulatory test to determine if prior NRC review and approval is required before the change is implemented.

Comment [NRC10]: Following QA requirements doesn't necessarily ensure a change is safe and within regulatory requirements. Flawed evaluations and poor engineering judgment can still compromise safety. See edits.

The QA program 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 4.9.

2.2.3 10 CFR 72.48 and the 212 Report

Comment [NRC11]: Refer to the NRC's previous interim letter, dated September 26, 2013, and its enclosures for the NRC's comments and recommendations for this section. See ML13260A029.

Activities authorized pursuant to 10 CFR 72.48 by the general licensee or by the CoC holder and used by the general licensee must be reviewed by the general licensee prior to implementation of the activity at the ISFSI for impact on the site's 212 Report and supporting analyses and evaluations. Modifications to those documents should be made as required.

The 212 Report documents compliance with the CoC and evaluations performed pursuant to 10 CFR 72.212(b)(5), (b)(6) and (b)(8). Consistent with guidance in NRC Regulatory Issue Summary 2012-05 "Clarifying the Relationship between 10 CFR 72.212 and 10 CFR 72.48 Evaluations," if any of the evaluations described in the 212 Report deviate from information in the cask UFSAR, those evaluations need to be reviewed in accordance with 10 CFR 72.48 to determine if a CoC amendment is required. This includes evaluations described in the initial version of the 212 Report, which is normally issued prior to loading the first cask and placing it into service at an ISFSI. The 212 Report, including the initial version, is not a substitute for a 72.48 review.

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

2.2.4 10 CFR 72.48 AND 10 CFR 50.59

The Applicability Determination (AD) process described in Section 4.0 is used by specific and general licensees to determine whether an activity is governed by one or more change control processes. Because cask loading and preparation activities take place in or near facilities licensed under 10 CFR 50, these activities can be subject to review under 10 CFR 72.48, 10 CFR 50.59, both processes, or neither (e.g., in the case of programs controlled under 10 CFR 50.54).

Licensees having an operating power plant co-located with an ISFSI need to carefully consider the activity being proposed and compare it to the information in the ISFSI or cask UFSAR and the Part 50 UFSAR to determine which change control process(es) apply. Certain configurations of cask components in or near

the Part 50 facility may require an evaluation or analysis, a 10 CFR 50.59 review, and/or a 10 CFR 72.48 review because that arrangement of equipment had not been contemplated in the plant design or in the cask UFSAR. Depending on the governing regulations, the method of evaluation used should be reviewed against those accepted in the Part 50 UFSAR or the Part 72 UFSAR when the 10 CFR 50.59 and/or 10 CFR 72.48 review is performed.

3 DEFINITIONS

3.1 10 CFR 72.48 EVALUATION

Definition:

A 10 CFR 72.48 evaluation is the documented review against the applicable 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 10 CFR 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 Screening and 10 CFR 72.48 Evaluation are intended to clearly distinguish between the process and documentation of 72.48 screenings and the further evaluation that may be required of proposed activities against the applicable criteria in 10 CFR 72.48(c)(2). Section 6 provides guidance for performing 10 CFR 72.48 evaluations. The §72.48 screening process is discussed in Section 5.0.

The phrase “activity implemented under 10 CFR 72.48” (or equivalent) refers to activities subject to the rule that either screened out (i.e., did not require a full 10 CFR 72.48 evaluation) 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 a 72.48 review (i.e., screening and, if necessary, a 72.48 evaluation) is required for the activity. The “10 CFR 72.48 process” includes screening, evaluation, documentation, and reporting to others (e.g., licensees, CoC holders and the NRC) of activities subject to the rule.

3.2 10 CFR 72.212 EVALUATION REPORT (212 REPORT)

Definition:

The 10 CFR 72.212 Evaluation Report (212 Report) is the compiled set of written evaluations required by 10 CFR 72.212 (b)(5), (b)(6), and (b)(8). The 212 Report is a licensing basis document developed and maintained by the general licensee documenting

compliance with the cask CoC and how the generic cask design is suitable for use at that particular site.

Discussion:

Guidance for applying this definition is provided in Section 2.2.3.

3.3 10 CFR 72.48 SCREENING

Definition:

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

Discussion:

The 10 CFR 72.48 screening process considers four possible aspects of a proposed activity:

1. Impact(s) on SSC design functions (Definitions 3.6, 3.9, 3.10, 3.11 and 3.12)
2. Impact(s) on procedures and how SSC design functions are performed and controlled (Definitions 3.6, 3.10 and 3.18)
3. Impact(s) on Methods of Evaluation (Definition 3.15 and 3.17)
4. Impact(s) on Tests or Experiments (Definitions 3.19 and 3.21)

The referenced definitions contain information 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., they are not changes, tests, or experiments and may be implemented without a 10 CFR 72.48 further evaluation. Engineering and technical information concerning a proposed activity may be used along with other information as a basis for determining if the activity screens out or requires a 10 CFR 72.48 evaluation. Although activities that screen out do not require a 10 CFR 72.48 evaluation, they do need to be captured in the biennial report and in the UFSAR or FSAR using the licensing change process.

Further discussion and guidance on screening is provided in Section 5.

3.4 ADOPTION

Definition:

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

Discussion:

Comment [NRC12]: The staff suggests that this text be clarified by providing specific examples of this type of information, or point to text in another section of this guidance that provides such clarification and/or examples.

Comment [NRC13]: These edits are for clarification.

Comment [NRC14]: Refer to the NRC’s previous interim letter, dated September 26, 2013, and its enclosures for the NRC’s comments and recommendations for this section. See ML13260A029.

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

3.5 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-man-made and natural phenomenon 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 ~~or unique aspects of the facility or cask design or operations. These should be~~ reflected in the UFSAR pursuant to 10 CFR 72.70 (specific licensee) or 10 CFR 72.248 (certificate holder and general licensee).

Comment [NRC15]: The text here is unnecessarily long and unclear. Suggested edits are to ensure clarity and accuracy.

3.6 CHANGE

Definition (§72.48(a)(1)):

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 ~~to~~ and removals ~~to from~~ 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...,” (Definition 3.12), and “procedures...” (Definition 3.18) 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~~ to 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 in Definition 3.10 and as follows:

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

“Evaluation that demonstrates that intended functions will be accomplished” means the method(s) used to perform the evaluation (as discussed in Definition 3.17), **including input parameters and assumptions**. For example, a thermodynamic calculation that demonstrates the storage cask design has sufficient heat removal capacity for responding to a postulated accident.

Temporary Modifications

Temporary modifications 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 modifications proposed as compensatory measures to address degraded or non-conforming conditions as discussed in Section 4.9.
- Other temporary modifications 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 modifications, to determine if prior NRC approval is required. Screening and, as necessary, evaluation of such temporary modifications may be considered as part of the screening/evaluation of a proposed permanent modification.

The Maintenance Rule, 10 CFR 50.65, does not apply to activities governed by 10 CFR Part 72. See Section 4.2 for additional clarifying discussion of the application of 10 CFR 72.48 to ISFSI or cask maintenance activities.

3.7 CLASS OF ANALYSIS

Definition:

The class of analysis is descriptive of the configuration being analyzed. For example, a cask stack-up seismic stability analysis is a different class of analysis than a cask tornado missile analysis, even though both are structural analyses.

Discussion:

Guidance for applying this definition is provided in Section 6.8.

Comment [NRC16]: It is not clear that the definition of "Class of Analysis" is used elsewhere in the document, or that it is important to the discussion of §72.48. Either remove this definition, or revise the discussion section to include an explanation of why this definition is needed and some examples of analysis classes.

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

Definition (§72.48(a)(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.

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 "method of evaluation" in Definition 3.17. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR 72.48(c)(2)(viii) is provided in Section 6.8.

Comment [NRC17]: Modify the text of section 3.8 to reflect changes made in section 6.8 regarding the NRC staff's position on methods of evaluation.

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). **The licensee or certificate holder should ensure that this determination holds over the range of applicability of the method of evaluation for the system being evaluated, and that the uncertainties in the method are accounted for.**

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 or CoC 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 or CoC holder to make future changes to the cask design or procedures that once again reduce the margin.

“Essentially the Same”

Licensees and CoC holders may change one or more elements of a method of evaluation such that results move in the conservative or 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.”

Comment [NRC18]: The staff suggests clarifying this text to describe the meaning of ‘margin of error’ (e.g., +/- 1 standard deviation), including for semi-quantitative and qualitative methods of evaluation.

“Approved by the NRC for the Intended Application”

Rather than make a minor change to an existing method of evaluation, a licensee or CoC holder may also adopt a 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 6.8.

3.9 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:

- 1) 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

- 2) 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. The NRC endorsed Appendix B to NEI 97-04 in Regulatory Guide (RG) 1.186. NEI 97-04, Appendix B states the following:

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 as reference bounds for the design to meet design bases functional requirements. These values may be (1) established by NRC requirement, (2) derived from or confirmed by safety analyses, or (3) chosen by the licensee from an applicable code, standard, or guidance document.

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.

3.10 DESIGN FUNCTION

Definition:

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

Design bases functions are functions performed by SSCs that are (1) required 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.

Discussion:

Comment [NRC19]: The staff suggests modifying the "Discussion" text to reflect that Part 72 includes requirements applicable to CoCs and CoC holders, unlike Part 50. For example:
1.Design bases functions include SSC functions that are required to meet CoC conditions, and
2.Design bases values include values chosen by the CoC holder from applicable codes, standards, or guidance documents.

Comment [NRC20]: The text here appears to repeat the text at the beginning of this "Discussion" section. Suggest consolidating the text into a single paragraph.

Comment [NRC21]: The difference between design bases functions and design functions is not clear. Recommend revising the "Discussion" section of this definition to clarify the difference.

The 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 not-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.

Design functions are also reflected in values or ranges of values of controlling parameters established as reference bounds for the design to meet design bases functional requirements. For instance, the design pressure of the confinement is a controlling parameter for its design basis function as a fission product barrier that is credited in the safety analyses. SSCs that impact confinement pressure have a design function.

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, and would not be applicable (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.

Numerical Values as Design Functions

A UFSAR contains a multitude of numerical values. Some of these numerical values are classified as input parameters, while others describe a feature, attribute or characteristic of an SSC. In either case, proposed SSC changes that involve, affect or impact a UFSAR-described numerical value must be considered in the 10 CFR 72.48 review process.

Design functions identify what SSCs are intended to do, when and how design functions are to be performed, and under what conditions. For each of these, the constituent may be described numerically. NEI 96-07 illustrates this concept with an example for 50.59 in Section 4.2.1, under the sub-heading titled "Screening for Adverse Effects." This example is also informative for 10 CFR 72.48 implementation.

Comment [NRC22]: This is the clearest statement of what a design function is. The NRC staff suggests bringing this text forward into the definition.

Comment [NRC23]: Provide an example here, or refer to one later in the document, which is directly applicable to 10 CFR 72.48, rather than referring to a 10 CFR 50.59 example.

3.11 FACILITY

Definition (§72.48(a)(3)):

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

Discussion:

In this guidance, references to “facility” address only ISFSIs. For specific licensees, this is the ISFSI described in the Part 72 UFSAR. For general licensees, this is the ISFSI described in the site 212 Report.

3.12 FACILITY OR SPENT FUEL STORAGE CASK DESIGN AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition (§72.48(a)(4)):

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:

The term “facility” as used in this guidance means the ISFSI facility as defined in Definition 3.11. It does not include the Part 50 facility.

For specific licensees, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the UFSAR 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 UFSAR 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 UFSAR revision adopted for the spent fuel storage casks deployed at the site’s ISFSI, as amended by changes and deviations authorized under 10 CFR 72.48.

See Definition 3.13 for additional clarifying discussion of the UFSAR.

3.13 FINAL SAFETY ANALYSIS REPORT (AS UPDATED) (UFSAR)

Definition (§72.48(a)(5)):

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-
revision, 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 specific licensees, the UFSAR is similar to that for a Part 50 UFSAR. That is, the specific licensee owns and maintains the ISFSI UFSAR. The applicable revision of the specific license ISFSI UFSAR is always the latest version submitted to the NRC pursuant to 10 CFR 72.70, as revised by any approved 10 CFR 72.48 changes between formal revisions.

For CoC holders, the UFSAR is always the latest approved revision plus any 10 CFR 72.48 changes. It is not required, but is recommended that CoC holders maintain the cask UFSAR in a manner that supports all approved amendments to the cask CoC. This would allow the general licensees using that cask to have a single UFSAR of record, even if casks were loaded under several different CoC **amendments**.

For general licensees, the UFSAR is owned and maintained by the CoC holder for the cask design(s) used at the ISFSI. Therefore, the UFSAR that forms the basis for 10 CFR 72.48 changes for the general licensee means the UFSAR revision used to load the particular serial number cask(s) and place them into storage at the ISFSI, as revised by any applicable 10 CFR 72.48 changes. Once the casks loaded under a particular cask UFSAR are placed into service at a generally licensed ISFSI, the UFSAR revision and 10 CFR 72.48 changes applicable to a given serial number cask remains constant unless a significant safety issue requires implementing a change to a previously loaded cask, or the general licensee chooses to apply a later CoC amendment and associated UFSAR revision to previously loaded casks pursuant to 10 CFR 72.212(b)(4). General licensees may choose to adopt a later cask UFSAR revision or apply a particular 10 CFR 72.48 change to casks under a prior CoC amendment at their discretion.

Because of this unique situation for general licensees, not all casks in service at the same ISFSI may have the same licensing basis. Thus, the licensing basis for each serial number cask should be documented by the general licensee in the 212 Report or other readily retrievable document to ensure the basis for the 10 CFR 72.48 program is clear for each cask at the ISFSI. **The licensing basis for each serial number cask should also be documented in the Cask Registration letter in accordance with 10 CFR 72.212(b)(2) and (4).**

Comment [NRC24]: The text here states that for CoC holders the UFSAR is always the latest approved revision plus any 10 CFR 72.48 changes. What about changes that are screened out, but still need to be reflected in the biennial report revision to and the UFSAR update? See also the latter part of this section; now NEI states that modifications and deviations authorized by the general licensee with respect to the cask UFSAR are documented in the general licensee’s 10 CFR 72.48 screening/evaluation records. This is not consistent with previous statements that screenings do not have to be kept as records (although they strongly suggest they should be kept).

Comment [NRC25]: A General Licensee (GL) may have several UFSAR revisions it is working with and 72.48’s may be particular to specific revisions that aren’t necessarily the latest revision. How is that kept straight if one is trying to have only one UFSAR of record? There may be things in later revisions that casks loaded under previous revisions can’t meet, can’t do, or are N/A for them. The text should be clarified.

Modifications and deviations authorized by the general licensee with respect to the cask UFSAR are documented in the general licensee's 10 CFR 72.48 screening/evaluation records. It is recommended that general licensee modifications and deviations with respect to the cask UFSAR be identified (i.e., listed and summarized) in the 212 Report or other readily retrievable document to ensure the current licensing basis is available to interested parties, including others performing 72.48 screenings and evaluations of activities for that ISFSI.

In accordance with 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 licensee or certificate holder since the last required update was submitted per 10 CFR 72.70 or 10 CFR 72.248, as applicable. 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 applicable pending UFSAR changes by the certificate holders of the casks they are using, so that these pending changes will be considered in subsequent 10 CFR 72.48 screenings/evaluations [performed by the licensees](#).

3.14 IMPLEMENTATION OF 72.48-AUTHORIZED ACTIVITY

Definition:

Implementation of an activity authorized under 10 CFR 72.48 is defined in two different contexts. For the CoC holder, implementation is deemed to have occurred at the time the 10 CFR 72.48 screening or evaluation document is approved, legally modifying the licensing basis.

For the specific or general licensee, implementation is deemed to have occurred when the activity authorized by 10 CFR 72.48 is deployed in the field. That is, the affected equipment is placed in service or declared operable.

Discussion:

Upon implementation of an activity by a CoC holder, the CoC holder then has 60 days to send a copy of the 10 CFR 72.48 documentation for the activity to affected licensees to comply with the requirements of 10 CFR 72.48(d)(6)(iii). If the activity (e.g., a physical cask design change) is revised again before fabrication to modify the original modification, the authorizing 10 CFR 72.48 review must be revised to recognize the

Comment [NRC26]: It is not clear that the definition here is appropriate for "implementation" for licensees. The text should be revised to define "implementation" for licensees as occurring when the licensee has taken the necessary actions to ensure that the change will be carried out in the future storage operations. These actions include making changes to procedures or hardware specifications (e.g., design drawing changes).

Thus, the activity should be considered as being "implemented" by the licensee upon the licensee's performing these kinds of actions even though activities associated with deploying the change in the field (e.g., ordering, installing or operating new equipment) have not yet occurred and may not occur for some time.

revision and re-submitted to the licensees. Upon implementation by a licensee, the licensees then has 60 days to comply with the applicable documentation requirements of 10 CFR 72.48(d)(6)(i) and (ii). Additional guidance for applying this definition is provided in Section 2.1.4.1.

3.15 INPUT PARAMETERS

Definition:

Input parameters are those values derived directly from the physical characteristics of SSCs 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 Definition 3.17) are evaluated under criterion 10 CFR 72.48(c)(2)(viii), whereas changes to input parameters described in the UFSAR are considered changes to the ISFSI facility or cask design that would be evaluated under the other seven criteria of 10 CFR 72.48(c)(2), but not criterion (c)(2)(viii).

There are two cases in which an input parameter is treated as an element within a method of evaluation. For guidance regarding these two cases, refer to Definition 3.17.

Examples illustrating the treatment of input parameters are provided in Appendix A. Appendix A also provides 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).

Comment [NRC27]: The first sentence of this paragraph states that “Examples illustrating the treatment of input parameters are provided in Appendix A.” Revise this paragraph to either point to specific examples in Appendix A, or to provide some examples in this section, similar to what was done for Section 3.17.

3.16 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 for applying this definition is provided in Sections 5 and 6.

Comment [NRC28]: Modify the definitions and discussions in Sections 3.15 and 3.17 to tailor them to the standards and practices used by the technical disciplines for Part 72 activities. The proposed definitions and examples, while taken from the SOCs don't account for differences between Parts 50 and 72 that affect how these terms are applied for activities in each part. Part 72 activities often make use of industry consensus standards and practices which may define terms such as these for the technical disciplines. For example, ANSI/ANS 8.1 defines calculational method for criticality safety analyses.

3.17 METHOD OF EVALUATION

Definition:

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

Discussion:

Examples of elements of methods of evaluation are presented below. Proposed activities involving modifications to such methods of evaluation require evaluation under 10 CFR 72.48(c)(2)(viii) only for methods of evaluation 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. Proposed activities involving modifications to methods of evaluation 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.

Comment [NRC29]: Modify the definition of MOE in Section 3.17 to include qualitative evaluation methods and qualitative aspects of an evaluation. For example, a conclusion may be reached based upon logical arguments (e.g., deductive reasoning) or credit given for expected actions. The definition should also define elements of these kinds of methods and provide examples.

Elements of Methodology	Example
Data correlations	<ul style="list-style-type: none"> Tipover and end drop analysis based on industry-referenced reports
Means of data reduction	<ul style="list-style-type: none"> ASME methods for evaluating cask parameters, e.g., elastic stress intensity
Physical constants or coefficients	<ul style="list-style-type: none"> Heat transfer coefficients, boundary conditions, burnup peaking factors, and cross-section libraries Friction coefficient in a tipover analysis
Mathematical models	<ul style="list-style-type: none"> Methods of heat transfer assumed (i.e., conduction, convection, and radiation), mesh size, material performance – elastic or plastic
Specific limitations of a computer program	<ul style="list-style-type: none"> Benchmarking and correlation ranges
Specified factors to account for uncertainty in measurements or data	<ul style="list-style-type: none"> Criticality calculation biases, fuel burnup, percent fuel burnup uncertainty
Statistical treatment of results	<ul style="list-style-type: none"> Vendor-specific analysis approach (e.g., material property testing of composite neutron poison, B-10 content validation from blackness testing, confidence and tolerance limits)
Dose conversion factors and assumed source terms	<ul style="list-style-type: none"> ICRP factors

Comment [NRC30]: Add “burnup profiles and their use” as an example of physical constants or coefficients in the table.

Comment [NRC31]: Based on the language used in the SOCs (64FR53582), add the words “and assumptions” after “Specific limitations” in the table for that element of a methodology.

Comment [NRC32]: Add “administrative margin (as applied to criticality safety analysis)” as an example of specified factors to account for uncertainty in the table.

Comment [NRC33]: Regarding the dose conversion factors element in the table, the guidance and examples should be clear that this includes the specific version of the factors (e.g., ICRP 26, 51, 57) and which factor set from that version is used (e.g., effective dose equivalent factors vs. dose equivalent factors, vs. ambient dose equivalent factors). The ones that are used should be consistent with the basis for the limits in the regulations. Revise the last line in the table to replace “ICRP factors” with “ANS 6.1.1 (1977) Neutron and Gamma-Ray Flux-to-Dose-Rate 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.
- Methods of evaluation subject to criterion 10 CFR 72.48(c)(2)(viii) do not include methods used to select fuel for loading into the cask (i.e., decay heat and burnup determinations) unless those methods are described in the UFSAR.

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.

3.18 PROCEDURES AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition (§72.48(a)(6)):

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

Comment [NRC34]: 3rd bullet: Clarify that "dynamic effects" includes man-made events or accidents (e.g., cask drops, fire). Remove the term "dynamic effects" and use the terminology found in NUREG-1536.

Comment [NRC35]: Regarding this paragraph, which starts with "If a methodology permits", the NRC staff notes that there is an exception to what is written. That exception is that the range of allowable values for which the method is derived/developed is an element of the method. If the choice of an input value is outside that range, then this would be a change in method of evaluation.

Comment [NRC36]: The guidance should provide examples that illustrate both of these two bullets.

Comment [NRC37]: Clarify the guidance in the first bullet to address:

1. The approval of the design is based on the conservatism inherent in a value that is more conservative than what would be required by the selection method. For example, the shielding design is approved based on an evaluation of contents that exceed the allowable contents specifications.
2. The impact, if any, on determining whether an input is an element of a method for the case when the amount of additional conservatism is not characterized.
3. The difference between the first statement of the paragraph and the first statement of this bullet for determining whether an input is an element of a method. The distinction is not clear though the guidance points to two different outcomes.

Comment [NRC38]: Replace the word "documents" with the word "procedures" to be consistent with the regulatory definition, since the definition here is supposed to be a direct quote of the definition in the regulation.

Discussion:

See Definitions 3.11 and 3.12 for discussion on the scope of information that is the focus of 10 CFR 72.48.

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 modifications to these activities or controls are made, such modifications are considered revisions to procedures described in the UFSAR, and the revisions 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. Section 4.4 identifies examples of procedures that are not subject to 10 CFR 72.48.

10 CFR 72.48 screening of procedures is discussed in Section 5.1.

3.19 REFERENCE BOUNDS

Definition:

Reference bounds are the limits or requirements (e.g., design, physical, operational, etc.) imposed by the numerical values or ranges of values of input parameters and any other applicable design bases values or ranges of values for the SSCs utilized or controlled in the test or experiment.

Discussion:

Guidance for applying this definition is provided in Section 5.2.

3.20 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:

Comment [NRC39]: The sentence, “See Definitions 3.11 and 3.12 for discussion on the scope of information that is the focus of 10 CFR 72.48,” is generic and apparently unrelated to this particular discussion. Either remove the sentence, or revise it to be applicable to the discussion of “Procedures as Described in the FSAR (As Updated).”

Comment [NRC40]: The staff suggests this text be clarified. Provide examples of the types of information described here, including examples that may not be obvious. Good examples are needed to assist the user of the guidance to distinguish what information meets the definition in Section 3.18 and what information does not meet this definition.

Comment [NRC41]: Clarify how this guidance is consistent with the 10 CFR 72.48(a)(6) definition. That definition’s use of the words “such as” immediately before “how SSCs are operated and controlled” shows that this phrase is only an example of information described in the FSAR. Thus, the guidance that changes to procedures described in the FSAR “are not subject to 10 CFR 72.48” unless such procedures pertain to information on how SSCs are operated or controlled, reads the 10 CFR 72.48(a)(6) definition too narrowly.

Comment [NRC42]: The definition of “Reference Bounds” should be clarified. It’s meaning is unclear.

- (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 10 CFR 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.

Comment [NRC43]: The staff suggests that this text be clarified as follows. First bullet: Clarify that NITS SSCs that support ITS SSCs in their functions are included in the SSCs referred to in this bullet. Such NITS SSCs should be included, based on the definitions of Design Bases and Design Functions.

3.21 TESTS OR EXPERIMENTS NOT DESCRIBED IN THE FSAR (AS UPDATED)

Definition (§72.48(a)(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:

- 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~~any activity that puts 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.

3.22 TYPE OF ANALYSIS

Definition:

The type of analysis is the discipline of the analysis (i.e., structural, thermal, shielding, criticality, etc.), and the numeric model (i.e., classical closed form equation, finite element, finite difference, Monte Carlo, discrete ordinate, etc.).

Discussion:

Guidance for applying this definition is provided in Section 6.8.

Comment [NRC44]: Clarify why this guidance defining "Type of Analysis" is needed. This term, as used in Section 6.8, is not consistent with this definition. The term as used in Section 6.8 is more a combination of the definition given here and the definition of the term "Class of Analysis" given in Section 3.7. Consider combining the 2 terms. As written, "Type of Analysis" does not convey a consistent meaning throughout the guidance.

4 10 CFR 72.48 APPLICABILITY OF DETERMINATION

ISFSI licensees and CoC holders must determine the applicability of 10 CFR 72.48 to proposed activities to determine if review under 10 CFR 72.48 is required.

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.

The purpose of the Applicability Determination (AD) is to determine the correct regulatory change control process, if any, for a proposed activity by answering the following questions for a given activity:

1. Does the proposed activity or part(s) of the proposed activity involve a modification to the ISFSI, or cask design or procedures in the ISFSI or cask UFSAR or the 212 Report that is an editorial/administrative correction or a modification to managerial or administrative procedure governing the conduct of operations?

If the answer to the above question is "yes" for all, or part(s) of a proposed activity, 10 CFR 72.48 is not applicable to the activity or applicable that part(s) thereof of the activity, and the activity or applicable that part(s) thereof of the activity may accordingly be implemented without further review under 10 CFR 72.48. If the answer to the above question is "no" for all, or part(s) of an activity, Question 2 must be answered for the activity or applicable the part(s) thereof that is not classified as an editorial/administrative correction or modification to a managerial or administrative procedure. See Subsections 4.3 and 4.4 for guidance on responding to this question.

2. Does the proposed activity or part(s) of the proposed activity require a change to the ISFSI license or cask CoC, including appendices?

If the answer to the above question is "yes" for all, or part(s) of a proposed activity, an ISFSI license amendment or CoC amendment (or exemption) is

required prior to implementing ~~to the activity or applicable that part(s) thereof of the activity.~~ ~~and the activity or applicable parts thereof may not be implemented without prior NRC approval.~~ If the answer to the above question is “no” for all, or part(s) of an activity, Question

3 must be answered for the activity or ~~applicable that part(s) thereof of the activity~~ not requiring an ISFSI license or CoC amendment.

3. Does a different regulation provide more specific criteria for accomplishing the proposed activity ~~or part(s) of the proposed activity?~~

If the answer to the above question is “yes” for all, or part(s) of a proposed activity, the other regulatory process should be applied prior to implementing the activity or ~~applicable that part(s) thereof of the activity.~~ If the answer to the above question is “no” for all, or part(s) of an activity, a 10 CFR 72.48 screening must be performed for the activity or ~~applicable that part(s) thereof of the activity that is~~ not subject to a ~~different~~ regulatory process ~~other~~ than 10 CFR 72.48. See Subsections 2.2.1 and 4.1 for guidance on responding to this question.

The subsections below provide additional guidance for responding to the above questions for a proposed activity.

Comment [NRC45]: Deleted portion of the statement here is redundant with the first part of the same sentence.

Comment [NRC46]: Provide examples, or refer to locations in this document (e.g., later sections) where examples are provided, to illustrate the guidance here in Section 4.0, particularly situations which may require both another regulation and 72.48 to be applied to the proposed activity (or part(s) of it).

4.1 APPLICABILITY TO LICENSEE AND CoC HOLDER ACTIVITIES

10 CFR 72.48 is applicable to tests or experiments not described in the UFSAR and to modifications to the ISFSI facility, ~~or spent fuel storage cask design,~~ or procedures as described in the UFSAR, including modifications 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 10 CFR 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 modifications to the ISFSI facility, ~~or 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) specify 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 modifications are directly related to the activity implemented via another regulation, applying 10 CFR 72.48 is not required. UFSAR modifications 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 ~~either or both of~~ the requirements of 10 CFR 72.48 and ~~that the~~ requirements of another regulation. The set of “other more specific requirements and criteria established by regulation” to be addressed in the AD differ among specific

Comment [NRC47]: Revise the text highlighted by this comment. The meaning of the text is unclear and difficult to understand. For example, it uses the term ‘applicable’ in multiple ways and does not appear to consistently address the need to consider the topics raised in the 3 questions both in terms of the activity (as a whole) and in terms of the parts of the activity. The staff has proposed edits to the text to address these items. However, the guidance should be further revised to ensure clarity of meaning.

licensees, general licensees, and CoC holders, although some may overlap:

- Specific licensees: ISFSI license amendments (§72.56), exemptions (§72.7), security (§72.44(e)), emergency plan (§72.44(f)), quality assurance (10 CFR 72, Subpart G) and radiation protection (10 CFR 20), among others. In addition, specific licensees with ISFSIs at operating reactor sites may have chosen to address Part 72 activities in their Part 50 programs (e.g., §50.54(p) for the security plan), rather than create a separate program. Specific licensees at an operating plant would also need to include 10 CFR 50.59 and any operating license conditions pertaining to change control for the Part 50 license (e.g., fire protection program).
- General Licensees: CoC amendments (§72.244), operating license amendments (§50.90), exemptions (§72.7 and §50.12), security (§50.54(p)), emergency plan (§50.54(q)), quality assurance (10 CFR 50, Appendix B), changes, tests and experiments (§50.59), radiation protection (10 CFR 20), and any operating license conditions pertaining to change control for the Part 50 license (e.g., fire protection program), among others.
- CoC Holders: CoC amendments (§72.244), exemptions (§72.7), quality assurance (10 CFR 72, Subpart G), and radioactive material transportation (10 CFR 71).

Each of the above entities needs to tailor their 10 CFR 72.48 program applicability determination process accordingly.

Comment [NRC48]: Clarify that 72.48 and/or other Part 72 regulations that describe more specific criteria and requirements would also apply to Part 50 programs that are used to cover Part 72 program requirements.

Comment [NRC49]: Revise this bullet to remove the reference to Part 71, or provide a specific applicable example. The reference to 10 CFR Part 71 does not appear to be applicable. Changes to a Part 72 approved cask system design to support transportation under Part 71 would likely still need to be evaluated under 72.48.

4.2 MAINTENANCE ACTIVITIES

Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Generally speaking, maintenance activities affecting the ISFSI or storage cask, other than those required by the Part 72 license, CoC, or technical specifications, 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 may include blocking storage cask air vents, placing temporary lead shielding on pipes and equipment, removal of barriers, and use of temporary scaffolding and supports.

The Maintenance Rule for operating power plants, 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. Thus, the guidance of NEI 96-07 for assessing and managing the risk impact of maintenance activities in accordance with 10 CFR 50.65(a)(4) does not apply to ISFSI/cask activities.

As discussed in Section 4.9, 10 CFR 72.48 should also be applied to temporary modifications proposed as compensatory measures for degraded or non-conforming

conditions. Corrective maintenance that restores a degraded or non-conforming component to its as-designed condition as described in the ISFSI or cask UFSAR does not require a 10 CFR 72.48 review, **provided the corrective maintenance does not require any temporary modifications affecting other SSCs of the ISFSI or cask.**

For recurring preventive maintenance that clearly does not modify the ISFSI facility or storage cask, such as weed trimming, fence repairs, like-for-like replacements, etc. licensees may wish to consider performing a one-time 10 CFR 72.48 screening to categorically exclude the procedure or work order from future review under 10 CFR 72.48. Care should be taken to ensure the scope of work in those categorically excluded procedures or work control documents does not get revised later to change the work or include new work, which would require a 10 CFR 72.48 review. **Thus, the scope of work should be considered in the 72.48 review for the categorical exclusion so it is clear when a change triggers a new 72.48 screening/evaluation.**

4.3 EDITORIAL AND ADMINISTRATIVE CORRECTIONS

Purely editorial and administrative corrections are not included in the scope of 10 CFR 72.48 because they clearly do not constitute a change, test, or experiment. However, a conservative approach should be applied in order not to erroneously classify a document modification as editorial or administrative and not perform a 10 CFR 72.48 review for the modification. Documentation modifications that are not clearly editorial or administrative should be subject to 10 CFR 72.48 screening to determine whether a full 10 CFR 72.48 evaluation is required. 10 CFR 72.48 need not be applied to the following types of activities:

- Editorial corrections to the UFSAR and 212 Report (including referenced procedures, topical reports, etc.), and implementing procedures, such as the correction of typographical errors and grammar
- Administrative corrections such as altering procedure step sign-offs, changing personnel titles, 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 modifications to UFSAR or 212 Report information that do not change or obscure the meaning or substance of information presented

Comment [NRC50]: Clarify these three bullets to indicate that the changes described here may be considered editorial and administrative corrections as long as the meaning of the affected information, especially that is the basis for approval, remains unchanged.

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. 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 10 CFR 72.248.

4.4 MODIFICATIONS TO PROCEDURES GOVERNING THE CONDUCT OF OPERATIONS

Even if described in the ISFSI or cask UFSAR, modifications to managerial and administrative procedures governing the conduct of ISFSI facility operations are controlled under 10 CFR 72, Subpart G or 10 CFR 50 Appendix B (quality assurance), 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
- 10 CFR 72.48 program and 212 Report control processes

Comment [NRC51]: Clarify the meaning of this bullet. It is not clear what is intended to be considered as not subject to control under 72.48 for the items listed in this bullet.

4.5 MODIFICATIONS 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. The impact of activities that affect the fire protection program (FPP) and/or site fire hazards analysis (FHA) as applied to ISFSI operations should be evaluated under the plant's process for FPP and FHA modifications.

Comment [NRC52]: Clarify this guidance as to the effects, if any, on the fire/explosion accident evaluations in the UFSAR (or 212 Report) for a facility/cask. If these UFSAR evaluations are affected, 72.48 would seem to be applicable since modifications affecting those evaluations have the potential to trip criterion (i), (iii), or (v) in 72.48(c)(2).

4.6 MODIFICATIONS TO WRITTEN EVALUATIONS REQUIRED BY 10 CFR 72.212

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

Comment [NRC53]: Refer to the NRC's previous interim letter, dated September 26, 2013, and its enclosures for the NRC's comments and recommendations for this section. See ML13260A029.

4.7 CASK DESIGN MODIFICATIONS MADE BY A CoC HOLDER AND ADOPTED BY A GENERAL LICENSEE

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

Comment [NRC54]: Refer to the NRC's previous interim letter, dated September 26, 2013, and its enclosures for the NRC's comments and recommendations for this section. See ML13260A029.

“The Commission envisioned that a general licensee who wants to adopt a change to the design of a spent fuel storage cask it possesses - which change was previously made to the generic design by the certificate holder under the provisions of Sec. 72.48 - would be required to perform a separate evaluation under the provisions of Sec. 72.48 to determine the suitability of the change for itself.”

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

4.8 APPLICABILITY DETERMINATION DOCUMENTATION

For any proposed activity, the ~~activity owner~~ licensee or CoC holder must determine the appropriate regulatory review process to determine whether a) 10 CFR 72.48 and/or another regulatory process applies, and b) prior NRC approval is required before the activity may be implemented. The guidance in this document provides direction for those proposed activities to which 10 CFR 72.48 applies. Licensees or CoC holders may devise any process ~~for the activity owner~~ to determine regulatory review process applicability. The two types of Applicability Determination (AD) processes are:

1. **Single portal:** In this type of AD process all proposed activities would funnel through a common AD process (e.g., the 10 CFR 50.59 AD process) to determine the other applicable regulatory review process(es), if any. The implementation of the applicable regulatory review process(es) would be governed by the procedure or guidance for the applicable process(es).
2. **Multiple portals:** In this type of AD process, the activity reviewer performs the AD effort in the primary process that most likely applies to the proposed activity. For example, the 10 CFR 72.48 applicability determination may be the starting point for a licensee cask loading procedure change and the 50.54(p) review may be the starting point for a security plan change. In any case, that primary AD process would need to contain a method for the reviewer to determine the applicability of other regulatory review processes to the proposed activity in part, or in whole. Implementation of the other applicable regulatory review process(es) would be governed separately by the procedure or guidance for the applicable process.

Comment [NRC55]: In addition to the edits as indicated, clarify what if any distinction there is between “regulatory review process applicability” and the “applicability determination” process.

In both AD models, the specific required regulatory reviews would be performed and documented under the processes established for those reviews for the applicable portion(s) of the proposed activity. Each proposed activity must be reviewed for the applicability of one or more regulatory review processes. A given activity may or may not affect the

ISFSI or storage cask **design or procedures** or may be an administrative/editorial correction. If the activity does not affect the ISFSI or storage cask **design or procedures**, is governed by a different regulation, or is administrative/editorial, 10 CFR 72.48 does not apply and the activity should be either implemented directly or reviewed under another regulatory review process, as appropriate.

If the activity does affect the ISFSI and/or storage cask **design or procedures**, other regulatory requirements may also apply (e.g., 10 CFR 50.59). In this case, the activity is reviewed under all applicable regulatory review processes.

The first consideration under the 10 CFR 72.48 AD process is whether the activity requires a change to the specific ISFSI license or cask CoC, including associated technical specifications and other requirements considered part of the specific license or CoC. If so, the activity does not receive a 10 CFR 72.48 screening and is not reviewed against the criteria of 10 CFR 72.48(c)(2). Four options are available:

1. Revise the activity so that a license amendment or CoC amendment is not required and begin the AD process again;
2. Process the license amendment (specific licensee) or CoC amendment (CoC holder);
3. Request an exemption in accordance with 10 CFR 72.7; or
4. Cancel the activity.

If the activity is not an editorial or administrative correction, affects the ISFSI or storage cask **design or procedures**, and does *not* require a change to the specific ISFSI license or CoC, the activity receives a 10 CFR 72.48 screening in accordance with Section 5 of this guidance. If required, as determined by the 10 CFR 72.48 screening, the activity is evaluated against the applicable criteria of 10 CFR 72.48(c)(2) in accordance with Section 6 of this guidance to determine if prior NRC review and approval is needed.

4.9 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 modification, 10 CFR 72.48 should be applied to the temporary modification. The intent is to determine whether the temporary modification/compensatory action itself (not the degraded condition) impacts other aspects of the ISFSI facility; or cask design; or procedures described in the UFSAR. In considering whether a temporary modification impacts other aspects of the ISFSI facility or cask design or procedures, a licensee or cask CoC holder should pay particular attention to ancillary aspects of the temporary modification 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 modify the ISFSI facility; or cask design; or procedures, 10 CFR 72.48 should be applied to the corrective action, unless another regulation applies that establishes more specific criteria for accomplishing the proposed changes. In these cases, the final corrective action becomes the proposed modification 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.

5 72.48 SCREENING

Once it has been determined that 10 CFR 72.48 is applicable to a proposed activity via the AD process, a screening is performed to determine if the activity should be reviewed 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 perform the 10 CFR 72.48 screening. The 10 CFR 72.48 screening is performed to determine whether the activity or part(s) thereof need to be evaluated in accordance with 10 CFR 72.48(c)(2) and Section 6 of this guidance. ~~Refer to Section 1.3 for discussion of the use of the word “change” in the context of 10 CFR 72.48.~~ A full 10 CFR 72.48 evaluation is required for a proposed activity or part(s) thereof that involve any one of the following:

- A change to a UFSAR-described design function of an SSC, facility or cask design,
- A change to a UFSAR-described method of performing or controlling a design function,

Comment [NRC56]: In addition to the edits in the text here, this bullet should be clear that while another regulation may apply, a 72.48 evaluation may still need to be done in some cases, as discussed in other sections of this document (see Section 4.1).

Comment [NRC57]: Refer to the NRC's previous interim letter, dated September 26, 2013, (See ML13260A029) for the NRC's comments regarding Section 1.3. This deletion is made in accordance with the staff's 2013 comments.

- A change to a UFSAR-described method of evaluation or use of an alternative method of evaluation for demonstrating that intended design functions will be accomplished, or
- A test or experiment not described in the UFSAR where an SSC is utilized or controlled in a manner that is outside the reference bounds of the design for that SSC or is inconsistent with analyses or descriptions in the UFSAR.

Sections 5.1 and 5.2 provide guidance for determining whether an activity is (1) a change to the ISFSI facility or 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 2.1.3.

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 activities 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 modifications to other systems or procedures; or (2) they are performed collectively to address a design or operational issue.

If concurrent activities are being made that are not linked, each must be screened separately and independently of each other. Un-linked modifications to separate documents (e.g., different procedures) should receive separate 72.48 screenings. For multiple modifications being made to a single document, such as the 212 Report, it is permissible to include un-linked modifications within the same 72.48 screening document, but each modification must be individually discussed in answering the screening questions.

Multiple activities considered in the same 72.48 screening document may result in some or all of the activities requiring a full 72.48 evaluation. Care must be taken to ensure the documentation is clear in such cases. If the reviewer chooses to document in a 72.48 screening why a full 72.48 evaluation is required for certain activities, it is recommended for clarity that a separate 72.48 screening be performed for those activities.

Activities that screen out may nonetheless require UFSAR and/or 212 Report 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 activities that screen out but result in needed UFSAR updates to licensees within 60 days of implementing the activity. The 212 Report is updated in accordance with the general licensee's internal control process.

Comment [NRC58]: The staff suggests the text be modified to include statements that, in order to consider activities as un-linked, the licensee/CoC holder should verify that proposed activities/changes are not linked (e.g., that they don't affect the same aspect of the design or procedures).

~~Specific guidance for applying 10 CFR 72.48 to temporary modifications proposed as compensatory measures for degraded or non-conforming conditions is provided in Section 4.9.~~

Comment [NRC59]: Suggest deleting this sentence. No distinction is made in screening actions between permanent and temporary modifications, maintenance, and so forth in this section (Section 5) at this point. Section 4.9 is for the Applicability Determination process and not the screening process. Thus, discussion of Section 4.9 does not appear to be relevant for this section (Section 5).

5.1 IS THE ACTIVITY A CHANGE TO THE ISFSI FACILITY, OR SPENT FUEL STORAGE CASK DESIGN, OR PROCEDURES AS DESCRIBED IN THE UFSAR?

5.1.1 Introduction

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 characteristic(s) of the SSC or cask?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system interaction?
- Does the activity adversely affect the ability or response time to perform required actions, e.g., alter equipment access or add steps necessary for performing tasks?
- Does the activity degrade the seismic, structural, heat removal, shielding, or criticality control capability 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?

Comment [NRC60]: The staff suggests this text be clarified by including a reference to degradation of the confinement capability.

The meaning of “change” discussed in Definition 3.6 indicates that 10 CFR 72.48 is applicable to additions as well as to modifications to, and removals from the ISFSI facility or; cask design; or procedures. Additions should be screened for their effects on the existing facility or; cask design, and or 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, proposed activities 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 activities would adversely affect a UFSAR-described design function, as described below.

Screening to determine if a 10 CFR 72.48 evaluation is required is straightforward when a proposed activity 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 (i.e., constitutes a “change”).

An ISFSI facility or cask design may also contain SSCs not described in the UFSAR. These can be components, subcomponents of larger components or even entire systems. Proposed activities affecting 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 proposed activity 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 activity 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.

5.1.2 Screening for Adverse Effects

A 10 CFR 72.48 evaluation is required for proposed activities that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished (i.e., “changes”). Activities that have none of these effects, or have positive effects, may be screened out.

Consistent with the definition of “design function,” SSCs may have preventive, as well as mitigative, design functions. Proposed activities that have adverse effects on preventive or mitigative design functions are changes, and must be screened in. Thus a proposed activity that decreases the reliability of a function whose failure could initiate an accident would be considered to adversely affect a design

Comment [NRC61]: The staff suggests that this text be inserted into Section 5.0 rather than stating it here.

Comment [NRC62]: Here and throughout the document, the staff would replace “activities” with “changes”, where appropriate, as per the staff’s comments in the NRC’s September 26, 2013 interim letter and its enclosures regarding the use of these terms in the guidance. (See ML13260A029) Other conforming changes should be made to the guidance throughout the document.

Comment [NRC63]: Refer to the NRC’s September 26, 2013 interim letter and its enclosures for the NRC’s comments and recommendations for this first paragraph of this section. See ML13260A029.

function and would screen in as a change. In this regard, proposed activities that would relax the manner in which Code requirements are met for certain SSCs should be screened for adverse effects on design function. Similarly, proposed activities that would introduce the possibility of a new type of accident or malfunction would screen in. This reflects an overlap between the technical/engineering (“safety”) review of the activity and 10 CFR 72.48. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

If a proposed activity has both positive and adverse effects, the activity should be considered a change and be screened in. The 10 CFR 72.48 evaluation should focus on the adverse effects of the activity that define it as a change pursuant to Definition 3.6.

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

Screening determinations are made based on the engineering/technical information supporting the proposed activity. 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 proposed activities 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 activity. If the effect of a proposed activity 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 activity is considered to be a change 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.

Proposed activities that entail updating safety analyses to reflect improved performance, capacity, timing, etc., resulting from a modification or alteration (beneficial effects on design functions) are not considered adverse and need not be screened in, even though the activity calls for safety analyses to be updated.

Specific guidance for identifying adverse effects of a proposed change, affecting the design, a procedure, an evaluation, or the design basis limit for a fission product barrier is provided in subsections 5.1.3, 5.1.4, and 5.1.5, respectively. Specific guidance for identifying adverse effects due to a proposed activity affecting the facility, a procedure or an evaluation is provided in subsections

Comment [NRC64]: Clarify the statement such that consideration of a modification/alteration that results in the listed improvements as not adverse also includes the determination that the activities have no negative effects for other aspects of the facility/cask design or operations, which were not the focus of the modification

Comment [NRC65]: The staff suggests the text here be modified as indicated.

| 5.1.3, 5.1.4 and 5.1.5, respectively.

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

The terms “design function” and “design bases functions” are discussed in Definition 3.10. “Design bases” is discussed in Definition 3.9. A basic understanding of the inter-relationship of these terms is helpful in fundamentally understanding what constitutes the necessary design functions to consider in a 10 CFR 72.48 screening.

The phrase “credited in the safety analysis” as used in characterizing a design basis function is further explained in the discussion supporting the definition of “design function.”

The design bases are a subset of the current licensing bases and include the bounding conditions under which SSCs must perform design bases functions. The bounding conditions may be derived from normal operation or any accident or events for which SSCs are required to function, including off-normal events, accidents, natural phenomena, and other events specifically addressed in the regulations.

Note that the licensee or CoC holder must also further cascade the application of “design function” to include controlling the appropriate environmental conditions (temperature, humidity, etc.) for SSCs to assure the equipment can perform its intended function or provide SSCs that can withstand potentially credible conditions (tornado missile, seismic, etc.).

Comment [NRC66]: Clarify what is meant by “further cascade the application of “design function””

This guidance further describes the relationship of design functions to design bases functions by explaining the phrase “support or impact design basis functions.” This discussion also helps understand the role of not-important-to-safety (NITS) equipment and design functions of such equipment as well as re-emphasizes that the conditions under which **NITS** equipment is required to function ~~is~~ **are** within the scope of 10 CFR 72.48.

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 (ITS) and NITS SSCs may perform design functions.

UFSAR descriptions 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 ITS or NITS SSCs and include functions that, if not performed, would initiate a transient or accident that the ISFSI or cask is required to withstand.

Proposed activities that indirectly as well as directly affect design functions must be considered within the scope of 10 CFR 72.48 and may require evaluation to address adverse impacts.

Codes and standards may be used in establishing acceptable values or ranges of values to support the design bases of the facility. The reliability of SSCs is also within the scope of 10 CFR 72.48, and ~~that~~ relaxation of **compliance with** such codes and standards (**that define/establish an SSC's reliability**) should be screened for adverse effects.

Another important consideration is that a modification to NITS SSCs not described in the UFSAR can indirectly affect the capability of an SSC(s) or a cask to perform its UFSAR-described design function(s). For example, increasing the heat generation from NITS equipment near the ISFSI or the cask during loading operations could compromise the cask's ability to remove heat from the spent fuel.

Seismic qualification, missile protection, flooding protection, and fire protection are some of the areas where alterations to NITS 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 activity performed on 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.

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

Comment [NRC67]: This paragraph should be further revised to indicate that the activities that have adverse effects in terms of the four bullet items at the beginning of Section 5 (including effect on design basis limit of fission product barrier) require evaluation under 72.48.

5.1.4 Screening of Proposed Modifications to Procedures as Described in the UFSAR

A procedure modification is any alteration to a procedure. Procedure modifications that are editorial/administrative or managerial do not require a 10 CFR 72.48 screening per the Applicability Determination process. Proposed procedure modifications 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 modifications to UFSAR-described procedures, assumed operator actions and response times). A modification 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 modifications that are determined to have a positive, or no effect on how SSC design functions are performed or controlled may also be screened out.

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

5.1.5 Screening Proposed Modifications to USFAR Methods of Evaluation

Methods of evaluation (MOEs) 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 MOEs (Definition 3.17) is considered to be a modification that is controlled by 10 CFR 72.48 and needs to be considered as part of this screening step. Changes to elements of an MOE 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 6.8). Changes to MOEs (only) do not require evaluation against the first seven criteria.

Proposed modifications to MOEs not described, outlined, or summarized in the UFSAR or MOEs described, outlined, or summarized in the UFSAR that are not used in the safety analyses or to establish design bases would screen out at this step. Proposed modifications to MOEs described, outlined, or summarized in the UFSAR (both elements of a method and use of an alternate method) that are used in the safety analyses or to establish design bases are considered “changes” and require evaluation under 10 CFR 72.48(c)(2)(viii), with the exception of certain minor modifications to elements of a method, explained later in this subsection.

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

5.1.5.1 Determining if an Activity Involves an MOE

The following step-by-step guidance may be used to determine if a proposed activity involves an MOE:

The discussion that follows is organized into four distinct steps:

Step 1 - Distinguish between input parameters and MOEs

Step 2 - Determine if an MOE is “...described, outlined or summarized in the UFSAR.”

Step 3 - Determine if the MOE is used for one of the three cited purposes

Comment [NRC68]: Modify the text in the 5.1.5 sections discussing MOEs to address non-numeric or qualitative evaluations. MOEs are not always purely calculations and/or analyses. For example, while radiation protection evaluations (demonstrating dose limit compliance) include dose rate calculations, they also include evaluations of personnel actions and assumptions regarding members of the public. Such assumptions include assumed annual occupancy times at/near the controlled area boundary, location of the closest resident, and evaluations of population data in the region surrounding an ISFSI facility.

Comment [NRC69]: The staff has seen statements like the following in at least one FSAR:

An analysis was performed using a method similar to the method described in Reference X.

Clarify whether such statements would be considered as being “described, outlined, or summarized in the UFSAR” as used in the context of this sentence. The scope of the guidance is not clear in cases such as the statement described above.

Comment [NRC70]: Revise Step 3 to clarify which three cited purposes this step is referring to. Add a parenthetical citation with appropriate page numbers.

Step 4 - Identification of the established design bases ~~Identification of intended design functions under design basis conditions~~

Each of these steps is discussed in detail below.

Step 1 - Distinguish Between Input Parameters and Methods of Evaluation

This step involves application of two separate definitions. They

are: Definition 3.15 – “Input Parameters”
Definition 3.17 – “Method of Evaluation”

The core definitions for each, along with explanatory paragraphs are provided below, with emphasis added:

Input Parameters:

Input parameters are those values derived directly from the physical characteristics of SSCs 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.

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

Method of Evaluation:

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

...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 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.*

Comment [NRC71]: This step should be to identify the established design bases, to be consistent with the Section 5.1.5 discussion above. The established design bases include information that identifies: (1) specific functions to be performed by SSCs, and (2) specific values, or ranges of values, for controlling parameters as design reference bounds.

The discussion of this step later in this section should be modified accordingly.

Comment [NRC72]: The text in this section for “Step 1” should be modified to address staff comments in Sections 3.15 and 3.17, which are applicable here as well.

- *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.*

There are examples and an extended discussion provided for each of the above elsewhere in this guidance. However, a few points/observations may be useful:

- Input parameters are values. Those values are derived from physical characteristics of SSCs or a process.
- MOEs are the "calculational framework." The examples in Definition 3.17 illustrate that MOEs tend to involve some type of mathematical equations or are related to physical constants of nature.

Comment [NRC73]: A MOE doesn't have to be a calculation or just limited to the calculation part of the evaluation/analysis. The discussion should be expanded to include the non-calculation aspects of the evaluation/analysis. For example, logic arguments are also MOEs.

So in many cases, a simple inspection of whether the topic of consideration is a value, a constant of nature, or some form of a mathematical expression would be insightful.

The two definitions, 3.15 and 3.17, must be read in their entirety. The stated purpose is to distinguish input parameters from MOEs. This is because the treatment under 10 CFR 72.48 is entirely different for input parameters and MOEs. The screening criteria are different and, as noted above, the 10 CFR 72.48 criteria to be answered are mutually exclusive.

Comment [NRC74]: Clarify this statement. This statement is not entirely consistent with Definition 3.15. Also, this statement seems inconsistent with the text on the preceding page. Text in both of these areas shows that in some cases input parameters may also be considered elements of a MOE. Therefore, it seems that the statement here is not always true and should be modified accordingly.

Criteria 1 through 7 of 10 CFR 72.48(c)(2) are answered for input parameters but not for MOEs. Criterion 8 is solely for MOEs that require such a review, including the two cases in which an input parameter is considered to be an element of the MOE. The remaining three steps described next will determine if a given modification to an MOE requires a 10 CFR 72.48 review.

Note that any calculational framework could potentially satisfy the meaning of "Method of Evaluation" in Definition 3.17. This creates a possible source of confusion because it is common to use the term "MOE change" to mean that any modification to an MOE requires a 10 CFR 72.48 evaluation. However, Steps 2 and 3 indicate that two more attributes are required to achieve that status as described in the "Discussion" section of Definition 3.17. They are:

- The MOE is described in the UFSAR (Step 2)
- The MOE is subject to 10 CFR 72.48 criterion (c)(2)(viii) review (Step 3)

Step 2 - Determine if an MOE is "...described, outlined or summarized in the UFSAR"

The paragraph entitled "Discussion" from Definition 3.17 is provided below, with emphasis added:

*Examples of methods of evaluation are presented below. Proposed activities involving modifications to such methods of evaluation require evaluation under 10 CFR 72.48(c)(2)(viii) **only for methods of evaluation 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.** Proposed activities involving modifications to methods of evaluation 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.*

Comment [NRC75]: Give examples of when something would be in the UFSAR but not in an UFSAR safety analysis and/or used to establish the design bases.

Proposed modifications 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.

Step #2 simply identifies if the method is "... described, outlined or summarized in the UFSAR."

The intention here is if the MOE was discussed *in any fashion*, then the MOE is considered to be "described in the UFSAR."

Comment [NRC76]: Clarify the statement "if the MOE was discussed in any fashion, then the MOE is considered to be described in the UFSAR." For example, does mentioning a MOE in a footnote constitute being described in the UFSAR?

Step 3 - Determine if the MOE is used for one of the three cited purposes

The second required feature is that the MOE must be "...used either in UFSAR safety analyses or in establishing the design bases..."

These purposes correspond to the language used in the defined term of 10 CFR 72.48(a)(2), which is repeated here:

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

Definition 3.17 expands upon the meaning of these purposes. The following phrases explicitly describe these three purposes:

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 confinement and accident analyses, to demonstrate that consequences*

Comment [NRC77]: The discussion of MOEs should be modified (here and at other appropriate places) to account for cases where MOEs are used to calculate design basis limits -- as referenced in and covered by 72.48(c)(2)(vii). A departure from a MOE could also mean a design basis limit has been altered, tripping both 72.48(c)(2)(vii) and (c)(2)(viii). The third paragraph in Section 6.7.2 appears to be an example of such a case.

of normal operations, off-normal events, and accidents do not exceed 10 CFR 72.104 or 10 CFR 72.106 dose limits, as applicable

- *Methods of evaluation used in supporting UFSAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the ISFSI or cask is required to withstand, including natural phenomena, environmental conditions, and dynamic effects.*

The three purposes can be summarized as MOEs:

1. Results demonstrate that design basis limits of fission product barriers are met or are not altered
2. Used to calculate consequences (on-site and off-site accident dose)
3. That demonstrate intended **design functions** will be accomplished under **design basis conditions**

Items 1 and 2 above should be self-evident to any 10 CFR 72.48 evaluator involved in such activities. Item 3 includes two embedded terms, each with their own extended source of guidance. Identification of this usage is the subject of Step 4.

Step 4 - Identification of Intended Design Functions under Design Basis Conditions.

Design function is a critical concept that is used throughout this guidance (Definition 3.10).

There are two points to be made here:

1. The definition for **design function** is rather lengthy and is heavily oriented around **design bases functions** and those functions that **support or impact design bases functions**.
2. The term **design bases functions** comes from NEI 97-04, which is endorsed in Regulatory Guide 1.186.

This discussion will not expand further on the meaning of these two critical terms, **design function** and **design bases functions**, other than to note that a complete understanding of both is required to fully understand the identification of MOEs subject to review under 10 CFR 72.48. The meanings of **design function** and **design bases functions** are included in Definition 3.10.

Comment [NRC78]: It seems like there is a 4th purpose missing, based on the language of 72.48(a)(2). That is the purpose of establishing the design bases (as noted in the 2nd paragraph of Section 5.1.5). This purpose should be added here.

Comment [NRC79]: Modify this purpose to address on-site and off-site dose for normal, off-normal (aka anticipated occurrences) and accident conditions and natural phenomenon events. MOEs and the associated 72.48 criterion ((c)(2)(viii)) are not limited to accidents only.

5.1.5.2 Software Revisions Associated with an MOE

This section discusses a **revision** to existing software that implements an MOE. A change to the software that implements an MOE does not necessarily cause a departure from an MOE, requiring prior NRC approval. Therefore, it is critical to understand the scope and type of changes that were made.

NOTE: This discussion does NOT address the replacement of, or implementation of new, MOEs or software.

Step 1 - Does the Software Need to be Considered?

The first step in determining the impact of the software revision is to determine if the software fits the definition of an MOE and is, therefore, within the scope of consideration. A discussion of the identification of applicable MOEs is included in Section 5.1.5.1.

Step 2 - Performing the Screening Review

If the software does meet the criteria for an MOE, then the next step is to understand the scope and type of modification(s) involved. There are many elements to a software package. Determining exactly which elements are being revised is critical. Examples of elements of methodology are given in Definition 3.17. A simple statement regarding the “revision,” “version” or “modification” identifier as the basis for a 10 CFR 72.48 screening response is inadequate.

One vendor/licensee may use several “versions” of a computer code revision to address errors and minor improvements, thereby saving a new revision for major modeling updates, while another vendor/licensee may change “revisions” of a computer code to address a number of **minor errors** without changing any analytical modeling.

5.1.5.3 Additional Concerns

A proposed activity involving an MOE is a change (i.e., screens in) if the modification is not in strict accordance with the constraints and limitations outlined in an NRC Safety Evaluation Report (SER), vendor/licensee topical report, or the UFSAR (hereafter referred to as “source documents”). A proposed activity to replace an MOE with an alternate MOE (i.e., different software package) always screens in.

The technical description of the MOE in the source documents defines any constraints and limitations on use of the MOE. For example, if a source document for a lattice physics analytical model describes its application to a particular fuel design (e.g., Westinghouse 15x15), the specific reference to the Westinghouse 15x15 fuel design shall be viewed as a constraint or limitation on the use of the analytical model unless the source document states that the analytical model may be used for other fuel designs.

Comment [NRC80]: Revise this section to include a discussion of code validation. For computer codes used as part of the UFSAR evaluations, the code validation methodology and results are part of the method of evaluation. A change to a different version of the same code may change the results of the code validation, especially if the code revision includes new or updated underlying data. This section should also include examples of code version changes that might screen in or screen out of §72.48 evaluation, or point to specific examples in the Appendixes.

Comment [NRC81]: Impacts of the errors across the spectrum of the application may need to be considered in determining if it was 'minor.' Also, it would need to consider if the code version is part of the MOE and is a change to the MOE.

For proposed modification to an element of an MOE, it is essential to identify and understand the details of the modification.

For each modification, the pertinent constraints and limitations associated with the MOE, if any, need to be identified.

Modifications to more than one element ~~may~~ need to consider the cumulative impact of all the modifications on the constraints and limitations. In these cases, the modifications to the MOE may be a “replacement MOE” rather than a “modification to an element of an MOE.”

The 10 CFR 72.48 screening should identify if a proposed modification to an MOE that is not consistent with the constraints and limitations affects an element of the MOE or effectively causes the MOE to become an alternative MOE. This distinction is necessary to correctly apply the Evaluation guidance in Section 6.8.

The following categories of proposed modifications to an element of an MOE are not adverse and would not require a full 72.48 evaluation:

- Modifications to an element of an MOE that are administrative, such as changing input/output descriptive labels, changing output table titles, adding/deleting intermediate output results, re-sequencing output tables, adding non-executable comments in the computer coding, etc.
- **Modifications** to MOEs that are within the constraints and limitations. Typical constraints and limitations may include the following:
 - Breathing rate of 3.47 E-4 m3/sec from an NRC regulatory guide for inhalation dose calculations
 - Use of dose conversion factors from a specific (ICRP) standard(s) (e.g., ANSI/ANS 6.1.1 1977)~~Use of dose conversion factors from an ICRP standard~~
 - Fractional release values for confinement analysis from NUREG-1536
 - Heat transfer correlations
 - Analysis performed “consistent with” a cited topical **report**.
 - Neutron absorber blackness is "appropriately **modeled**."
 - A subroutine iterates to a specified convergence limit
 - A boundary condition is set to a specified value.
 - Cross sections were obtained by collapsing the library from “x” groups to “y” groups.

Comment [NRC82]: Clarify what kind of modifications are envisioned by this statement, providing some examples. It is not clear that such changes are always not adverse.

Comment [NRC83]: Modify this item to read “Analyses performed in the manner described in a cited topical report”.

Comment [NRC84]: Clarify what is considered to be “appropriately modeled”.

If the pertinent constraints and limitations for an MOE are not known or cannot be identified, then the modification to the element of the MOE is considered to be adverse and screens in.

If a source document identifies that a particular feature is included in an MOE, but does not describe how the feature is modeled, a modification to the specific modeling of the feature is not adverse because the modification is consistent with the terms (and level of detail) of the approved MOE. However, if a source document states that a particular feature is modeled, a modification to eliminate that feature would not be consistent with the description in the source document and would be adverse.

If an MOE contains a built-in mechanism for making modifications to the method of evaluation, then modifications to the MOE made in accordance with the built-in change mechanism are not adverse. For example, a fuel vendor may have a process for licensing a new fuel design that explicitly includes a way of determining new coefficients for the critical power correlation, based on new data. Therefore, new coefficients calculated using the new data are not changes to physical coefficients in the context of 10 CFR 72.48 (i.e., adverse) because they are developed using a previously approved mechanism for calculating the coefficients.

See Section 6.8 for guidance on completing the evaluation.

Comment [NRC85]: Justify the statements in this paragraph, particularly the first sentence. It is not clear that a lack of description of how a feature is modeled that is included in a MOE necessarily means that a change to the modeling of the feature is not adverse. This can be only determined by the change in the results.

Comment [NRC86]: Modify this sentence to clarify that it is accurate only for the condition that the data and resulting new coefficients are within the MOE's area of applicability.

5.2 IS THE ACTIVITY A TEST OR EXPERIMENT NOT DESCRIBED IN THE UFSAR?

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 (Definition 3.19) of the design for that SSC or cask or is inconsistent with analyses or descriptions 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.

Comment [NRC87]: The staff suggests this guidance be clarified by explaining why appropriate isolation of affected SSCs would mean that tests and experiments not described in the UFSAR can be screened out and not require evaluation against the 72.48 criteria.

5.3 SCREENING DOCUMENTATION

10 CFR 72.48 record-keeping 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 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 **proposed** modifications or revisions, 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 modification or revision package.

Screening 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. However, screening documentation that supports modifications to the ISFSI or cask UFSAR and the UFSAR revisions themselves should be retained in accordance with the licensee’s or CoC holder’s QA program and made available by CoC holders to general licensees. This ensures the general licensees have a current cask UFSAR document between formal updates to the UFSAR and the supporting documentation for the revisions. Screening records need not be retained for activities that were never implemented.

Comment [NRC88]: Clarify whether or not, while the screening documentation is not part of the record of changes, the changes themselves will be identified in submittals to the NRC.

6 72.48 EVALUATION

Once it has been determined that a given activity is a change, test, or experiment and 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 **the whose effects of which** 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 unless the activity is canceled, modified, or an exemption is sought. The evaluation against each criterion should be appropriately documented. Subsections 6.1 through 6.8 provide guidance for evaluating proposed activities against the eight **criteria**.

Comment [NRC89]: List here the eight 72.48 criteria as a means of introduction

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. Un-linked changes in separate documents

(e.g., different procedures) should receive separate 72.48 evaluations. For multiple changes being made to a single document, such as in a revision to the 212 Report, it is permissible to include un-linked changes within the same 72.48 evaluation document, but each change must be individually discussed in answering the evaluation questions. Multiple changes considered in the same 72.48 evaluation may result in some or all of the un-linked changes requiring prior NRC approval. Care must be taken to ensure the documentation is clear in such cases.

The effects of a proposed activity being evaluated under 10 CFR 72.48 should be assessed against each of the applicable 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 modifications proposed as compensatory measures for degraded or nonconforming conditions is provided in Section 4.9.~~

Comment [NRC90]: Delete this entire sentence as it is not relevant to the evaluation process described herein.

6.1 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 **frequency categories** for 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.

Because 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 occurrence of an accident.

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

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

The effect of a proposed activity on the frequency of an accident must be discernible 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 frequency of an accident when a 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). A proposed activity that has a negligible effect satisfies the 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). 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.

Frequencies of occurrence of natural phenomena were established as part of initial licensing for specific licensees. Frequencies of occurrence of natural phenomena were not established as part of the generic storage cask certification because no particular geographic location is considered in the generic certification. An assumed set of design

Comment [NRC91]: With regard to discussions of PRA use for 72.48 evaluations in this section, refer to the staff's comments in the 2nd interim letter, of which this document is an enclosure.

Comment [NRC92]: Cite the studies mentioned here.

criteria for natural phenomena were chosen for cask design, but the frequency of occurrence was not defined. The likelihood of natural phenomena events is necessarily site-specific. In either case, the frequency of occurrence of environmental phenomena at any particular site are not expected to change. Thus, changes in design requirements for earthquakes, tornadoes and other natural phenomena should be treated as potentially affecting the likelihood of a malfunction rather than the frequency of occurrence of an accident.

Comment [NRC93]: This text from the 2001 guidance is no longer accurate. For a few of the Central and Eastern United States (CEUS) sites, as well as for some Western United States (WUS) sites, frequencies of occurrence of earthquakes have changed.

The change in frequency of occurrence of an accident is calculated to support the evaluation of the proposed activity, and one of the following criteria are met:

- The increase in the pre-change accident or transient frequency does not exceed 10 percent.
- 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 occurrence of an accident, and prior NRC approval is required.

Comment [NRC94]: This text, which is from the 2001 guidance, appears to be duplicated from an example in the 50.59 guidance in NEI 96-07. However, it is missing the context to clarify its meaning and use here.

6.2 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 6.6.

Additionally, this text should be modified to be described as an example(s) of what, in some cases, may be appropriate criteria for determining whether the frequency of an accident is increased by more than a minimal amount. This would be consistent with the use of this same text in the NEI 96-07 guidance for 50.59 evaluations. It is not clear that the criteria are appropriate for all accidents (as the EPRI PRA and the NRC’s pilot PRA appear to indicate).

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

Direct effects are those where the proposed activity affects the SSCs. 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 discernible 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. If, for example, the change in likelihood of occurrence of a malfunction is calculated in support of the evaluation, and is less than or equal to two times, this would not exceed the “more than a minimal increase” standard and would not require prior NRC approval. (Note: The factor of two should be applied at the component level.)

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). Further, departures from the design, fabrication, construction, testing, and performance standards as outlined in the General Design Criteria (Appendix-Subpart F to Part 72) are not compatible with a “no more than minimal increase” standard.

Comment [NRC95]: Provide a reference or technical basis for the factor of two. The factor seems to be too large and inappropriate.

Comment [NRC96]: Clarify this note and provide an example of what it means by the factor should be applied only at the component level.

6.3 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; (i.e., at the ISFSI controlled area boundary). Changes in barrier performance or other outcomes of the

Comment [NRC97]: The staff suggests this guidance be clarified by providing examples to illustrate this statement either in this section or in the appendices.

Comment [NRC98]: Explain how this guidance is consistent with the NRC’s statements in the 1999 SOCs (pg. 53591, 3rd column), including addressing consequences both onsite and offsite. Also, address consideration of anticipated occurrences. The text here and the subsequent text should be modified to address these aspects of the consequences as necessary.

proposed activity that do not result in increased radiological dose to the public are addressed under Section 6.7, 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. Operation of an ISFSI, including cask loading and unloading, must not result in doses exceeding the limits of 10 CFR 20 or 10 CFR 72.104 as a result of a proposed activity. Regulatory limits can never be exceeded. Proposed activities resulting in doses exceeding regulatory limits must be canceled or revised such that the doses do not exceed regulatory limits.

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 at the ISFSI controlled area boundary that would likely result from accidents associated with the proposed activity. If a proposed activity would result in more than a minimal increase in the controlled area boundary 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 controlled area boundary dose limits for ISFSI design basis 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 and reported that value in their 212 Report, the higher cask UFSAR value would remain the value used for the purposes of the 72.48 evaluation. These dose values must be within the

Comment [NRC99]: Given the highlighted statement, the 72.48 evaluation should start with or use the same assumptions in the analysis and MOE that is in the UFSAR to make this determination. Modify the guidance to be clear regarding this point.

10 CFR 72.106 limits, as applicable. An increase in accident consequences from a proposed activity is defined to be not more than minimal if the increase is less than or equal to 10 percent of the difference between the current cask UFSAR dose value and the regulatory limit (10 CFR 72.106). The current calculated dose values are those documented in the most up-to-date UFSAR 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. 10 CFR 72.104 dose limits are not the subject of 10 CFR 72.48. Thus, 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.

In determining if there is more than a minimal increase in consequences, the first step is to determine which accidents evaluated in the UFSAR are associated with 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 offsite 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 offsite radiological consequences of any accident analysis described in the UFSAR, then either:

- (1) Demonstrate and document that the off-site 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 6.8.

Comment [NRC100]: It would seem that guidance similar to that given here for 72.48(c)(2)(iii) also applies to 72.48(c)(2)(i) and should appear in the section of the guidance that addresses 72.48(c)(2)(i).

Comment [NRC101]: No examples are provided. Revise the sentence to include references to specific examples of this evaluation criterion in the Appendices.

6.4 DOES THE ACTIVITY RESULT IN MORE THAN A MINIMAL INCREASE IN THE CONSEQUENCES OF A MALFUNCTION OF AN SSC IMPORTANT TO SAFETY?

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions evaluated in the UFSAR are associated with 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 6.3.

6.5 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 governed by the dose limits of 10 CFR 72.104, and accidents as less likely but more serious. This criterion deals with creating the possibility for accidents of similar or higher frequency and significance to those already included in the licensing basis for the ISFSI facility or dry storage cask. 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, that 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 for a particular cask or ISFSI. 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 and scenarios could already be discussed in the UFSAR.

Comment [NRC102]: The staff suggests this guidance be clarified. It is not clear why possible accidents are only considered as an accident of a different type only when they become at least as likely as accidents analyzed/assumed in the UFSAR vs. when they become credible instead of incredible (as stated in the paragraph following this one).

Comment [NRC103]: The staff suggests this guidance be clarified to include a specific example of “scenarios that have been analyzed extensively,” or provide a reference to such example(s) in the appendices.

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.

6.6 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 component or system 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 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 or dry storage cask 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.

6.7 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, the fission product barriers for a spent fuel storage cask system include the fuel cladding and the confinement boundary for the storage

Comment [NRC104]: The staff suggests clarifying the relevance of whether or not the effects results of malfunctions analyzed in the UFSAR are bounding in determining whether a malfunction with a different result has been created due to an activity/a change. The statement appears to mix 72.48 criteria (iv) and (vi) and what should be considered for each criterion. The example in Appendix A appears to, at least in part, do the same thing. This comment also applies to the last sentence of this paragraph.

Comment [NRC105]: The staff suggests this guidance be clarified. It is not clear why possible malfunctions are only considered as a malfunction with a different result only when they become at least as likely as malfunctions analyzed/assumed in the UFSAR vs. when they become credible instead of incredible.

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 may be required to preserve the assumptions of the criticality analysis and ensure sub-criticality of the stored spent fuel. Even if the cladding is not explicitly credited in the UFSAR as a confinement boundary, gross rupture of the fuel cladding is prohibited as a result of storage by 10 CFR 72.122(h)(1) and must be considered when addressing the 72.48(c)(2)(vii) criterion.

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.

6.7.1 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:

1. 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

Comment [NRC106]: This last sentence of the paragraph applies only to undamaged fuel, and the guidance needs to be revised to be clear on this point.

Additionally, the guidance in this section needs to address damaged fuel and fuel debris, since some cask design CoCs and ISFSI licenses allow for storage of such fuel (e.g., by canning it).

Comment [NRC107]: Describe how this 72.48(c)(2)(vii) evaluation process is done for damaged fuel and fuel debris, which may be allowed for storage in the cask CoC, ISFSI license or amendment.

on design bases limits for the fuel clad and the canister (e.g., clad integrity and canister pressure).

2. 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.
3. The limit is identified in the UFSAR. As required by 10 CFR 72.24(c) or 10 CFR 72.230, design basis limits ~~were~~ are 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.

Comment [NRC108]: The staff suggests the text should be written to address normal and off-normal conditions as well as accidents. The staff's edits here are for that purpose.

Consistent with the discussion of 10 CFR 72.48 applicability in Section 4.0, 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	Thermal: Maximum Fuel Cladding Temperature Maximum Fuel Cladding Thermal Cycles
		Structural: Maximum Fuel Cladding Stress Maximum deceleration or g-load
		Criticality: Maximum K-effective
Confinement boundary	Preservation of confinement boundary	Structural: Maximum Canister/Cask Design Pressure
		Stresses: Allowable values determined by Code compliance as described in the UFSAR Maximum deceleration or g-load
		Leak Rate: Maximum UFSAR-specified leak rate for the cask and/or canister

*Changes cannot cause these limits to be exceeded nor can these limits be altered without prior NRC approval.

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.

6.7.2 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.

Comment [NRC109]: The staff suggests this guidance be clarified by providing an example, such as “(e.g., temperature of barrier exceeds the temperature limit).”

Comment [NRC110]: The staff suggests this guidance be clarified by explaining how the stated example involves altering the design basis limit.

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, the response to criterion 10 CFR 72.48(c)(2)(vii) may be simply stated that no fission product boundary is affected either directly or indirectly, with appropriate justification. 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 and a design basis limit is not altered, 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.

Comment [NRC111]: Include a statement that this justification should include a list of parameters identified as being affected and a list of parameters for which limits exist and show that there is no overlap in those limits.

6.8 DOES THE ACTIVITY RESULT IN A DEPARTURE FROM A METHOD OF EVALUATION USED IN ESTABLISHING THE DESIGN BASES OR IN THE SAFETY ANALYSES?

The cask or ISFSI UFSAR contains design and licensing basis information for an ISFSI facility or spent fuel storage cask design, including descriptions of 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.

Comment [NRC112]: The staff made significant changes to the text in Sections 6.8, 6.8.2 and 6.8.2.1 to address concerns with MOE approval. Other comments that appear in these sections should also be addressed, with the text modified as needed.

Comment [NRC113]: Modify the text in the 6.8 sections discussing MOEs to address non-numeric or qualitative evaluations. MOEs are not always purely calculations/analyses. For example, while radiation protection evaluations (demonstrating dose limit compliance) include dose rate calculations, they also include evaluations of personnel actions and assumptions regarding members of the public. Such assumptions include assumed annual occupancy times at/near the controlled area boundary, location of the closest resident, and evaluations of population data in the region surrounding an ISFSI facility.

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 methods of evaluation (MOEs) described in the UFSAR may 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 an MOE 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 new or different MOEs without first obtaining a license or cask CoC amendment if those MOEs have been approved by the NRC for the intended application.

Approval "for the intended application", as stated in the 1999 NRC guidance regarding this phrase in the 10 CFR 72.48(a)(2)(ii) definition, "includes assuring that the approved method was approved for the type of analysis being conducted, generically approved for the type of facility using it, and that all terms and conditions for the use of the method are satisfied." October 4, 1999 FRN, at 53598. In reviewing a specific application regarding an ISFSI license, or dry cask storage design CoC, the NRC staff does not generically

approve MOEs described, outlined, summarized, or referenced in these applications. Such generic approval of an MOE could be requested by cask vendors or licensees seeking approval of a topical report. As stated in the 1999 NRC guidance, if the topical report “is applicable to the facility,” and the MOE “is used within the terms and conditions specified in the approved topical report,” use of such an MOE would not be a “departure” as defined in 10 CFR 72.48(a)(2), and could thus be used without obtaining a license or CoC amendment, in accordance with the 10 CFR 72.48(c)(2)(viii) criterion (October 4, 1999 FRN, at 53599). Approval of a topical report may thus constitute a generic approval of MOEs discussed in the topical report.

As indicated above, licensees and CoC holders may prepare and obtain NRC approval of topical reports. In approving topical reports, the NRC would approve the use of the MOEs for a given class of ISFSIs or spent fuel storage casks. Terms, conditions and limitations relating to the application of the MOEs would be documented in the topical reports, and in the Regulatory Guides approving the topical reports.

In submitting a request that the NRC approve a specific cask design, or the design of an ISFSI, applicants, licensees, and CoC holders often discuss one or more MOEs in the supporting SAR. The NRC staff’s approval of a specific design does not signify any generic approval of MOEs relied upon or referenced in the SAR. This reflects the fact that no two designs are identical, and the margin of safety varies from design to design. In some instances, the MOEs are not relied upon by the NRC staff, either where they are deemed to have no impact on the specific design (or design change) being reviewed, or they did not otherwise prevent the NRC from approving the specific design. In instances where the MOEs are reviewed in approving a specific design, the staff may find that the MOEs have flaws or limitations that are not identified in the SAR, but that for design-specific reasons the flaws or limitations do not prevent design approval. In such instances, the MOEs are deemed adequate to demonstrate that the specific cask or ISFSI design being reviewed meets the regulatory requirements for safe storage.

As indicated above, NRC approval of a specific analysis would typically be part of an ISFSI or cask design’s licensing basis. Such approval is limited to a given ISFSI or spent fuel storage cask design and a given application. Thus, the staff’s approval of a specific design does not also mean that the MOEs described, outlined, summarized, or referenced in the SAR are “approved for the intended application.” This type of NRC approval of MOEs is generic in that it is not limited to specific cask or ISFSI designs. Cask vendors or licensees seeking this type of generic MOE approval should submit topical reports, as discussed above. The NRC’s approval would be in the form of a Regulatory Guide that specifies the type of analysis and the type of facility or cask design for which the MOE can be used, and the other terms and conditions that must be satisfied to use the MOE. The discussion of NRC approval of a MOE in this guidance is limited to generic approvals.

If the proposed activity does not involve a change to an MOE, then the licensee’s or cask CoC holder’s (i.e., the one making the change) evaluation should reflect that the 10 CFR 72.48(c)(2)(viii) ~~evaluation should reflect that this~~ criterion is not applicable. Alternatively, if the activity involves only a change to an MOE, then licensee’s or cask CoC holder’s ~~the 10 CFR 72.48~~ evaluation should reflect that the ~~criteria~~ 10 CFR 72.48(c)(2)(i—vii) ~~criteria~~ are not applicable.

The first step in applying ~~the 10 CFR 72.48(c)(2)(viii)~~~~this~~ criterion is to identify the MOEs that are affected by the change. This is accomplished during application of the screening criteria as described in Section 5.1.5.

Next, the licensee or cask CoC holder must determine whether the change constitutes a departure from a ~~method of evaluation~~MOE 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~~MOE described, outlined, or summarized in the UFSAR and used in the safety analysis or in establishing ~~the~~ design bases:

- Changes to any element of an MOE that yield results that are not conservative or not essentially the same as the results from the analyses of record.
- Use of a new or different MOE that is not approved by NRC for the intended application.

By way of contrast, the following changes are not considered departures from a ~~method of evaluation~~MOE:

- ~~Departures from methods of evaluation~~MOEs that are not described, outlined or summarized in the UFSAR (such changes will have been screened out as discussed in Section 5.1.5);
- 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~~-MOE 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~~-MOE or ~~with another methodology previously accepted by NRC through issuance of an SER~~an MOE described in a topical report approved by the NRC.
- ~~Use of a methodology that is described in the UFSAR, but has not been specifically approved by the NRC either through a Topical Report review or through endorsement in the storage system or ISFSI SER to support a change that modifies input parameters. For example, 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."~~

Comment [NRC114]: The staff has seen statements like the following in at least one FSAR:

An analysis was performed using a method similar to the method described in Reference X.

Clarify whether such statements would be considered as being "described, outlined, or summarized in the UFSAR" as used in the context of this sentence. The scope of the guidance is not clear in cases such as the statement described above.

Subsection 6.8.1 provides guidance for making changes to one or more elements of an existing MOE. Subsection 6.8.2 provides guidance for adopting an entirely new MOE to replace an existing one.

~~It should be noted that the NRC staff, in reviewing dry cask storage designs, historically has not generically approved methodologies described or referenced in UFSARs for use by other licensees or vendors. Instead, the NRC states in its SERs, following the guidance in the Standard Review Plan, that the design has been found to be acceptable in each review discipline area. If, however, vendors or licensees choose to submit detailed methodologies to the NRC for generic review and approval as part of applications for design approval or as separate topical reports, the staff may document NRC endorsement or approval in appropriate SERs on a broader basis. Such endorsements or approval will facilitate vendors and licensees to use the 10 CFR 72.48 process that deals with approved methodologies.~~

~~It is important to note, however, that while explicit NRC approval of the MOEs may not appear in the ISFSI or cask SER, the MOEs are NRC approved for that particular cask system or ISFSI described in the CoC or license, to the extent the MOEs are used as described in UFSAR. This is because the UFSAR is the basis for the cask CoC or ISFSI license and is approved as part of the licensing process when the CoC or license is granted. Extrapolation of NRC approval of MOEs beyond the description of the methods in the UFSAR should be avoided, unless the NRC has described such extrapolation in the SER supporting that CoC or license. Departures from those UFSAR described MOEs, as defined herein, require NRC approval if those methods are used in the safety analysis or to demonstrate the cask system/ISFSI can perform its design function.~~

6.8.1 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 elements of MOEs ~~whose which yield results that~~ are “conservative” or that are ~~not important essentially the same~~ (with respect to the demonstrations of performance that the analyses provide). Changes to elements of MOEs that yield conservative results or results that are essentially the same over the entire range of use for the method would not be departures from approved MOEs.

The guidance is summarized in the following table.

Margin	Results	Prior NRC Approval
Lost	Conservative	No
Gained	Non-Conservative	Yes
~Same	Essentially The Same	No

To determine if the new results are conservative, non-conservative or essentially the same, the guidance in Sections 6.8.1.1 and 6.8.1.2 is applied.

6.8.1.1 **Conservative versus Non-conservative Results**

Gaining margin by changing one or more elements of an MOE is considered to be a non-conservative change and thus a departure from an MOE for purposes of 10 CFR 72.48. Such departures require prior NRC approval of the revised MOE. Analytical results obtained by changing any element of an MOE 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 MOE would be considered a conservative change when applying this criterion. In other words, the revised MOE 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/CoC amendment.

In contrast, if the use of a modified MOE 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.

6.8.1.2 **“Essentially the Same” Results**

Licensees or cask CoC holders may change one or more elements of an MOE such that results move slightly 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 an MOE 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 an MOE 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 MOE to the existing one, or may be apparent from the nature of the differences between the MOEs. When benchmarking a revised MOE 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, and the revised MOE should only be used where the benchmarking has demonstrated it to be conservative or essentially the same. Comparison of analysis MOEs should

Comment [NRC115]: Clarify the text in this section to state that determination of whether or not a change results in “gaining margin” (i.e., is non-conservative vs. conservative) involves benchmarking of the revised MOE, similar to what is stated in Section 6.8.1.2 below. Statements regarding benchmarking in Section 6.8.1.2 (the 2nd paragraph of Section 6.8.1.2) apply equally to Section 6.8.1.1.

Further clarify the guidance by stating that in performing benchmarking of a revised MOE accepted benchmarking practices for the technical disciplines affected by the proposed change should be followed. For example, ANSI/ANS 8.1 defines benchmarking of calculational methods, which are MOEs, for nuclear criticality safety analyses.

Comment [NRC116]: The staff suggests clarifying this guidance by specifying the type of calculation being referred to at the end of the 4th sentence “for this type of calculation.”

consider both the peak values and time behavior of results, and engineering judgment should be applied in determining whether two MOEs yield results that are essentially the same.

Comment [NRC117]: The staff suggests modifying the statement to be generically applicable to all (technical) disciplines or to explicitly state the analyses to which it applies.

6.8.2 Guidance for Changing from One Method of Evaluation to Another

The 10 CFR 72.48(a)(2) definition of “departure ...” provides licensees with the flexibility to make changes under 10 CFR 72.48 from one MOE to another provided that the new MOE is approved by the NRC for the intended application. Whether a new MOE is may be considered as approved by the NRC “for intended application” is discussed above in Section 6.8, and is further discussed below. if it is approved for the type of analysis (Definition 3.22) being conducted, and the applicable terms, conditions and limitations for its use as defined in the Safety Evaluation Report and FSAR are satisfied.

NRC approval would typically follow one of two paths. Some licensees and CoC holders may prepare and obtain NRC approval of topical reports that describe MOEs for the performance of a given type or class of analysis (Definitions 3.22 and 3.7). Through a SER, the NRC would approve the use of the MOEs for a given class of ISFSIs or spent fuel storage casks. In some cases, the NRC would accord “generic” approval of analysis MOEs. Terms, conditions and limitations relating to the application of the MOEs would usually be documented in the topical reports, the SER, and correspondence between the NRC and the MOE owner that is referenced in the SER or associated correspondence.

The second path is the approval of a specific analysis rather than a more generic MOE. 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 MOE 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 MOE owner that is referenced in the SER or associated correspondence.

Methods of evaluation, to the extent they are described in the ISFSI UFSAR or the generic cask UFSAR are approved by the NRC for use in analyzing the design described in the UFSAR, whether or not the SER states explicitly that the method of evaluation is approved. This is because the NRC approves the UFSAR without restriction when they approve the ISFSI or cask design. Furthermore, the 72.48 program is founded upon the information in the UFSAR and the MOEs described in the UFSAR are used to evaluate other changes, such as to the cask design, input parameters, or operating procedures. In this respect, a CoC holder’s UFSAR for a generic cask design would function similar to a topical report for licensees using the MOE or evaluating changes to the MOE described in the UFSAR for the cask design approved in the UFSAR. Use of an MOE for a specific cask design or ISFSI facility described in the associated UFSAR for a different cask design or ISFSI facility depends greatly on the wording of the SER. In such cases, use of an

~~MOE in which the SER does not explicitly approve or discuss the acceptability of the MOE would not be permitted.~~

It is incumbent upon the user of a new MOE - even one ~~generically~~ approved by the NRC - to ensure ~~they have~~ that it has a thorough understanding of the MOE 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 MOEs are technically appropriate ~~and approved~~ 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~~ MOE is appropriate and approved for the intended application. To obtain an adequate understanding of the MOE and basis for determining it is approved for use in the intended application, licensees or CoC holders should consult ~~any approved topical reports and any Regulatory Guides documenting the NRC's approval of the topical reports. various sources, as appropriate. These include SERs, topical reports,~~ licensee or CoC holder or vendor correspondence with the NRC, and licensee or CoC holder personnel familiar with the existing application of the MOE, ~~may also be useful sources of information.~~ If adequate information cannot be found on which to base the intended application of the MOE, the MOE should not be considered "approved by the NRC for the intended application."

When considering the application of a MOE, it is necessary to adopt the MOE in its entirety and apply it consistent with applicable terms, conditions and limitations. Mixing attributes of new and existing MOEs is considered a change to an element of an MOE and must be evaluated as such per the guidance in Section 6.8.1.

6.8.2.1 Additional Considerations for Determining if New MOEs 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 MOE is technically appropriate ~~and approved~~ 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 MOE 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)? ~~Is the application of the MOE within the terms, limits and conditions for its use, as specified in the approved topical report and Regulatory Guide?~~ Will the MOE supersede ~~a~~ MOE addressed by other regulations or the ISFSI license or cask CoC, ~~including the license or CoC~~ Technical Specifications? Is the MOE consistent with relevant industry standards?

If application of the new MOE requires exemptions from regulations or ISFSI license- or cask CoC conditions, or is not within the terms, limits or conditions of the new MOE's use, then prior NRC approval would be required. ~~If application of the new MOE requires 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 MOE.

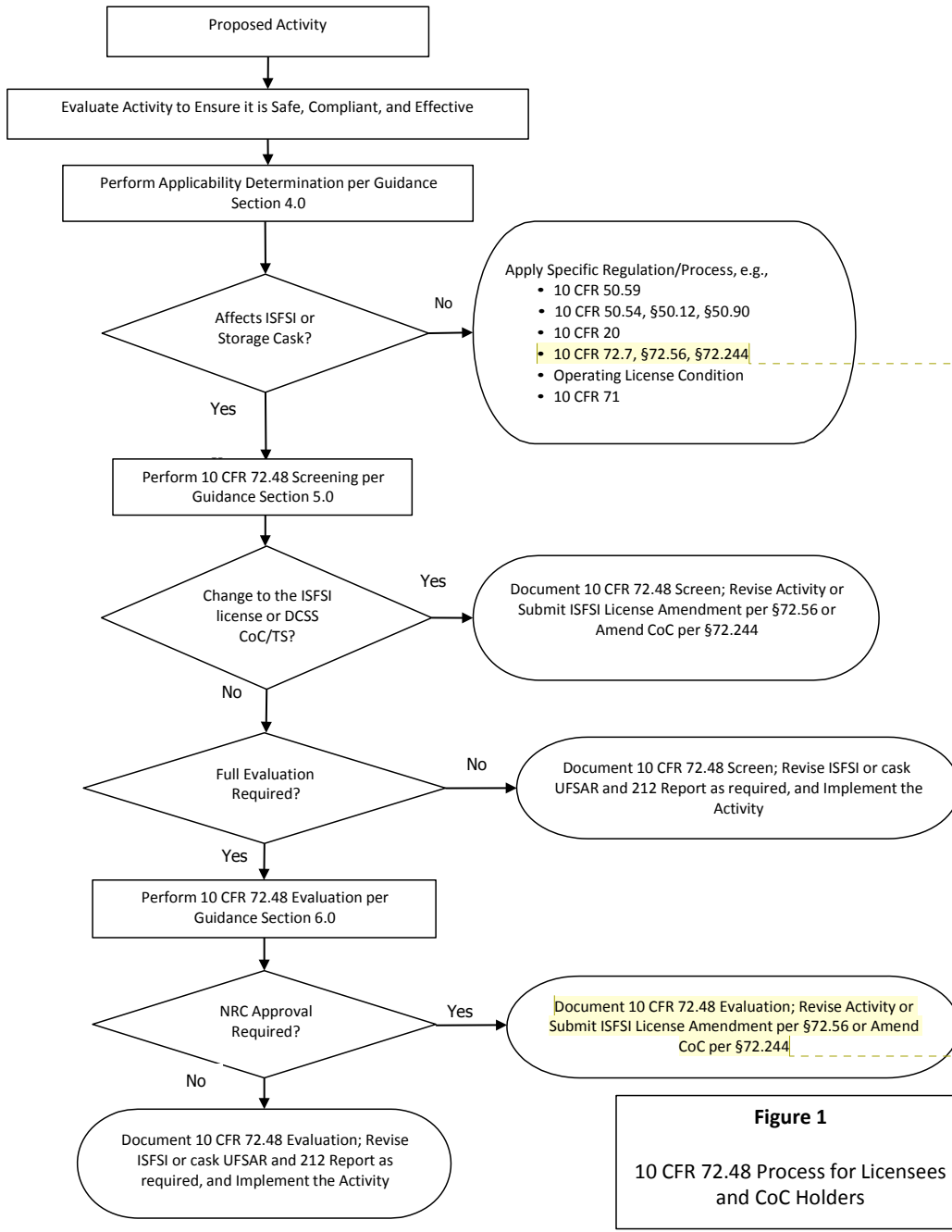
- If a computer code is involved, has the code been installed in accordance with applicable software Quality Assurance requirements? Has the ISFSI- or cask design-specific model been adequately qualified through benchmark comparisons against test data, empirical data, or approved engineering analyses? 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 MOE has been approved designed and operated in the same manner as the ISFSI facility or cask design to which the MOE 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 MOE:~~
 - ~~— How could those differences affect the MOE?~~
 - ~~— 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 MOE?~~
- ~~Differences in the~~The evolution of ISFSI or cask design configurations and licensing bases over time could create differences that invalidate the application of a particular MOE. 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 are included in a particular MOE that was developed to be consistent with those in the licensing basis for more recent vintage cask designs. The existence of these differences does not necessarily preclude application of a new MOE to an ISFSI facility or cask design; however, differences must be identified and understood, and the basis documented for concluding that the terms, limits and conditions for use of the new MOE are satisfied, and that application of the new MOE is technically appropriate despite these differences. ~~are not relevant to determining that the new application is technically appropriate.~~

7 FIGURES

1. Figure 1: 10 CFR 72.48 Process
2. Figure 2: General or Specific Licensee 60-Day reports to CoC Holder
3. Figure 3: CoC Holder 60-Day Reports to Licensees



Comment [NRC118]: Delete the bullet showing 72.7, 72.56, and 72.244 in the bubble next to the first/top decision diamond in Figure 1. If the proposed change does not affect the ISFSI/cask, it is not clear why any of these procedures would be applied.

Comment [NRC119]: Add 72.7 to this bubble and in the bubble next to the 'Change to the ISFSI license...' decision diamond. The 72.7 process could be applicable to the 'yes' situation for these two decision diamonds.

Figure 1
10 CFR 72.48 Process for Licensees and CoC Holders

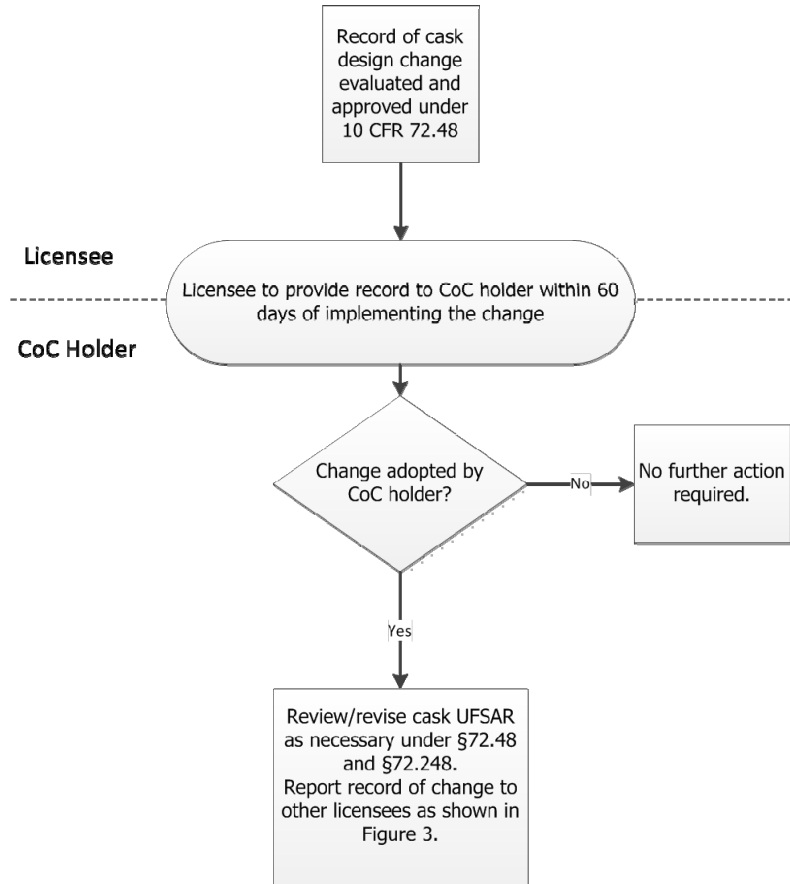
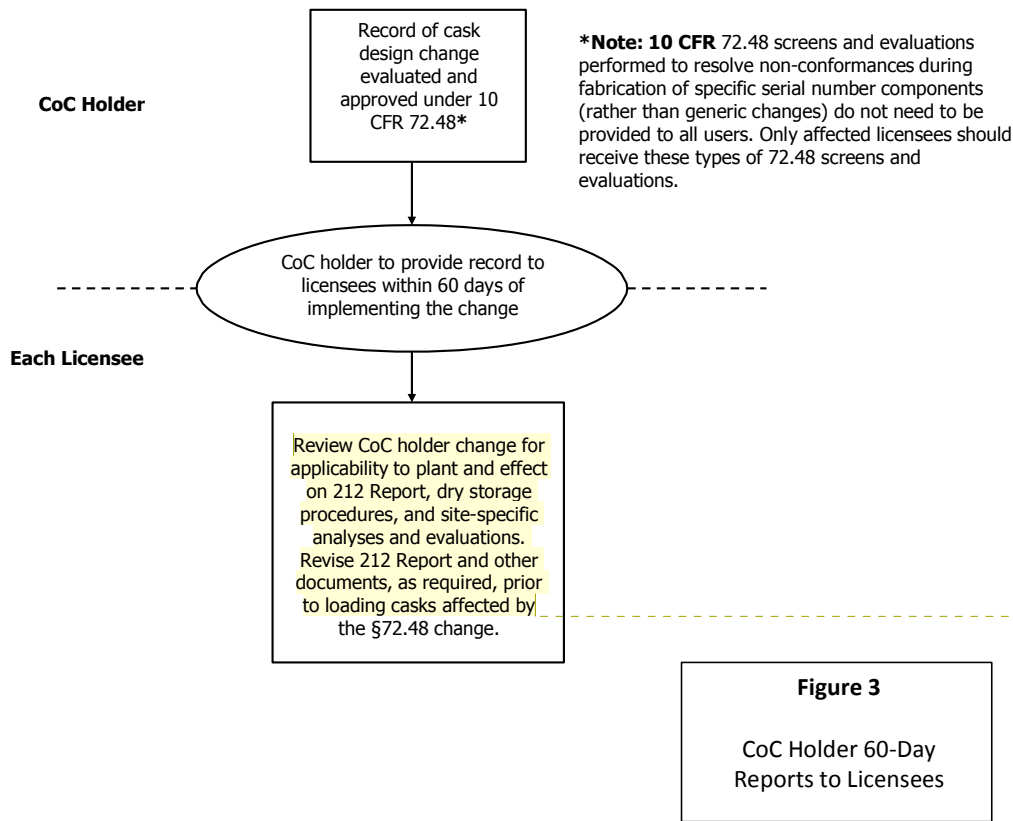


Figure 2
General or Specific Licensee
60-Day Reports to CoC Holder



Comment [NRC120]: Is it not clear that licensees need to adopt changes made by CoC holders. Also, general licensees must evaluate modifications to their 72.212 Reports, etc. per 72.48. Figure 3 should be consistent with these two points.

Suggest replacing this box and its text with something like the figure inserted below/on the following page.

