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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# ACKNOWLEDGEMENTS

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

# 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

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

Analyses in the UFSAR also demonstrate that offsite doses during normal operations and anticipated occurrences will not exceed the limits of 10 CFR 72.104. In addition, the confinement barriers and systems must meet the criteria established in 10 CFR 72.122(h) for specific and general licensees, and 10 CFR 72.236 for CoC holders. Thus, the UFSAR analyses provide the final verification of the nuclear safety design phase by documenting ISFSI facility and/or spent fuel storage cask performance in terms of public protection from uncontrolled releases of radiation. 10 CFR 72.48 addresses this aspect of design by requiring prior NRC approval of proposed activities which, although safe, require a change to the specific license, CoC, or technical specifications, or meet specific threshold criteria for NRC review.

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

- UFSAR accidents and malfunctions are analyzed in terms of their effect on the physical barriers. There is a relationship between barrier integrity and dose.

- The principal "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.

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.

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 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.

As discussed in Section 5.0, licensees may elect to use screening criteria to determine for which activities a full 10 CFR 72.48 evaluations 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.

### 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).

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 CoC holders 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.

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

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 §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 ISFSI facility and cask design 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 ensures 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.

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

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 CFR72.48 evaluation. Engineering and technical information concerning a proposed activity may be used along with other information as basis for determining if the activity screens out or requires a 10 CFR 72.48 evaluation.

Further discussion and guidance on screening is provided in Section 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**:

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 events for which the ISFSI facility or cask design is required to cope and which are described in the UFSAR (e.g., tornado missiles, fire, earthquakes and flooding).

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

### 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 and removals to the ISFSI facility or spent fuel storage cask design or procedures can adversely impact the performance of SSCs and the bases for the acceptability of their design and operation. Thus, the definition of change includes

modifications of an existing provision (e.g., SSC design requirement, analysis method or parameter), additions or removals (physical removals, abandonment, or non-reliance on a system to meet a requirement) to the ISFSI facility or spent fuel storage cask design or procedures.

The definitions of "change…," "facility or spent fuel storage cask design…," (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 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). 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.

## 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.

**Conservative vs. Non-Conservative Evaluation Results**

Gaining margin by revising an element of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR 72.48. Such departures require prior NRC approval of the revised method. In other words, analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines).

For example, a change in an element of a method of evaluation that changes the result of a cask peak pressure analysis from 45 psig to 48 psig (with design basis limit of 50 psig) would be considered a conservative change for purposes of 10 CFR 72.48(c)(2)(viii). This is because results closer to limiting values are considered conservative in the sense

that the new analysis result provides less margin to applicable limits for making future physical or procedure changes without a license 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."

**"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 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 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:**

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 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 (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.

## 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 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.

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.

## 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

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).

### 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.

### 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.

| **Elements of Methodology** | **Example** |
|---|---|
| Data correlations | • Tipover and end drop analysis based on industry-referenced reports |
| Means of data reduction | • ASME methods for evaluating cask parameters, e.g., elastic stress intensity |
| Physical constants or coefficients | • Heat transfer coefficients, boundary conditions, burnup peaking factors, and cross-section libraries<br>• Friction coefficient in a tipover analysis |
| Mathematical models | • Methods of heat transfer assumed (i.e., conduction, convection, and radiation), mesh size, material performance – elastic or plastic |
| Specific limitations of a computer program | • Benchmarking and correlation ranges |
| Specified factors to account for uncertainty in measurements or data | • Criticality calculation biases, fuel burnup, percent fuel burnup uncertainty |
| Statistical treatment of results | • 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 | • ICRP factors |

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

- Methods of evaluation used in analyses that demonstrate that design basis limits of fission product barriers are met (i.e., for the parameters subject to criterion 10 CFR 72.48(c)(2)(vii)).

- Methods of evaluation used in UFSAR safety analyses, including cask and accident analyses typically presented in the accident analyses section(s) of the UFSAR, to demonstrate that consequences of accidents do not exceed 10 CFR 72.106 dose limits.

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

- Methods of evaluation used in UFSAR analyses that demonstrate that radioactive doses from normal operations and anticipated occurrences will be within the limits of 10 CFR 72.104.

- 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).

**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:

(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.

## 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 that put the ISFSI facility or cask design in a situation that has not previously been evaluated (e.g., unanalyzed storage conditions) or that could affect the capability of SSCs to perform their intended design functions (e.g., high stresses, high temperatures) are evaluated before they are conducted to determine if prior NRC approval is required.

### 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.

## 4 APPLICABILITY OF DETERMINATION

ISFSI licensees and CoC holders must determine the applicability of 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 involve a modification to the ISFSI, cask design or procedure 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 "yes" for all, or part(s) of a proposed activity, 10 CFR 72.48 is not applicable to the activity or applicable part(s) thereof, and the activity or applicable part(s) thereof may 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 part(s) thereof 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 require a change to the ISFSI license or cask CoC, including appendices?

   If the answer to the above question "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 part(s) thereof, 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 part(s) thereof not requiring an ISFSI license or CoC amendment.

3. Does a different regulation provide more specific criteria for accomplishing the proposed activity?

If the answer to the above question "yes" for all, or part(s) of a proposed activity, the other regulatory process should be applied prior to implementing the activity or applicable part(s) thereof. 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 part(s) thereof not subject to a different regulatory process 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.

## 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, 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, 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 of another regulation. The set of "other more specific requirements and criteria established

by regulation" to be addressed in the AD differ among specific 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), 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.

## 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 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.

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.

## 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 the meaning or substance of information presented

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

## 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.

## 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.

## 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:

> "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 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 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.

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 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 or may be an administrative/editorial correction. If the activity does not affect the ISFSI or storage cask, 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, 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 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, 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, cask design, or procedures described in the UFSAR. In considering whether a temporary modification impacts other aspects of the ISFSI facility or cask design, a licensee or cask CoC holder should pay particular attention to ancillary aspects of the temporary 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, cask design, or procedures, 10 CFR 72.48 should be applied to the corrective action, unless another regulation applies. In these cases, the final corrective action becomes the proposed 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 or cask design,

- A change to a UFSAR-described method of performing or controlling a design function,

- 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, 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.

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.

## 5.1 IS THE ACTIVITY A CHANGE TO THE ISFSI FACILITY, 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 characteristics of the SSC or cask?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system interaction?
- Does the activity adversely affect the ability or response time to perform required actions, e.g., alter equipment access or add steps necessary for performing tasks?
- Does the activity degrade the seismic, structural, heat removal, shielding, or criticality control capability 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?

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, cask design, or procedures. Additions should be screened for their effects on the existing facility, cask design, and procedures as described in the UFSAR and, if required, a 10 CFR 72.48 evaluation should be performed. NEI 98-03 can provide guidance for determining whether additions to the ISFSI facility and procedures should be reflected in the UFSAR per 10 CFR 72.70 (specific licensee) or 72.248 (cask CoC holder).

Consistent with historical practice, 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

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 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 evaluation that demonstrates that intended design functions will be accomplished, is a change and is screened in. The magnitude of the adverse effect (i.e., is the minimal increase standard met?) is the focus of the 10 CFR 72.48 evaluation process.

Screening determinations are made based on the engineering/technical information supporting the 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 due to a proposed activity affecting the facility, a procedure or an evaluation is provided in subsections 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.).

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 equipment is required to function is 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 such codes and standards 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 SSCs 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.

### 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

**Step 4 -** 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 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.*
>
> - *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.

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.

Criteria 1 through 7 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 CFR72.48(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.*

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."

**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***

***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

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.

#### 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.

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 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.

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 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.

## 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 inconsistent with analyses or description in the UFSAR.

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

## 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 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.

# 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 whose effects are not bounded by previous analyses.

Criteria (c)(2)(i—vii) are applicable to activities other than changes in methods of evaluation. Criterion (c)(2)(viii) is applicable to changes in methods of evaluation. Each activity must be evaluated against each applicable criterion. If any of the criteria are met, a specific licensee must apply for and obtain a license amendment per 10 CFR 72.56, and a CoC holder must apply for and obtain a CoC amendment per 10 CFR 72.244 (for itself or for a general licensee) before implementing the activity 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.

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.

### 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 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, 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

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.

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.

## 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.

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 F to Part 72) are not compatible with a "no more than minimal increase" standard.

## 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

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 exceed 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

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.

### 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 frequency and significance to those already included in the licensing basis for the ISFSI facility. Thus, accidents that would require multiple independent failures or other circumstances in order to "be created" would not meet this criterion.

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

The possible accidents of a different type are limited to those that are as likely to happen as those previously evaluated in the UFSAR. The accident must be credible in the sense of having been created within the range of assumptions previously considered in the licensing basis. A new initiator of an accident previously evaluated in the UFSAR is not a different type of accident. Such a change or activity, however, 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. However, if a change or activity is proposed such that a scenario becomes credible, the change or activity could create the possibility of an accident of a different type. In some instances these example accidents could already be discussed in the UFSAR.

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

### 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 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

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

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 presented in the original FSAR and continue to reside in the UFSAR. They may be located in a vendor topical report that is incorporated by reference in the UFSAR.

Consistent with the discussion of 10 CFR 72.48 applicability in Section 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:**<br>Maximum Fuel Cladding Temperature<br>Maximum Fuel Cladding Thermal Cycles |
| | | **Structural:**<br>Maximum Fuel Cladding Stress<br>Maximum deceleration or g-load |
| | | **Criticality:**<br>Maximum K-effective |
| Confinement boundary | Preservation of confinement boundary | **Structural:**<br>Maximum Canister/Cask Design Pressure |
| | | **Stresses:**<br>Allowable values determined by Code compliance as described in the UFSAR<br>Maximum deceleration or g-load |
| | | **Leak Rate:**<br>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.

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, 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.

## 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.

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.

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

The first step in applying this criterion is to identify the 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 that would require prior NRC approval. As discussed further below, for purposes of evaluations under this criterion, the following changes are considered a departure from a method of evaluation described, outlined, or summarized in the UFSAR and used in the safety analysis or establish 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:

- Departures from methods of evaluation 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 revision that is documented as providing results that are essentially the same as or more conservative than either the previous revision of the same methodology or with another methodology previously accepted by NRC through issuance of an SER.

- Use of a methodology 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."

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 results are "conservative" or that are not important 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

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.

### 6.8.2 Guidance for Changing from One Method of Evaluation to Another

The definition of "departure …" provides licensees with the flexibility to make changes under 10 CFR 72.48 from one MOE to another provided that the new MOE is approved by the NRC for the intended application. A new MOE is approved by the NRC for intended application 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 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 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 an 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 various sources, as appropriate. These include SERs, topical reports, licensee correspondence with the NRC and licensee or CoC holder personnel familiar with the existing application of the MOE. 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 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 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)? Will the MOE supersede an MOE addressed by other regulations or the ISFSI or cask Technical Specifications? Is the MOE consistent with relevant industry standards?

  If application of the new MOE requires exemptions from regulations or ISFSI- or cask-specific commitments, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with an ISFSI facility's or cask's licensing basis, then prior NRC approval may be required. The applicable change process must be followed to make the ISFSI facility's or cask's licensing basis consistent with the requirements of the new 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 ISFSI or cask design configurations and licensing bases could 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 those in the licensing basis for more recent vintage cask designs. The existence of these differences does not preclude application of a new MOE to an ISFSI facility or cask design; however, differences must be identified, understood and the basis documented for concluding that the differences are not relevant to determining that the new application is technically appropriate.

# 7 FIGURES

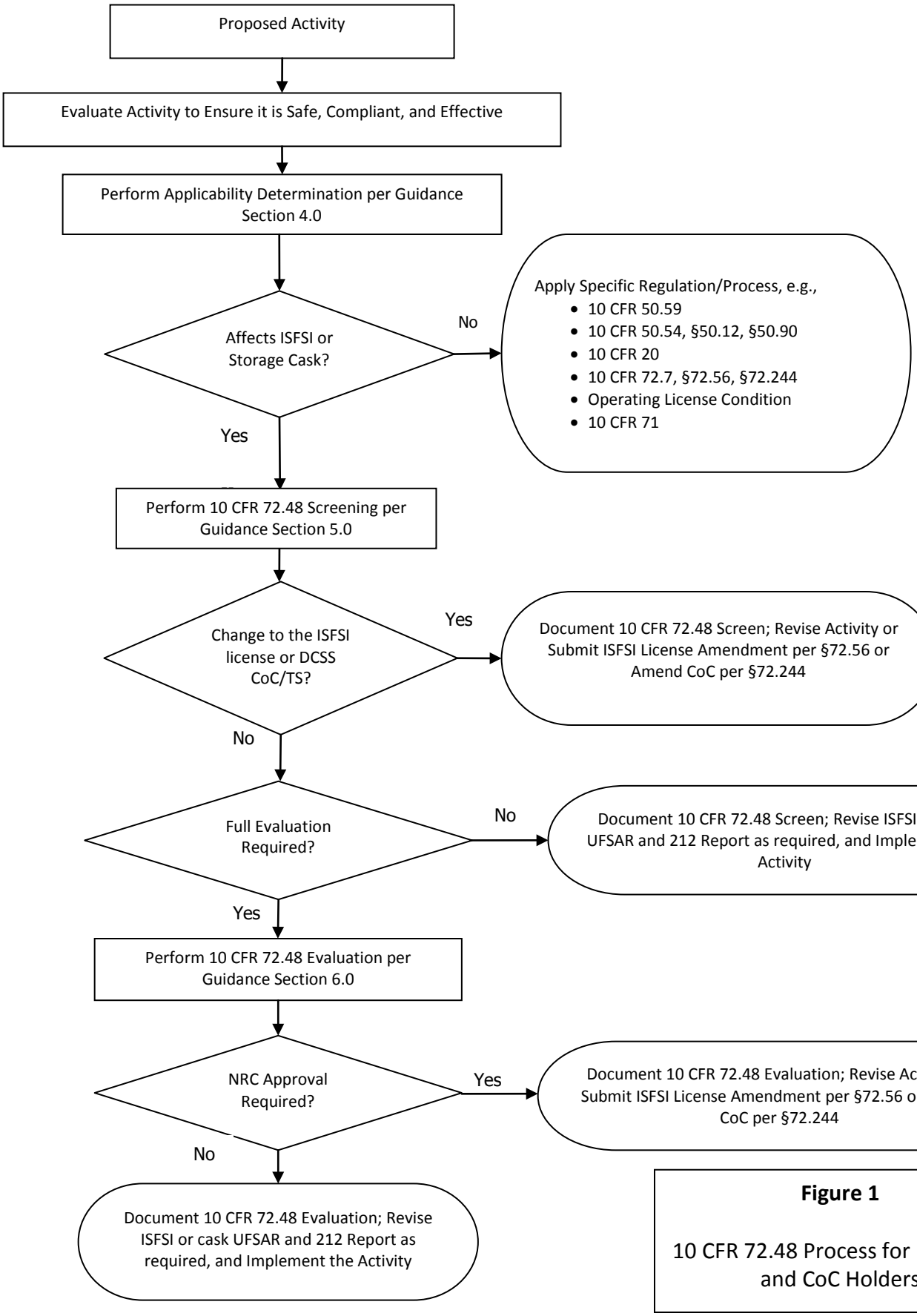



**Figure 1**

10 CFR 72.48 Process for Licensees and CoC Holders

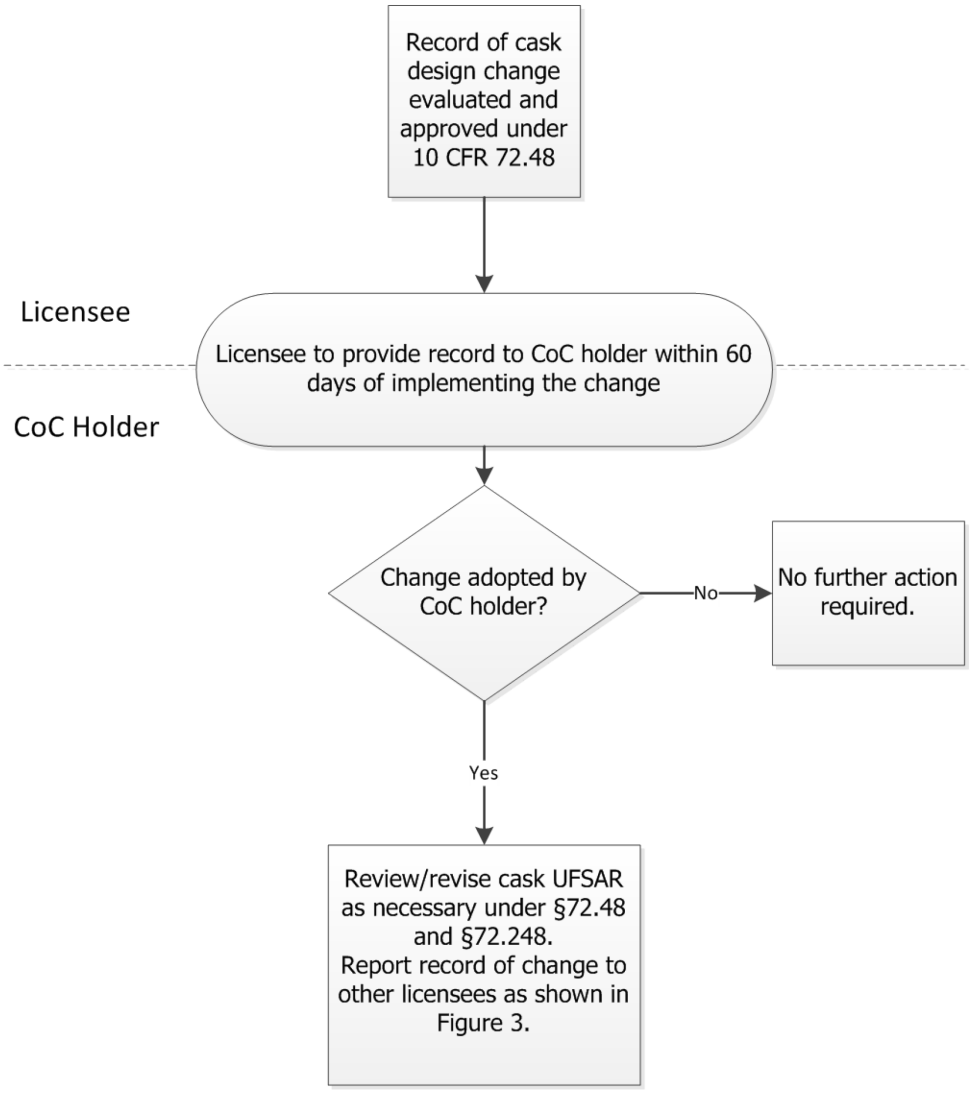



**Figure 2**
General or Specific Licensee
60-Day Reports to CoC Holder

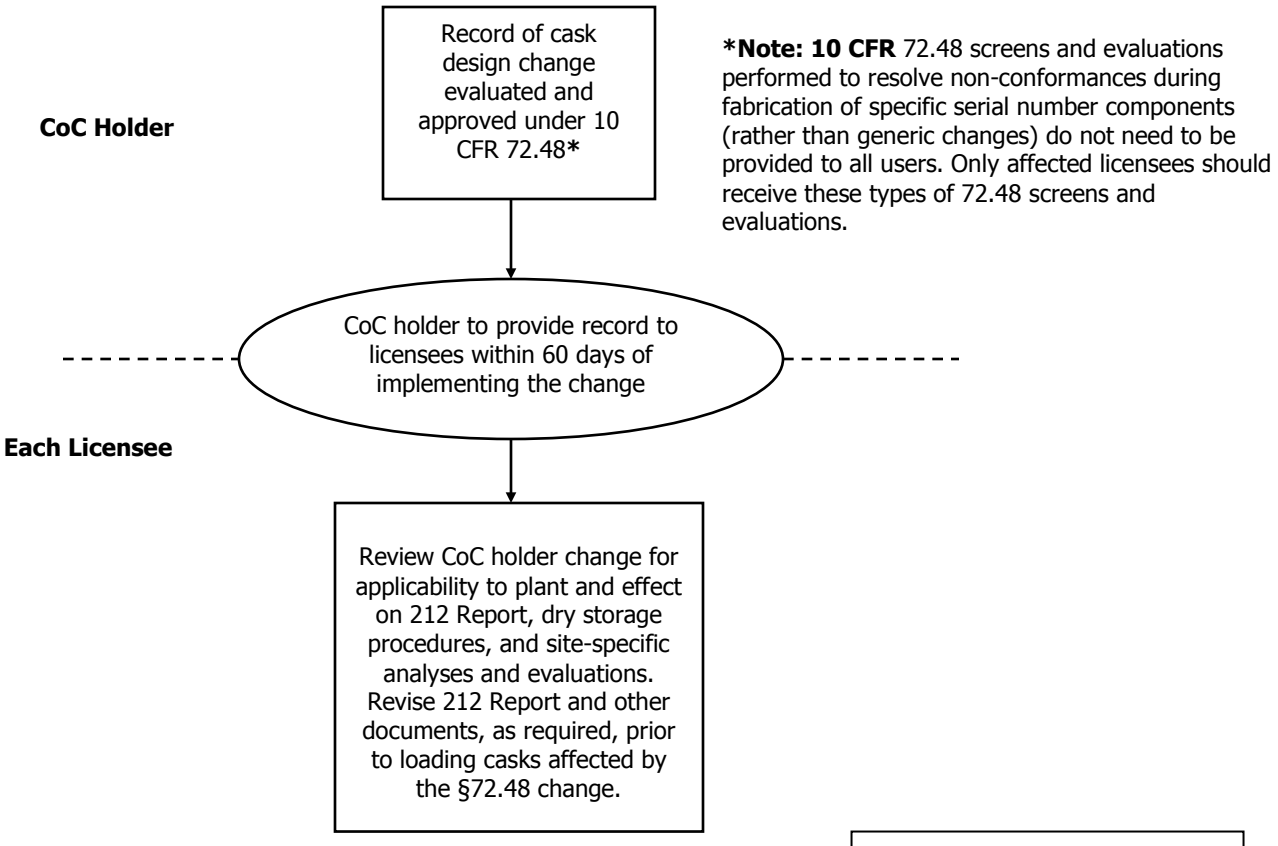



**Figure 3**

CoC Holder 60-Day Reports to Licensees

# APPENDIX A – EXAMPLES FOR INDIVIDUAL GUIDANCE SUBSECTIONS

## EXAMPLES OF PROCESSING OF COC HOLDER AND LICENSEE-INITIATED ACTIVITIES (NEI 2.1.5.1 AND 2.1.5.3)[1]

The examples below demonstrate three different types of interaction between general licensees and CoC holders related to 72.48 activities implemented by the either the CoC holder or the licensee.

**Example 1**

The CoC holder makes a modification to reduce the thickness of the neutron absorber in the spent fuel canister basket. The areal density of the Boron-10 in the neutron absorber is not altered and the CoC is not affected. Canister drawings and the cask UFSAR text are revised to reflect the modification. All canisters fabricated after the date of implementation will contain the thinner neutron absorber. General licensees using that cask system review this modification against their 72.212 Report for impact. Those general licensees that will use the modified canisters and have determined that there is no impact on their 212 Report or procedures have no further action. No 72.48 screening or evaluation is required by the licensee. Those that determine a revision to the 212 Report is required will process that revision and perform any reviews under 72.48 that the process determines are necessary.

**Example 2**

The CoC holder makes a modification under 72.48 that reduces the outer diameter of the storage cask and reduces the thickness of the concrete between the stored fuel and the environment. This reduced concrete thickness decreases the weight of the cask and slightly increases the direct radiation dose from the side of the cask. Those general licensees that intend to use the modified casks determine that there is an impact on their 212 Report in the sections describing the ISFSI pad design and the dose analysis performed to demonstrate compliance with 10 CFR 72.104. These general licensees must evaluate the modification to the 212 Report under 10 CFR 72.48. The licensee's 72.48 screening/evaluation focuses solely on the impact on the 212 Report and supporting evaluations. It does not repeat the generic 72.48 screening or evaluation performed by the CoC holder (the design authority) to determine if prior NRC review is required based on the impact of the modification on the generic cask UFSAR.

**Example 3**

The cask UFSAR operating procedures require the installation of a specific type of temporary shielding on the top of the canister and above the canister-to-transfer cask annulus during canister welding activities. A general licensee has devised an alternate

[1] Refers to NEI 12-04 throughout this appendix.

approach of providing the necessary shielding by attaching the shielding to the bottom of the automatic welding machine. The general licensee must review the modification to the cask loading procedures and 212 Report, if affected, under 10 CFR 72.48 and identify this deviation from the cask UFSAR operating procedures in the 72.212 Report. Site-specific deviations from the cask UFSAR are controlled by the general licensee in any manner that ensures retrievability and availability of the deviations to any person implementing cask UFSAR modifications or deviations pertaining to that ISFSI in the future.

## EXAMPLES OF OTHER REGULATORY PROCESSES (NEI 2.2.1)

### Example 1

A modification to an ISFSI facility or cask design involves revising how the transfer of a loaded spent fuel storage cask from the power plant to the ISFSI will be performed. The modification affects how the transfer is described in the UFSAR, and also affects a specific transfer requirement contained in the cask technical specifications. Thus, a license/CoC amendment to revise the technical specifications under 10 CFR 72.56 (specific licensee) or 72.244 (cask CoC) would be required to implement the revised transfer requirements that are in the technical specifications. 10 CFR 72.48 should be applied to the balance of the modification.

### Example 2

A cask loading procedure section governing an activity taking place in the reactor fuel handling building is proposed to be modified. This activity could require a licensee to apply both 72.48 and another regulation when proposed activities could affect both the 10 CFR Part 50 reactor facility described in the reactor UFSAR and the 10 CFR Part 72 ISFSI facility or cask design described in the ISFSI/cask UFSAR. Another example could be a modification to the cask handling crane. In this case, both a 50.59 and 72.48 screening/evaluation may need to be performed.

### Example 3

A CoC holder modifies a dual-purpose canister design feature that appears on the Part 72 licensing drawings in the cask UFSAR and the canister drawings incorporated by reference into the Part 71 CoC. The CoC holder would need to review the Part 72 modification pursuant to 10 CFR 72.48 and amend the Part 71 CoC to adopt the design as depicted in the later drawing revision.

## EXAMPLE OF A NUMERICAL VALUE AS A DESIGN FUNCTION (NEI 3.10)

### Example

The shielding analysis for a storage cask or module takes credit for specific thicknesses of steel, concrete, lead, etc. to provide gamma and neutron shielding. These thicknesses

are credited in the shielding analysis to provide a certain reduction in dose rate for a particular source term for the fuel inside the storage canister. This credit is taken for both normal and accident dose analyses. These numerical values therefore, have a design function.

## EXAMPLE OF SINGLE AND MULTIPLE APPLICABILITY DETERMINATION PORTALS (NEI 4.8)

### Example

A proposed activity involves a modification to the configuration and power supply for the plant security system as described in the security plan. Using the single portal Applicability Determination (AD) model, the activity owner uses the 50.59 AD process to choose the correct regulatory review process(es) for the proposed activity. In this case, 10 CFR 50.54(p) would likely apply and other processes, such as 10 CFR 50.59 and 10 CFR 72.48 may also apply. The activity owner is directed to the procedure or guidance for the applicable review process(es) by the questions on the 50.59 AD form.

In the multiple portal AD model, the 10 CFR 50.54(p) review process might be the primary regulatory review process and would include checks of other review processes, such as 10 CFR 50.59 and 10 CFR 72.48, for applicability. The reviewer is directed to the procedure or guidance for the other applicable review process(es) by the questions on the 50.54(p) AD form, or whichever form has been chosen for use.

## EXAMPLES OF 72.48 APPLICABILITY TO COMPENSATORY ACTIONS FOR DEGRADED CONDITIONS (NEI 4.9)

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

### Example 1

In reviewing cask documentation, a licensee discovers that a loaded cask does not meet the drop analysis and is outside the analyzed space for cask transfer activities. The licensee will perform an alternative analysis (using NRC Inspection Manual Part 9900, Section C.4 guidance) in a timely manner to establish operability/functionality (as appropriate) and leave the cask in place until the new analysis is completed. The degraded condition would not be subject to 10 CFR 72.48 because the licensee would document the degraded condition in their corrective action program.

### Example 2

While digging a trench outside of the ISFSI, a licensee accidentally cuts some cask temperature monitoring wires. An interim compensatory measure is implemented to connect a temporary temperature monitoring instrument. The cut wires will be repaired in a timely manner. This degraded condition of cut wires would not be subject to 10 CFR

72.48. The compensatory measure to connect the temporary instrument under a temporary modification would be subject to 10 CFR 72.48 to determine if it has any impact on other aspects of the ISFSI facility or cask.

**Example 3**

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

## EXAMPLES OF SCREENING MODIFICATIONS TO THE ISFSI FACILITY OR CASK DESIGN (NEI 5.1.1, 5.1.2, AND 5.1.3)

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

**Example 1**

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

**Example 2**

The bolts for retaining the outside lid of the outer concrete cask are being replaced with bolts of a different material with similar properties including load capacity and strength and with no other design function affected such that the lid will still be secured with the same strength as before the modification. Because the replacement bolts are equivalent in function to the original bolts and the outer lid of the concrete cask continues to meet the same functional requirements, this activity may be screened out as an equivalent modification. If the replacement bolts have a reduced load capacity or strength, the activity would screen in and would require a full 10 CFR 72.48 evaluation.

**Example 3**

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

**Example 4**

A licensee plans to place a motor vehicle fuel storage tank in close proximity to the cask transfer route from the fuel building to the ISFSI. A 72.48 screening identifies that a fire or explosion of the tank adversely impacts the UFSAR-described design capability of a cask to withstand a fire or explosion. The screening would conclude that a 72.48 evaluation of the modification is needed. Alternatively, if the screening identifies that the tank would be far enough away from the cask transfer route that the cask could not be affected by a tank fire or explosion or remains bounded by the cask UFSAR analysis, the screening would conclude that no 72.48 evaluation is needed.

## EXAMPLES OF SCREENING FOR MODIFICATIONS TO PROCEDURES (NEI 5.1.1, 5.1.2, AND 5.1.4)

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

**Example 1**

Operating procedures include operator actions for transport and placement of the filled cask, which are described in the UFSAR, but also address operator actions for maintenance of the transport equipment that are outside the cask and ISFSI design basis and not described in the UFSAR. A procedure modification would screen out at this step if the modification was to those procedures or parts of procedures dealing with maintenance of the transport equipment.

**Example 2**

If the UFSAR description of the cask loading procedure contains eight fundamental sequences, the licensee's or CoC holder's decision to eliminate one of the sequences would screen in. On the other hand, if the licensee or CoC holder consolidated the eight fundamental sequences and did not affect the method of controlling or performing cask loading, the modification would screen out.

**Example 3**

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

### EXAMPLES OF SCREENING FOR METHOD OF EVALUATION (NEI 5.1.1, 5.1.2, AND 5.1.5)

The following example illustrates the screening of a proposed alteration to a method of evaluation (MOE):

**Example**

The UFSAR identifies the name and version of the computer code used for performing cask confinement performance analyses, with no further discussion of the methods employed within the code for performing those analyses. Alterations to the computer code may be screened out provided that the alterations are within the constraints and limitations identified in the associated topical report and SER. An alteration that goes beyond restrictions on the use of the method is a change to an element of the method of evaluation and must be evaluated under 10 CFR 72.48(c)(2)(viii) to determine if prior NRC approval is required.

### EXAMPLES OF SCREENING FOR TESTS AND EXPERIMENTS (NEI 5.2)

Examples of proposed activities that would screen in as tests and experiments at this step (assuming they were not described in the UFSAR) are:

- Testing the heat transfer capabilities of a loaded spent fuel storage cask by blocking the air vents.
- Drawing gas from a loaded canister by penetrating the canister after it has been sealed.
- Testing a pressure switch on a loaded cask by raising the internal pressure beyond that described in the UFSAR

Examples of proposed activities that would “screen out” would be:

- Performing a radiography check of a concrete overpack prior to loading spent fuel.
- Information gathering that is nonintrusive to the operation or design function of the associated SSC.

## EXAMPLES OF RESPONSES TO 72.48 EVALUATION QUESTION 1 (NEI 6.1)

### Example 1

The proposed activity has a negligible effect on the frequency of occurrence of an accident. A negligible effect on the frequency of occurrence of an accident exists when the increase in frequency is so small or the uncertainties in determining whether an increase in frequency has occurred are such that it cannot be reasonably concluded that the frequency has actually increased (i.e., there is no clear trend toward increasing the frequency).

### Example 2

The proposed activity meets applicable NRC requirements as well as the design, material, and construction standards applicable to the SSC being modified. If the proposed activity would not meet applicable requirements and standards, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.

### Example 3

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

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

### Example 4

A modification in cask operating procedures results in a situation where the case would tip over during a seismic event (i.e., the cask center-of-gravity moves over the location of the bottom edge of the cask). The cask is designed for a non-mechanistic tipover event. However, the seismic analysis of the new operating configuration has changed the tipover event from a non-mechanistic event to an event than can now occur at this site. Therefore, this modification of the operating procedures changes the frequency category of the tipover accident event to a more frequent category. The increase in the frequency of occurrence of this accident is more than minimal, and requires prior NRC approval.

## EXAMPLES OF RESPONSES TO 72.48 EVALUATION QUESTION 2 (NEI 6.2)

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

**Example 1**

The modification involves installing additional equipment or devices (e.g., cabling, manual valves, protective features, etc.) provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met.

**Example 2**

The modification involves substitution of one type of component for another of similar function, provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met and any new failure modes are bounded by the existing analysis.

**Example 3**

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

**Example 4**

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

- The action (including required completion time) is reflected in procedures and training programs
- The licensee has demonstrated that the action can be completed in the time required considering the aggregate affects, such as workload or environmental conditions, expected to exist when the action is required
- The evaluation of the modification considers the ability to recover from credible errors in performance of manual actions and the expected time required to make such a recovery
- The evaluation considers the effect of the modification on ISFSI and cask design functions

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

**Example 5**

The modification would cause design stresses to exceed their code allowables or other applicable stress or deformation limit (if any), including vendor-specified stress limits.

**Example 6**

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

**Example 7**

The modification in likelihood of occurrence of a malfunction is calculated in support of the evaluation and increases by more than a factor of two. Note: The factor of two should be applied at the component level. Certain activities that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval, e.g., exceed the minimal increase standard for accident frequency under criterion 10 CFR 72.48(c)(2)(i).

## EXAMPLES OF RESPONSES TO 72.48 EVALUATION QUESTION 3 (NEI 6.3)

**Example 1**

A cask CoC holder has prepared a calculation showing that the ISFSI controlled area boundary may be defined at a point closer to the ISFSI than currently described in the UFSAR, and the ISFSI would still meet the 10 CFR 72.106 accident dose limits and all other regulatory requirements, including 10 CFR 72.104 limits. The new calculated offsite accident dose would be 1.1 rem. The current calculated accident dose described in the UFSAR is 1.0 rem, and the 10 CFR 72.106 limit is 5 rem. Since 10% of the difference between the UFSAR calculated dose (1.0 rem) and the regulatory limit (5.0 rem) is 0.4 rem, the increase of 0.1 rem to 1.1 rem would be less than a minimal increase in consequences (less than 10% of the difference between 1.0 rem and 5.0 rem), and prior NRC approval is not required. If the new calculated dose was 1.4 rem or higher, the change would be more than a minimal increase (more than 10% of the difference between the UFSAR value and the regulatory limit) and would require prior NRC approval. In either case, once the change is made, the new value would become the bounding value for the next 72.48 evaluation and would be put in the UFSAR at the next update.

If this change were to be made by a general ISFSI licensee on a site-specific basis, the record of the 72.48 evaluation containing the updated calculated offsite dose value would be retained and the revised value used as the bounding value for the next 72.48 evaluation. If prior NRC approval is required under 72.48, the general licensee could either request that the CoC holder for their cask system submit a CoC amendment request to the NRC under 10 CFR 72.244, if appropriate, or could submit, under 10 CFR 72.7, a request for an exemption to the 72.48(c)(2) requirement that a general licensee shall request that the CoC holder obtain a CoC amendment. An exemption request should describe the proposed change and include justification for why the CoC holder is not requesting a CoC amendment for the change, and justification for the change itself.

**Example 2**

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

The licensee wishes to improve the constructability of the concrete storage module by removing the “dog leg” from the pathway of the outlet vents through the concrete, and instead, use a straight-line path. The change results in a negligible increase in dose rates during normal operation. However, in the accident scenario with the loss of the shield block, it is found that the offsite dose consequences would be 200 mrem TEDE, or an increase of 170 mrem.

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

**Example 3**

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

The direct effects of a decrease in effective lead thickness would be reviewed to identify potentially affected design basis parameters. In addition, the indirect effect of increased dose rates would be considered. In this case the review concludes that the offsite accident dose consequences would not increase. Therefore, no prior NRC approval would be required.

Note: For spent fuel storage systems that have Technical Specification limits on shield plug dose rates, the change would be evaluated separately for compliance with the Technical Specification. Further, normal operation offsite dose consequences of the change must be evaluated per 10 CFR 72.104. This evaluation would be documented in the general licensee’s 212 Report.

## EXAMPLES OF RESPONSES TO 72.48 EVALUATION QUESTION 6 (NEI 6.6)

**Example**

A cask CoC holder desires to replace the fuel support breakaway clips used in a particular cask design by an energy absorption device. The breakaway clips are used to mitigate the effects of a cask drop event. This modification may introduce a new failure mechanism that could affect the mitigation of a cask drop event. But if this effect (failure of the

energy absorption device to mitigate the effects of a cask drop) was bounded by a UFSAR description of the effects of a failure of the breakaway clips to mitigate the effects of a cask drop, then a malfunction with a different result has not been created, and prior NRC approval under the criterion of 72.48(c)(2)(vi) would not be required. If failure of the breakaway clips to mitigate a cask drop event had not been described in the UFSAR, then the replacement of the clips with an energy absorption device would create a possibility for a malfunction of an SSC important to safety with a different result, and prior NRC approval under the criterion of 72.48(c)(2)(vi) would be required.

The following example illustrates this point:

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

## EXAMPLES OF RESPONSES TO 72.48 EVALUATION QUESTION 7 (NEI 6.7)

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

### Example 1

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

### Identification of design basis limits

The effects of the reduced material thickness would be reviewed. The effects would include the impact on the criticality, heat transfer, and structural analyses, at a minimum. Thus, the proposed activity may impact certain numerical design basis limits such as k-effective, fuel cladding temperature, and fuel basket stresses.

### Exceeded or altered

Any increase in reactivity in the criticality analysis would be compared to the k-effective design basis limit. If the revised reactivity result from the criticality analysis (i.e., the calculated k-effective) causes the k-effective design basis limit to be exceeded, then a license/CoC amendment would be required. Likewise, any revised results in the heat transfer or structural analyses would be compared to the respective design basis limits specified in the UFSAR for those disciplines.

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

**Example 2**

The as-built interior length of a concrete overpack is found to be less than the minimum length in the fabrication specification and drawings. An analysis shows that thermal expansion of the storage canister when placed in the overpack would result in an interference when the canister is loaded with design basis fuel assemblies. It is proposed to limit the decay heat of the fuel to be stored in the concrete overpack to 75 percent of the value reflected in the safety analysis.

**Identification of Design Basis Limit**

The affected parameter is cask decay heat load.

**Exceeded or altered**

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

# APPENDIX B – EXAMPLES OF 72.48 REVIEWS OF REALISTIC ACTIVITIES

This appendix includes six examples of full 72.48 reviews of realistic activities. Each 72.48 review follows the same format, and includes references to the main guidance of NEI 12-04 for justifying conclusions. Users of these examples MUST read the details of the entire example and variants, and the entire guidance in NEI 12-04 to fully understand how it is applied in these cases. Understanding how the guidance is applied in these cases can aid in performing 72.48 reviews for other activities in the future. The following table summarizes the examples and their variants, i.e. the changes and conclusions, but should not be used to make general determinations of how to apply the guidance in NEI 12-04.

| No. | Example-Variant | Change Description | Conclusion – NRC Approval Required? |
|---|---|---|---|
| 1 | #1 – Main | Change structural analysis computer code from Alpha to Bravo. {Codes with different theories} | Yes – Bravo was not previously approved for the intended application |
| 2 | #1-Variant 1 | Change structural analysis computer code from Alpha 5.6 to Alpha 6.0. | No – Methods of evaluation are essentially the same |
| 3 | #1-Variant 2 | Change structural analysis computer code from Alpha to Delta. {Codes with same theories} | No – Change in element of method of evaluation where new results are conservative |
| 4 | #1-Variant 3 | Change in the structural re-bar of the over-pack. {No change to codes} | No – No specific NRC acceptance based on size or spacing of re-bar, cask still meets standards. {This is not a method of evaluation change} |
| 5 | #2 – Main | Reduction in weight of transfer cask: 1) include new supplemental shielding components, and 2) apply thermal analysis used for other NRC approved conditions to this condition for the first time. | #1) No – Crane malfunctions and results are Part 50 issues. Personnel dose is a Part 20 issue.<br>#2) Yes – Method of evaluation was not approved for intended function |
| 6 | #2-Variant 1 | Same, except TS require user to have a Part 50 Radiation Program that would apply to these activities. | #1&2 Yes – Same reason as main example {Does not require TS change} |
| 7 | #3 – Main | Removal of a helium leak test (HLT) of canister fabrication welds. | Yes – Because the HLT was relied upon by the NRC, in the SER, to provide reasonable assurance that the as-fabricated cask performed the design functions. Also, this would result in a malfunction with a different result, since the test is being eliminated. |
| 8 | #3-Variant 1 | Replace the helium leak test of canister fabrication welds, with an equivalent test. | No – Because the HLT is being replaced with an equivalent test and the HLT was not relied upon by the NRC, in the SER, to provide reasonable assurance. {The QA and Test programs still need to be reviewed to determine if replacing a test would violate either of these programs} |
| 9 | #4 – Main | Change the criticality code from Alpha 1.0 to Alpha 2.0. | No – It is a change in an element of the method of evaluation, but the results are conservative. |
| 10 | #4-Variant 1 | Change the criticality code from Alpha to Bravo. | No – It is a change to a new method of evaluation, however, the new method of evaluation was already |

| | | | |
|---|---|---|---|
| | | | approved by the NRC for the intended application by SER of another CoC. |
| 11 | #4-Variant 2 | Change to the basket cell wall thickness. | No – There is no change to any parameter listed in the CoC/TS, and the results using the same method of evaluation resulted in no change to the maximum calculated k-eff. {This is a change to an input to a method of evaluation, and is not a change to a method of evaluation itself} |
| 12 | #5 – Main | Reduction in the diameter of the concrete over-pack. | No – There is no change to the CoC or approved contents. This is a change to the assumptions (from overly-conservative/simplistic to conservative/detailed) of the shielding calculation, and the NRC did not mention in the SER that the assumptions were relied upon to provide reasonable assurance. |
| 13 | #5-Variant 1 | Reduction in the diameter of the concrete over-pack. | Yes – This is a change to inputs and method of evaluation, since they were part of the NRC's basis for determining adequate protection. |
| 14 | #6 – Main | Installation of an enclosure structure over the casks for a site-specific ISFSI. The proposed structure is open-air, but has a roof and walls. | No – The impact the thermal design function described in the FSAR would not result in a positive finding for any of the evaluation questions. |
| 15 | #6-Variant 1 | Installation of an enclosure structure over the casks for a site-specific ISFSI. The proposed structure is a sun-cover. | No – The screening would identify that there is no impact to any FSAR described design function. |
| 16 | #6-Variant 2 | Installation of an enclosure structure over the casks for a site-specific ISFSI. The proposed structure is enclosed by a roof and walls, and contains vents. | Yes – This would either a) require a TS change to include a surveillance requirement for the enclosure's vents, or b) potential blockage of the vents would result in a malfunction with a different result. |

## EXAMPLE 1 – CHANGE IN STRUCTURAL ANALYSIS

### PROPOSED ACTIVITY

Change in computer code from computer code ALPHA to computer code BRAVO. Code ALPHA uses elastic theory methods and code BRAVO uses plastic theory methods. No changes to any SSCs.

### NRC-APPROVED LICENSING BASIS

Computer code ALPHA uses elastic theory methods and was previously reviewed and accepted by the NRC for the overpack shell analysis performed by the CoC holder.

### CoC, TS and Approved Contents

*Does not include the name of the computer code and does not discuss the structural analysis.*

### FSAR

*Describes that code ALPHA was used and includes a description of the analysis method.*

### 72.48 APPLICABILITY DETERMINATION

*{72.48 applies unless "Yes" is answered to one or more of the three questions for <u>all</u> aspects of the proposed activity}*

[NEI 4.0.1[2]]: Does the proposed activity involve a modification to the ISFSI, cask design or procedure in the ISFSI or cask FSAR or the 212 Report that is an editorial/administrative correction (4.3) or a modification to a managerial or administrative procedure governing the conduct of operations (4.4)?

Response: No. The Method of Evaluation (MOE) is described in the FSAR and used to demonstrate the acceptability of the overpack shell design; therefore, the activity requires screening under 10 CFR 72.48 to determine if an evaluation is required.

[NEI 4.0.2]: Does the proposed activity require a change to the ISFSI license or CoC, including appendices?

Response: No. The activity would not require an alteration to the CoC or Tech Specs.

[NEI 4.0.3]: Does a different regulation provide more specific criteria for accomplishing the proposed activity?

[2] Refers to NEI 12-04 throughout this appendix.

Response: No. The activity falls under FSAR design basis.

Conclusion: *72.48 applies,* and the proposed activity must be screened.

**72.48 SCREENING**

{*72.48 evaluation is required if "Yes" is answered to any of the following questions*}

1. [NEI 5.0, 1st Bullet, 5.1.1, 5.1.2, and 5.1.3]: Does the proposed activity involve a change to a UFSAR-described design function of an SSC or cask design?

Response: No, this activity does not involve a change to an SSC, but rather is associated with methods of evaluation.

2. [NEI 5.0, 2nd Bullet, 5.1.1, 5.1.2, and 5.1.4]: Does the proposed activity involve a change to a UFSAR-described method of performing or controlling a design function?

Response: No, this activity does not involve a procedure, but rather is associated with methods of evaluation.

3. [NEI 5.0, 3rd Bullet, 5.1.1, 5.1.2, and 5.1.5]: Does the proposed activity involve 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?

Response: Yes, as follows:

MOE means the calculational framework used for evaluating behavior or response of the ISFSI facility, cask design, or an SSC. Activities that involve MOEs require evaluation only when 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.

A new computer code BRAVO using plastic versus elastic theory methods is being used for evaluating the shell structural acceptability. The use of BRAVO results in a change in methodology because the proposed activity involves replacing a dry storage cask FSAR described evaluation methodology that is used in establishing the design bases or used in the safety analyses.

4. [NEI 5.0 and 5.2]: Does the proposed activity involve 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 cask FSAR?

Response: No. This activity does not involve a test or experiment.

Conclusion: *A 72.48 evaluation is required.* One or more "yes" answers to the screening questions indicates a 72.48 evaluation is required to be performed. In this case, only Screen question 3 is answered "yes." When only Screen question 3 is answered "yes", then only evaluation question 72.48(c)(2)(viii) (change in method of evaluation) is applicable.

MOE means the calculational framework used for evaluating behavior or response of the ISFSI facility, cask design, or an SSC. Activities that involve MOEs require evaluation only when 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.

A new computer code BRAVO using plastic versus elastic theory methods is being used for evaluating the shell structural acceptability. The use of BRAVO results in a change in methodology because the proposed activity involves replacing a dry storage cask FSAR described evaluation methodology that is used in establishing the design bases or used in the safety analyses.

The proposed activity modifies an MOE and requires an evaluation per 10 CFR 72.48(c)(2)(viii), and criteria 10 CFR 72.48(c)(2)(i-vii) are not applicable.

**72.48 EVALUATION**

{*Prior NRC approval is required if "Yes" is answered to any of the following questions*}

[NEI 6.0, 2nd para]: "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."

The proposed activity modifies an MOE and requires an evaluation per 10 CFR 72.48(c)(2)(viii), and criteria 10 CFR 72.48(c)(2)(i-vii) are not applicable.

Question 8 [NEI 6.8]: Does the activity result in departure from a method of evaluation used in establishing the design bases or in the safety analyses?

Response: Yes, as follows:

This activity changes from the ALPHA computer code, using elastic theory methods, to BRAVO computer code using plastic theory method which substitutes a different MOE than previously used.

*There are two (2) options for which an activity by a Licensee or cask certificate holder may vary the Method of Evaluation (MOE) as described in the UFSAR to an extent such that the activity is not considered a departure from the method and does not require prior NRC approval.*

*Licensees or cask certificate holders do not need prior NRC approval (a license amendment or cask CoC amendment) to perform an activity resulting in the following:*

1. *Modification to one or more elements of the methodology provided the results are essentially the same as, or more conservative than, previous results, or*

2. *Substitution of a different MOE than previously used, but that has been approved by the NRC for the intended application.*

The evaluation should proceed by addressing the changes to the MOE by determining if the methodology has been previously approved by the NRC for the intended application.

The licensee or cask certificate holders would evaluate whether or not the MOE change for the overpack shell analysis could be used under 10 CFR 72.48(c)(2)(viii) without obtaining a license amendment or cask CoC amendment by determining if the proposed MOE has been previously approved by NRC for this intended application. A method is considered "approved by the NRC for intended application" if it is approved for the type of analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied. It should be noted that the NRC staff, in reviewing dry cask storage designs, historically has not generically approved methodologies referenced in FSARs for use by other licensees or vendors.

When considering the application of the computer code BRAVO plastic theory method versus the computer code ALPHA elastic theory method, it is necessary to adopt the methodology in its entirety and apply it consistent with applicable terms, conditions and limitations.

*Previously approved MOEs by the NRC for the intended application would typically follow one of two paths.*

1. *Through a Safety Evaluation Report, the NRC would approve the use of the methodologies for a given class of ISFSIs or spent fuel storage casks. In some cases, the NRC would accord "generic" approval of analysis methodologies.*

2. *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.*

*Only ISFSI licensees or cask CoC holders qualified to perform MOEs can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another ISFSI's or cask design's licensing basis, without requiring prior NRC approval. The guidance of Generic Letter 83-11, Supplement 1 may be useful to ISFSI licensees and cask CoC holders as a method to demonstrate that they are generally qualified to perform safety analyses (have a thorough understanding of the methodology.) ISFSI Licensees or cask CoC holders that have not satisfied the guidelines of Generic Letter 83-11, Supplement 1, may, of course, continue to seek ISFSI-specific or cask design-specific approval to use new methods of evaluation, but should do so by seeking prior approval by the NRC.*

The ISFSI licensee or cask CoC holder proposing to use the computer code BRAVO plastic theory method for the overpack shell design (even one generically approved by the NRC)

must have a thorough understanding of the MOE, the terms of its existing application and conditions/limitations on its use. This information may be found in the topical report (original license or CoC application or license or CoC amendment request), the SER, and any correspondence between the NRC and the methodology/analysis owner that is referenced in the SER or associated transmittal letter. In some cases, information clarifying the application of the MOE is contained in proprietary submittals to the NRC and not publically available without consulting the original ISFSI licensee or cask CoC holder that was approved to use this MOE.

This MOE uses the computer code BRAVO plastic theory method versus the computer code ALPHA elastic theory method for the overpack shell analysis. The NRC has not accepted the use of the plastic theory method for performing overpack shell structural analysis.

Conclusion: *Prior NRC approval is required* because the MOE cannot be considered previously approved for overpack shell structural analysis, and therefore use of computer code BRAVO is a departure from a method of evaluation described in the UFSAR. Prior approval by the NRC is required in the form of a license amendment or cask CoC amendment.

#### ADDITIONAL CONSIDERATIONS

The following variations to the main example demonstrate how small changes in the specific conditions can result in different conclusions from the 72.48 review.

**Variant 1:**

Should this activity only revise the version of computer code ALPHA being used from 5.6 to 6.0, then the activity would be evaluated only for modifying one or more elements of the MOE. (In some cases, a new version of a code's MOE may be so extensive that the new version must be considered a "substitution of a different MOE than previously used" and should be evaluated as such.) The following process for evaluation would be followed.

*The licensee or cask certificate holder would determine if computer code ALPHA 6.0 could be used under 10 CFR 72.48(c)(2)(viii) without obtaining a license amendment or cask CoC amendment by demonstrating that the results are "conservative or essentially the same" as previous results.*

*Results are considered "essentially the same" if they are within the margin of error for the type of analysis being performed. Code improvements that yield more conservative (accurate) results would have a narrower band for margin of error and, therefore, would be considered "essentially the same." 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 "conservative or essentially the same."*

*Results are considered "conservative" when the analytical results obtained by using computer code ALPHA 6.0 are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines) than those results by using computer code ALPHA 5.6. Gaining margin by changing one or more elements of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR 72.48.*

*To determine whether the new analysis result would be considered "conservative or essentially the same", the licensee or CoC holder may benchmark computer codes ALPHA 5.6 and 6.0.*

*When benchmarking computer code ALPHA 5.6 to determine how it compares to computer code ALPHA 6.0, the analyses that are done must be:*

- *for the same set of conditions to ensure that the results are comparable, and*
- *over the entire range of use for the method.*

*Comparison of analysis methods should consider both the peak values and time behavior of results, and engineering judgment should be applied in determining whether two methods yield results that are "conservative or essentially the same". Engineering judgments should be provided with a clearly stated basis such that any reasonably knowledgeable engineer could read it and agree with it.*

*Twenty-four (24) verification computer benchmarks were performed for computer codes ALPHA 5.6 and 6.0 using the same input variables. The results obtained from 20 of the 24 computer benchmarks were compared and found to have exact numerical matches. The results from the 4 remaining computer benchmarks that did not match were further evaluated for the significance of their mismatches. The detailed evaluation of these 4 computer benchmarks were found that the results for 3 differed by less than 1- percent which is within the expected analytical tolerance of computer codes ALPHA 5.6 and 6.0. The remaining computer run of ALPHA 6.0 was determined to result from different user selectable option chosen between the verification scripts for versions 5.6 and 6.0.*

*Conclusion: It is therefore concluded that ALPHA version 6.0 is essentially the same as ALPHA version 5.6 and use of computer code ALPHA 6.0 is not a departure from a described methodology in the UFSAR. Prior review and approval by the NRC is not required.*

**Variant 2:**

Should this activity revise the computer code ALPHA to the computer code DELTA for the shell structural analysis and computer code DELTA is based on the same theory as code ALPHA (elastic theory methods), then the activity may be evaluated only for modifying one or more

elements of the MOE for the DELTA computer code. The DELTA computer code should first be evaluated to assure the following, as applicable, to determine if it is the same methodology with updates with one or more elements:

- Uses the same data type of correlation (e.g., direct integration, modal, static)
- Uses the same type of data reduction (e.g., solution routines, analysis engines)
- Uses the same physical constants or coefficients (e.g., gap and sliding, friction, damping, isotropic vs. anisotropic materials)
- Uses the same type of mathematical models (e.g., elastic theory vs. non-linear, stick vs. 3-D or shells of revolution models)
- Limitations of the DELTA computer program are consistent with the ALPHA computer program
- Specified factors to account for uncertainty in measurements or data are consistent
- Statistical treatment of results is consistent (e.g., Monte Carlo vs. probability and confidence)
- Same dose conversion factors and assumed source term(s) are used (ICRP)

*The licensee or cask certificate holder would determine if computer code DELTA could be used under 10 CFR 72.48(c)(2)(viii) without obtaining a license amendment or cask CoC amendment by demonstrating that the results are "conservative or essentially the same" as previous results. In this particular variation, a likely approach is to determine if computer code DELTA provides conservative results with respect to computer code ALPHA.*

*Results are considered "conservative" when the analytical results obtained by using computer code DELTA are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines) than those results by using computer code ALPHA. Gaining margin by changing one or more elements of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR 72.48.*

*The determination of whether the new analysis result would be considered "conservative or essentially the same" licensee or CoC holder may benchmark computer codes ALPHA and DELTA.*

*When benchmarking computer code ALPHA to determine how it compares to computer code DELTA, the analyses that are done must be:*

- *for the same set of conditions to ensure that the results are comparable, and*

- *over the entire range of use for the method.*

*Comparison of analysis methods should consider both the peak values and time behavior of results, and engineering judgment should be applied in determining whether two methods yield results that are "conservative or essentially the same". Engineering judgments should be provided with a clearly stated basis such that any reasonably knowledgeable engineer could read it and agree with it.*

*Seven (7) verification computer benchmarks were performed for computer codes ALPHA and DELTA using the same input variables. The results obtained from all 7 computer benchmarks were compared and in each benchmark, computer code DELTA yielded results closer to limits established in the UFSAR than computer code ALPHA for both the peak values and time behavior.*

*Conclusion: It is therefore concluded that computer code DELTA is more conservative than computer code ALPHA and use of computer code DELTA is not a departure from a described methodology in the UFSAR. Prior review and approval by the NRC is not required.*

**Variant 3:**

Should this activity be revised to use the NRC approved version of computer code ALPHA to re-analyze a change from #8 rebar on 12 inch spacing to #6 rebar on 9 inch spacing, then the activity would proceed as follows. {Note this case is not a change in method of evaluation, but is a change to an SSC}

*The licensees or cask certificate holders would verify change in rebar size and spacing meet applicable codes and standards committed to in the UFSAR. In addition, the licensees or cask certificate holder would review the NRC SERs on the cask overpack design to determine that no specific NRC acceptance of the structural analysis for the cask overpack design is based on the specific size or spacing of the rebar.*

*Upon conclusion that the NRC acceptance is based on compliance with applicable codes and standards and the new rebar size, spacing and section capacity meets these applicable codes and standards, the licensees or cask certificate holder could conclude that the planned change in rebar size and spacing is an input to computer code ALPHA. A change in input to a methodology does not involve an adverse change to an element of a cask FSAR described evaluation methodology, nor use of an alternative evaluation methodology, that is used in establishing the design bases or used in the safety analyses.*

*Conclusion: It is therefore concluded that use of computer code ALPHA to re-analyze a change from #8 rebar on 12 inch spacing to #6 rebar on 9 inch spacing may be "screened out" and an evaluation pursuant to 10 CFR 72.48(c)(2) is not required.*

## EXAMPLE 2 – REDUCTION IN SIZE OF TRANSFER CASK

### PROPOSED ACTIVITY

The storage system uses transfer casks (TCs) for transporting storage canisters from the fuel building to the ISFSI for insertion into storage modules. Currently licensed TCs include lead shielding and generally require a 100 ton crane for use. An alternative TC is proposed, for use with a 70-ton crane. Although this proposed change would involve multiple activities, most of which would screen out of the 72.48 process, only the following two activities are carried forward here, for the purpose of demonstrating the 72.48 process.

**Activity No. 1 –** The alternative TC will involve supplemental shielding components not lifted with the TC/canister, in place of the integral lead shielding, as follows:

- When in the decontamination area, the TC/canister is placed within a shielding sleeve and then a shield bell is placed atop the sleeve.
- When the TC/canister is down-ended onto the transfer skid/trailer, inner and outer bottom skid shielding is already in place, and inner and outer top skid shielding is then installed.

**Activity No. 2 –** Based on the geometries involved, the previous method of evaluation for the thermal analysis of the *TC/canister while being transferred on the trailer/skid* is incapable of analyzing the new design. The closest previously-NRC-approved thermal method of evaluation for the *TC/canister inside the supplemental transfer trailer/skid shielding* is the method of evaluation used for a *canister inside a concrete storage module*. This thermal method involves a cylinder inside a rectangular enclosure, with convective air flow entering the bottom and exiting the top of the enclosure. Proposed Activity No. 2 is to use this alternative method of evaluation.

### NRC-APPROVED LICENSING BASIS

#### CoC, TS and Approved Contents

*The CoC discusses the function of the TC but does not go to the level of detail of lead shielding. The Tech Specs also do not discuss lead shielding.*

*The Tech Specs do not have TC dose rate limits and the Tech Specs do not specifically require a radiation protection program.*

#### FSAR

*The FSAR provides full analytical results for existing TCs with lead shielding integral to the TC itself. It does not include any analyses of supplemental shielding of any kind, including that to be used with the alternate TC design.*

*The FSAR contains the previously NRC-approved thermal analytical results for a canister inside a concrete storage module and inside a TC in the vertical and horizontal orientations.*

*The FSAR states that the cask handling crane is described in the plant's 10 CFR Part 50 SAR, and does not require the crane to be single-failure-proof or otherwise discuss crane malfunctions or failures. The FSAR mentions the possibility of licensees using supplemental shielding for cask operations in accordance with the site's radiation protection program.*

*The FSAR includes dose rate and personnel dose estimates for cask loading and transfer operations.*

**72.48 APPLICABILITY DETERMINATION**

{*72.48 applies unless "Yes" is answered to one or more of the three questions for <u>all</u> aspects of the proposed activity*}

[NEI 4.0.1]: Does the proposed activity involve a modification to the ISFSI, cask design or procedure in the ISFSI or cask FSAR or the 212 Report that is an editorial/administrative correction (4.3) or a modification to a managerial or administrative procedure governing the conduct of operations (4.4)?

Response: No. Both activities fall under the FSAR design basis.

[NEI 4.0.2]: Does the proposed activity require a change to the ISFSI license or CoC, including appendices?

Response: No. Neither of the two activities would require an alteration to the CoC or Tech Specs.

[NEI 4.0.3]: Does a different regulation provide more specific criteria for accomplishing the proposed activity?

Response: Yes, in part. The subject of increased dose rate from the TC inside the plant and operating dose to site personnel for installing and removing supplemental shielding for the TC is a matter primarily governed by 10 CFR Part 20. That issue is not the subject of 10 CFR 72.48. At the same time, the FSAR includes dose rate and personnel dose estimates that will need to be modified for the use of the lightweight TC.

The cask FSAR assigns cask handling crane design and malfunctions (e.g., potential for load drops) to the Part 50 license, to be reviewed by each licensee under the heavy load control and 10 CFR 50.59 programs.

Conclusion: 72.48 is applicable and the proposed activities must be screened.

**72.48 SCREENING**

*{72.48 evaluation is required if "Yes" is answered to any of the following questions}*

1. [NEI 5.0, 1st Bullet, 5.1.1, 5.1.2, and 5.1.3]: Does the proposed activity involve a change to a UFSAR-described design function of an SSC or cask design?

Response: *Yes* for Activity No. 1 and *No* for Activity No. 2, as follows.

[NEI 5.1.2, 5th para.] Because the effect of Activity No. 1 (use of supplemental shielding SSCs in place of integral lead shielding) is such that existing safety analyses are no longer bounding and therefore FSAR safety analyses must be re-run to demonstrate that all required safety functions and design requirements are met, the change is considered to be adverse.

Activity No. 2 is not a change to an SSC, but rather is associated with methods of evaluation.

Neither activity affects design basis limits for fission product barriers.

2. [NEI 5.0, 2nd Bullet, 5.1.1, 5.1.2, and 5.1.4]: Does the proposed activity involve a change to a UFSAR-described method of performing or controlling a design function?

Response: *Yes* for Activity No. 1 and *No* for Activity No. 2, as follows:

Due to Activity No. 1, procedure changes are necessary due to handling and placement of the supplemental shielding. These procedure changes fundamentally alter the existing means of controlling the TC shielding design function. Outside the Part 50 facility, different dose rates from the TC considering the supplemental shielding could affect calculated normal, off-normal, and accident doses to offsite personnel, which is a Part 72 issue. Per NEI 5.1.4, 2nd paragraph, in part, "...changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in."

Activity No. 2 does not involve a procedure, but rather is associated with methods of evaluation.

3. [NEI 5.0, 3rd Bullet, 5.1.1, 5.1.2, and 5.1.5]: Does the proposed activity involve 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?

Response: *No* for Activity No. 1 and *Yes* for Activity No. 2, as follows:

Activity No. 1 is not associated with evaluation methodologies.

Activity No. 2, (thermally modeling the TC/canister inside the supplemental transfer trailer/skid shielding using the method of evaluation of a canister inside a concrete storage module, previously approved by the NRC) involves a different method from that used

previously for the analysis of the TC/canister on the transfer trailer/skid, and therefore involves use of an alternative evaluation methodology. Although results from the alternative evaluation methodology were also described in the cask FSAR, those results do not imply that the alternative evaluation methodology may be applied to cases other than those previously approved.

4. [NEI 5.0 and 5.2]: Does the proposed activity involve 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 cask FSAR?

Response: *No*. Neither activity involves a test or experiment.

Conclusion: *A 72.48 evaluation is required.* One or more "yes" answers to the screening questions indicates a 72.48 evaluation is required to be performed. For Activity 1, Screen questions 1 and 2 were answered 'yes', therefore, only evaluation questions 72.48(c)(2)(i-vii) are applicable. For Activity 2, Screen question 3 is answered "yes." When Screen question 3 is answered "yes", then only evaluation question 72.48(c)(2)(viii) (change in method of evaluation) is applicable.

**72.48 EVALUATION**

{*Prior NRC approval is required if Yes is answered to any of the following questions*}

[NEI 6.0, 2nd para]: "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."

- Activity No. 1 (not related to methods of evaluation) requires evaluation only against the first seven criteria.
- Activity No. 2 (related to methods of evaluation only) requires evaluation only against the eighth criterion.

*{Questions 1 through 7 are answered for Activity 1 only, they do not apply to Activity 2}*

Question 1 [NEI 6.1]: Does the activity result in more than a minimal increase in the frequency of occurrence of an accident?

Response: No. The relevant accidents are the Tornado Winds and Generated Missiles, TC Drop with Loss of Neutron Shield, and Design Basis Earthquake. The use of supplemental shielding in place of integral shielding is not an initiator of any of these accidents.

Question 2 [NEI 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?

Response: No. There are no malfunctions affected by the use of supplemental shielding in place of integral shielding.

Question 3 [NEI 6.3]: Does the activity result in more than a minimal increase in the consequences of an accident?

Response: No. For the Tornado Winds and Generated Missiles and Design Basis Earthquake, the existing TC analyses are bounding. For the TC Drop with Loss of Neutron Shield, the offsite dose increase is 102.4 mrem (103.2 mrem – 0.8 mrem), which is 2% of the margin to the [72.106] 5 rem limit.

Note that "10 CFR 72.48 accident dose consequence criteria and evaluation guidance are not applicable to proposed activities affecting normal operations governed by 10 CFR Part 20 and 10 CFR 72.104 requirements. An ISFSI must not exceed the limits of 10 CFR 20 and 10 CFR 72.104 as a result of a proposed activity." Therefore, general licensees incorporating this proposed activity into their 72.212 report, either by completing this 72.48 themselves or adopting this 72.48 from a CoC holder, would need to account for 10 CFR Part 20 and 10 CFR 72.104 requirements as well. For those particular aspects, this could be documented in the Applicability Determination, in responding to the question as to whether a different regulation provides more specific criteria for accomplishing the proposed activity.

Question 4 [NEI 6.4]: Does the activity result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety?

Response: No. There are no malfunctions associated with crane use or TC shielding discussed in the FSAR. Increased dose rates and personnel doses due to the use of a lightweight TC are governed by 10 CFR 20.

Question 5 [NEI 6.5]: Does the activity create a possibility for an accident of a different type?

Response: No. The basic system design is still the same, so those accidents previously evaluated bound this new condition.

Question 6 [NEI 6.6]: Does the activity create a possibility for a malfunction of an SSC important to safety with a different result?

Response: No. The potential for load drops is reviewed by each licensee under the heavy load control program governed by 10 CFR 50.59. The lightweight TC is used in the same way as the base TC to facilitate DSC fuel loading and transfer into the HSM. Installation and removal of supplemental shielding in the decontamination pit and on the transfer trailer are new activities for which no new malfunctions are created under Part 72. Therefore, no new malfunction results are created.

Question 7 [NEI 6.7]: Does the activity result in a design basis limit for a fission product barrier being exceeded or altered?

Response: No. The use of supplemental shielding in place of integral shielding does not involve any fission product barrier design basis limits.

*{Following Question is for Activity 2 only; previous seven questions did not apply to Activity 2}*

Question 8 [NEI 6.8]: Does the activity result in departure from a method of evaluation used in establishing the design bases or in the safety analyses?

Response: Yes, as follows:

> Activity No. 2 proposes to thermally model the TC/canister inside the supplemental transfer trailer/skid shielding as a cylinder inside a rectangular enclosure, with convective air flow entering the bottom and exiting the top of the enclosure, using the same method of evaluation as a canister inside a concrete storage module, previously approved by the NRC.
>
> Per [NEI 6.8.2], a thorough knowledge of the details of the methods is important for determining if a particular application of a different method is technically appropriate.
>
> Review of the details of the methods involved here show that evaluation of the canister inside a storage module used 3D modeling, while evaluation of the TC/canister inside the supplemental trailer/skid shielding used 2D modeling. Also, the temperatures for the different components of the TC/canister, including the maximum fuel cladding temperature, were obtained by extrapolation of data, which is an approach that differs from that used for the canister in the storage module.
>
> Based on this, the previous NRC approval was not for the intended application. Therefore this is a departure from a method of evaluation

Conclusion: *Prior approval from the NRC is not required* for Activity 1 and *is* required for Activity 2. Activity 2 requires prior NRC approval because the method of evaluation was not approved for the intended application (Question 8).

#### ADDITIONAL CONSIDERATIONS

The following variation to the main example demonstrate how small changes in the specific conditions can result in different conclusions from the 72.48 review.

### Variant 1

The current licensing basis Tech Specs require a Radiation Protection Program and indicate that the license shall ensure that activities inside the Part 50 facility related to transfer cask operations are performed in accordance to their Part 50 facility's Radiation Protection Program. This would not result in the need for NRC approval of a change to the Tech Specs. However, as the other aspects of the base case would still apply, the overall change would still need NRC review and approval.

## EXAMPLE 3 – REMOVAL OF HELIUM LEAK TEST OF CANISTER FABRICATION WELDS

### PROPOSED ACTIVITY

Remove the requirement in the FSAR to perform a helium leak test on the Dual-Purpose Canister (DPC) shell welds and the shell to baseplate welds that are performed after fabrication. These welds will be referred to as the fabrication welds going forward. This proposed activity does not change the design or construction of the DPC, including welding and non-destructive testing and pressure testing of the DPC required by ASME III, Subsection NB, as clarified by approved alternatives in the CoC.

### NRC-APPROVED LICENSING BASIS

#### CoC, TS and Approved Contents

*The CoC does not include requirements for leak testing DPC shell welds or fabrication welds in the shop. The CoC includes a commitment to the ASME Section III, Subsection NB Code for DPC design, fabrication, inspection, and testing, with certain NRC-approved alternatives. ASME III, NB-6000 requires pressure testing of the DPC after final closure welding. The technical specifications only require helium leakage testing in the field after the vent and drain port cover plate welds are complete, but not of the DPC lid-to-shell.*

#### Safety Evaluation Report

*The SER states that the DPC's confinement function is verified through hydrostatic testing, helium leak testing, and weld examinations. It further states that a fabrication helium leak rate test is performed on the canister shell weld and shell to baseplate weld to ensure a maximum helium leakage rate. This helium leak rate test is performed in accordance with ANSI N14.5-1997 and confirms that the amount of helium lost from the canister over the approved period will not result in a degradation of the canister's performance of the heat transfer or confinement functions. The SER states that the helium leak rate test provides the NRC with reasonable assurance that no credible leakage would occur from the final closure welds of austenitic stainless steel canisters.*

#### FSAR

*The FSAR describes a helium leak test of the DPC pressure boundary shop welds during fabrication.*

*It is noteworthy for this example that the DPC, while it* is *the Part 72 storage confinement boundary, it is* not *the Part 71 containment boundary. The containment function for transportation is provided by the overpack in which the DPC resides during transport.*

**Applicable Regulations**

*There is no regulation requiring a helium leak rate test of any SSC, nor is the any requirement for a helium leak rate test to confirm the cask's ability to perform any safety function.*

**72.162, Test Control**

"The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish a test program to ensure that all testing, required to demonstrate that the structures, systems, and components will perform satisfactorily in service, is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the ISFSI, MRS, or spent fuel storage cask license or CoC."

**72.232, Inspections and Tests**

"(c) The certificate holder and applicant for a CoC shall perform, and make provisions that permit the NRC to perform, tests that the Commission deems necessary or appropriate for the administration of the regulations in this part."

**72.234, Conditions of Approval**

"(a) The certificate holder and applicant for a CoC shall ensure that the design, fabrication, testing, and maintenance of a spent fuel storage cask comply with the requirements in § 72.236."

"(f) The certificate holder shall ensure that written procedures and appropriate tests are established prior to use of the spent fuel storage casks."

**72.236, Specific Requirements for Spent Fuel Storage Cask Approval and Fabrication**

"(l) The spent fuel storage cask and its systems important to safety must be evaluated, by appropriate tests or by other means acceptable to the NRC, to demonstrate that they will reasonably maintain confinement of radioactive material under normal, off-normal, and credible accident conditions."

**72.48 APPLICABILITY DETERMINATION**

*{72.48 applies unless "Yes" is answered to one or more of the three questions for all aspects of the proposed activity}*

[NEI 4.0.1]: Does the proposed activity involve a modification to the ISFSI, cask design or procedure in the ISFSI or cask FSAR or the 212 Report that is an editorial/administrative correction (4.3) or a modification to a managerial or administrative procedure governing the conduct of operations (4.4)?

Response: No. The removal of this fabrication shop helium leak test is a change to the cask FSAR that is not editorial or administrative.

[NEI 4.0.2]: Does the proposed activity require a change to the ISFSI license or CoC, including appendices?

Response: No. Neither the CoC, nor the appendices, describe the shop helium leak test for the canister shell weld or shell to baseplate weld.

[NEI 4.0.3]: Does a different regulation provide more specific criteria for accomplishing the proposed activity?

Response: No.

Conclusion: *72.48 applies,* and the proposed activity must be screened. The change to a test than verifies the as-fabricated cask meet the approved design also requires review of the requirements for an adequate test program and quality assurance.

It is noted that independent of the conclusions from the 72.48 review the CoC holder still needs to address the question as to the appropriateness of deleting the DPC fabrication shop helium leakage test in the context of meeting the regulations requiring an adequate test program for the spent fuel cask (10 CFR 72.236) and quality assurance (10 CFR Subpart L). In particular, 10 CFR 72.236(l) states: " The spent fuel storage cask and its systems important to safety must be evaluated, by appropriate tests or by other means *acceptable to the NRC*, [emphasis added] to demonstrate that they will reasonably maintain confinement of radioactive material under normal, off-normal, and credible accident conditions." This example demonstrates how CoC holders and licensees must ensure that all proposed activities continue to meet the regulations as part of the design control process, not only in applying the 72.48 process.

**72.48 SCREENING**

*{72.48 evaluation is required if "Yes" is answered to any of the following questions}*

1. [NEI 5.0, 1st Bullet, 5.1.1, 5.1.2, and 5.1.3]: Does the proposed activity involve a change to a UFSAR-described design function of an SSC or cask design?

Response: Yes. The FSAR-described design functions are confinement and decay heat removal. Per 72.48 guidance Sections 5.1.1 through 5.1.3, this proposed change *adversely affects design function by eliminating a* test that validates the as-fabricated condition meets the design basis. Thus, a potential fabrication defect could go undetected, possibly resulting in the as-fabricated cask not being able to perform the FSAR described design function. Further supporting this conclusion is the language in the NRC's SERs that DPC helium leakage testing was relied upon to verify the DPC's confinement function.

2. [NEI 5.0, 2nd Bullet, 5.1.1, 5.1.2, and 5.1.4]: Does the proposed activity involve a change to a UFSAR-described method of performing or controlling a design function?

Response: No. This proposed activity pertains to a fabrication shop test for the DPC hardware. Per 72.48 guidance Section 5.1.4, it does not involve a procedure used to perform or control a design function.

3. [NEI 5.0, 3rd Bullet, 5.1.1, 5.1.2, and 5.1.5]: Does the proposed activity involve 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?

Response: No. The helium leak rate test is to confirm that the as-fabricated cask meets the NRC approved design. Per 72.48 guidance Section 5.1.5, a method of evaluation is the calculational framework used for evaluating behavior or response of the ISFSI facility, cask design**,** or an SSC. The change (i.e. helium leak rate test) is not an element of the method of evaluation, but rather it is a test, which is not part of the calculational framework. Therefore, this proposed activity does not involve a change to a method of evaluation, and the method used is identical to that for the original configuration as described in the FSAR.

4. [NEI 5.0 and 5.2]: Does the proposed activity involve 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 cask FSAR?

Response: No. This proposed activity involves a fabrication shop leakage test performed before the spent fuel cask is placed into service. Per 72.48 guidance Section 5.2, a test or experiment is defined as any SSC 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. This proposed activity meets neither of those criteria.

Conclusion: A 72.48 evaluation is required. One or more "yes" answers to the screening questions indicates a 72.48 evaluation is required to be performed. In this case, only Screen question 1 was answered 'yes', therefore, only evaluation questions 72.48(c)(2)( i-vii) are applicable.

**72.48 EVALUATION**

{*Prior NRC approval is required if Yes is answered to any of the following questions*}

[NEI 6.0, 2nd para]: "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. "Since only Screen question 1 was answered 'yes', then only the first 7 evaluation questions in 72.48 are applicable.

Question 1 [NEI 6.1]: Does the activity result in more than a minimal increase in the frequency of occurrence of an accident?

Response: No. The conduct of a fabrication shop leak test does not involve operation of the spent fuel cask. Thus performing the test or not has no effect on any accident initiators described in the cask FSAR.

Question 2 [NEI 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?

Response: No. The SSC involved is the DPC and the relevant design functions are decay heat removal and confinement. The FSAR describes the DPC pressure boundary as "leaktight," and no effluents are assumed to leak from the DPC. Helium leakage in the approved cask design was previously thought to be incredible based, in part, on the performance of a shop helium leak test to verify the confinement design function, and therefore this is not a previously evaluated malfunction. (However, leakage may result in a new malfunction and/or a malfunction with a different result, which will be addressed in Question 6.) This proposed activity does not change the design or construction of the DPC, including welding and non-destructive testing and pressure testing of the DPC required by ASME III, Subsection NB, as clarified by approved alternatives in the CoC.

Question 3 [NEI 6.3]: Does the activity result in more than a minimal increase in the consequences of an accident?

Response: No. The radiological consequences (dose to the public) of the accidents described in the cask FSAR, to the extent there are any, remain the same. The design of the DPC, the amount of DPC helium backfill, materials of construction, welding, and the source term of the allowed contents are unchanged by this proposed activity. Therefore, any offsite dose consequences based on these parameters would remain the same.

Question 4 [NEI 6.4]: Does the activity result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety?

Response: No. There are no malfunctions with radiological consequences (dose to the public) described in the cask FSAR. The design of the DPC, the amount of DPC helium backfill, and the source term of the allowed contents are unchanged by this proposed activity.

Question 5 [NEI 6.5]: Does the activity create a possibility for an accident of a different type?

Response: No. The proposed activity does not alter the operation of the spent fuel cask or how it is prepared for storage. Removal of the helium leak test is not an initiator of any accident and no new failure modes are introduced. Thus, there is no creation of an accident of a different type than previously described in the cask FSAR.

Question 6 [NEI 6.6]: Does the activity create a possibility for a malfunction of an SSC important to safety with a different result?

Response: Yes. A test that verifies the as-fabricated cask meets the approved design is being eliminated, and the SER states that the test was relied upon by the NRC to provide adequate assurance. The SSC involved is the DPC and the relevant design functions are decay heat removal and confinement. Eliminating the fabrication test would no longer provide one element of assurance that the as-fabricated cask is able to perform the design basis functions. Specifically, this would introduce the potential for a fabrication defect to go undetected, possibly resulting in the as-fabricated cask not being able to perform the FSAR described design functions. An unanticipated loss of helium from the DPC could cause the DPC to fail to perform both of these design functions in the manner (for confinement) and to the degree (for decay heat removal) described in the cask FSAR. This new malfunction of loss of DPC pressure boundary integrity would create a result different than that currently described in the cask FSAR.

The FSAR describes the DPC pressure boundary as “leaktight,” and no effluents are assumed from the DPC that would result in dose to workers or the public. This malfunction was previously thought to be incredible based, in part, on the performance of a shop helium leak test to verify the confinement design function. A malfunction that breaches the DPC confinement boundary would have a different result in the form of some amount of effluent dose to workers or the public, compared to the zero effluent dose currently described in the cask FSAR.

Question 7 [NEI 6.7]: Does the activity result in a design basis limit for a fission product barrier being exceeded or altered?

Response: No. The fission product barriers are the fuel cladding and the canister confinement boundary. The proposed change involves only a test that verifies the as-fabricated cask meets the approved design. Therefore, elimination of the test does not alter the approved design

basis limits, only whether the as-fabricated cask has been demonstrated to perform to those limits. The design basis limit for confinement, namely the leakage rate of the canister confinement boundary, is unchanged. There is no change to an analysis, design code, or other change that would alter or exceed any design basis limit for a fission product barrier. The DPC stress limits, design pressure, and design temperature all remain the same.

Conclusion: *Prior approval from the NRC is required* for eliminating the fabrication helium leak rate test, because the test was relied upon by the NRC, in the SER, to provide reasonable assurance that the as-fabricated cask performed the design functions. This activity, therefore, requires prior NRC approval because the activity results in the possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the UFSAR (Question 6).

### ADDITIONAL CONSIDERATIONS

The following variations to the main example demonstrate how small changes in the specific conditions can result in different conclusions from the 72.48 review.

**Variant 1 – SER is silent on the Helium Leak Test**

The SER does not include a discussion that the helium leak rate test was relied upon by the NRC to determine that there is reasonable assurance that no credible leakage would occur. The CoC Holder is proposing to replace the fabrication helium leak test with an alternative test (not eliminate as in the main example).

*Because the NRC did not rely on the helium leak rate test to determine there is reasonable assurance that no credible leakage would occur, then the actual test performed to verify the as-fabricated cask meets the approved design can be changed without prior NRC approval. In the original example, the answer to Question 6 was "yes" because the test was eliminated entirely, thus there was no verification that the as-fabricated cask meets the approved design. However, if the CoC holder were to replace the test with an equivalent test capable of verifying the as-fabricated cask meets the approved design (in this case capable of detecting helium leakage to the levels of the maximum allowable leakage rate), and the NRC did not rely on the helium leak rate test to provide reasonable assurance, then the answer to Question 6 would be no. Specifically, the new test provides the same level of assurance that the as-fabricated cask meets the approved design. It is noted that, even if replacing the test passed 72.48, the CoC holder would still have to evaluate the change in test type as to whether the new test meets the adequate test program and quality assurance program requirements.*

## EXAMPLE 4 – CHANGE IN CRITICALITY ANALYSIS CODE

### PROPOSED ACTIVITY

The computer code used by CoC Holder A is Code Alpha Version 1. Code Alpha, Version 1 is a Monte Carlo code that uses the ENDF-V 238 group-wise cross-sections in the software. The maximum calculated k-effective in the FSAR is 0.948.

CoC Holder A would like to use Code Alpha Version 2, the latest version, with the same ENDF-V 238 group-wise cross-sections used in Code Alpha Version 1. CoC Holder A reviewed the differences between Version 1 and 2 and concluded that most of the differences are minor and are related to improving the runtime. CoC Holder A did identify one difference in Version 2 that would classify as a change to an element of the method of evaluation, namely a different algorithm for convergence. The maximum calculated k-effective for Cole Alpha Version 2 is calculated to be 0.949.

The CoC holder also performed a comparison of Code Alpha Version 1 and Version 2 by benchmarking Code Alpha Version 2 to the same set of benchmark experiments. The criticality analysis methodology, including which uncertainties and biases are included, and how they are included in the calculated k-effective, is identical to the methods as they are described in the FSAR approved by the NRC. No changes to the analysis method are proposed, the only change is to the computer code used.

### NRC-APPROVED LICENSING BASIS

#### CoC, TS and Approved Contents

*Does not include the name of the computer code and does not include the maximum calculated k-eff. The only description in the CoC is a reference that the maximum calculated k-effective is in the FSAR.*

#### SER

*Describes that Code Alpha Version 1 was used and that the calculated maximum k-effective is less than 0.95, and therefore within the regulatory limit of sub-critical.*

#### FSAR

*Describes that Code Alpha Version 1 and the 238 group-wise cross-section library was used. Describes the set of benchmark experiments, mechanical and depletion uncertainties that were used in the analysis.*

**72.48 APPLICABILITY DETERMINATION**

*{72.48 applies unless "Yes" is answered to one or more of the three questions for <u>all</u> aspects of the proposed activity}*

[NEI 4.0.1]: Does the proposed activity involve a modification to the ISFSI, cask design or procedure in the ISFSI or cask FSAR or the 212 Report that is an editorial/administrative correction (4.3) or a modification to a managerial or administrative procedure governing the conduct of operations (4.4)?

Response: No. A change in the computer code, or another version, will require a change to the FSAR. The change is not editorial since it affects a computer code that was used to determine the design basis.

[NEI 4.0.2]: Does the proposed activity require a change to the ISFSI license or CoC, including appendices?

Response: No. Neither the CoC, nor the appendices, describe the computer code that was used. Therefore use of another computer code, or another version of the same computer code would not require a change in the CoC.

[NEI 4.0.3]: Does a different regulation provide more specific criteria for accomplishing the proposed activity?

Response: No.

Conclusion: *72.48 applies,* and the proposed activity must be screened.

**72.48 SCREENING**

*{72.48 evaluation is required if "Yes" is answered to any of the following questions}*

1. [NEI 5.0, 1st Bullet, 5.1.1, 5.1.2, and 5.1.3]: Does the proposed activity involve a change to a UFSAR-described design function of an SSC or cask design?

Response: No, changing the computer code, or version of the same code, is not a change to an SSC, but rather is associated with methods of evaluation. There is no effect on the design basis limits for fission product barriers since the system remains sub-critical.

2. [NEI 5.0, 2nd Bullet, 5.1.1, 5.1.2, and 5.1.4]: Does the proposed activity involve a change to a UFSAR-described method of performing or controlling a design function?

Response: No, changing the computer code, or version of the same code, does not involve a procedure, but rather is associated with methods of evaluation.

3. [NEI 5.0, 3rd Bullet, 5.1.1, 5.1.2, and 5.1.5]: Does the proposed activity involve 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?

Response: Yes: Because the computer code is part of the UFSAR safety analyses and established the design bases (in this case was used as part of the criticality analysis), then the computer code is an element of the existing methods described in the UFSAR. Changes to methods described in the UFSAR, such as changing the computer code, or version of the same code, must be evaluated under 10 CFR 72.48(c)(2)(viii).

4. [NEI 5.0 and 5.2]: Does the proposed activity involve 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 cask FSAR?

Response: No. Changing the computer code version does not involve a test or experiment.

Conclusion: *A 72.48 evaluation is required.* One or more "yes" answers to the screening questions indicates a 72.48 evaluation is required to be performed. In this case, only Screen question 3 is answered "yes." When only Screen question 3 is answered "yes," then only evaluation question 72.48(c)(2)(viii) (change in method of evaluation) is applicable.

**72.48 EVALUATION**

{*Prior NRC approval is required if Yes is answered to any of the following questions*}

[NEI 6.0, 2nd para]: "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."

Because only Screening question 3 is answered "yes", only 72.48 evaluation Question 8 (change in method of evaluation) is applicable.

Question 8 [NEI 6.8]: Does the activity result in departure from a method of evaluation used in establishing the design bases or in the safety analyses?

Response: No – not a departure from a method of evaluation as described below:

- Proposed change is to an element of a method of evaluation, since Code Alpha Version 1 is part of the calculational framework, i.e. it contains physical constants and mathematical models. {NEI Definition 3.17}

- Proposed change is <u>not</u> a departure, since the new results are conservative as compared to the results in the UFSAR. New calculated maximum k-effective with all biases and uncertainties is 0.949, compared with previous maximum calculated k-effective of 0.948

with all biases and uncertainties. Both approaches included the same benchmark experiments, and included the same biases and uncertainties. "*Results are conservative relative to the previous results if they are closer to design bases limits or safety analyses limits."* {NEI 3.17 and 6.8.1.1} In this case, the new result is closer to the regulatory limits, which is conservative.

Conclusion: *No prior approval from the NRC is required* to change from Code Alpha Version 1 to Code Alpha Version 2, since the change is to an element of the MOE, and the result is conservative or essentially the same. Thus, this change in an element of the MOE is not a departure in the MOE, and only changes that are categorized as departures in the MOE require prior NRC approval.

### ADDITIONAL CONSIDERATIONS

The following variations to the main example demonstrate how small changes in the specific conditions can result in different conclusions from the 72.48 review.

### Variant 1

CoC Holder A wishes to perform the criticality analysis using Code Bravo with a continuous energy cross-section library (i.e. change both the code and cross-section library). Code Bravo is a transport code, which is a different method of evaluation than the Monte Carlo method of Code Alpha. However, this code and cross-section library combination is used by CoC Holder B, which has an SER from the NRC. CoC Holder B's SER states that Code Bravo was used with the continuous energy cross-section library, and cask B's FSAR describes the set of benchmark critical experiments that demonstrates the cask is within the area of applicability for this combination of code and cross-section library. CoC Holder B used the same benchmarks as CoC Holder A in the original FSAR. CoC Holder A using Code Bravo and the continuous energy cross-section library, and including the same biases and uncertainties that are described in the FSAR, calculates a maximum k-effective of 0.949.

Topical Report's SER: *Describes that Code Bravo was used with a continuous-energy cross-section library.*

*Prior NRC approval* is not *required.* A change to the code and cross-section library combination is a change to a new method of evaluation. However, since the new method of evaluation has already been approved for the intended application by the NRC in an SER, it is not a departure from a MOE. In this case, CoC Holder A demonstrates that their application of the MOE is the same as the CoC Holder B's MOE (e.g. same intended application) by using the same set of benchmark critical experiments (i.e. same set described in cask A FSAR and cask B FSAR), and by demonstrating that the cask design is within the area of applicability of the benchmark critical experiments.

Conclusion: *No prior approval from the NRC is required* to change from Code Alpha Version 1 with 238 group-wise cross sections to Code Bravo with continuous energy cross-sections, since the change is to a new MOE that has previously been reviewed and approved for the intended application by the NRC in an SER. Thus, this change to a new MOE is not a departure in the MOE, and only changes that are categorized as departures in the MOE require prior NRC approval.

**Variant 2**

CoC Holder A makes a slight increase in the basket cell wall thickness. There is no change to the center-to-center spacing, or any other parameter listed in the CoC/TS, and therefore a change to the CoC/TS is not needed. CoC Holder A performs the criticality analysis according to the methods described in the FSAR, including using Code Alpha, Version 1 with the 238 group-wise cross-section library. There is no change in method of evaluation. The new criticality analysis for the revised basket cell wall thickness results in no change in the maximum calculated k-effective described in the FSAR.

*{Note this case is not a change in method of evaluation, but is a change to an input parameter}*

*Since the basket cell wall thickness is an input parameter to the criticality analysis, and not an element of the method of evaluation, this case would be evaluated under 72.48(c)(i) to (vii), and would not be evaluated under 72. 48(c)(viii) as a change to the method of evaluation. If the 72.48 evaluation demonstrates that the proposed activity does not result in 1) more than a minimal increase in the frequency of occurrence of an accident, 2) more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety, 3) more than a minimal increase in the consequences of an accident, 4) more than a minimal increase in the consequences of a malfunction, 5) a possibility for an accident of a different type, 6) a possibility for a malfunction of an SSC important to safety with a different result, 7) a design basis limit for a fission product barrier being exceeded or altered, then prior NRC approval <u>is not</u> required.*

## EXAMPLE 5 – REDUCTION IN DIAMETER OF CONCRETE OVERPACK

### PROPOSED ACTIVITY

The storage system is a vertical canister-based system with a cylindrical concrete ventilated outer cask. The CoC holder seeks to reduce the diameter of the outer concrete cask by 12 inches (six inches radially) in order to meet the needs of a particular cask user. The remaining characteristics of the cask structure, concrete, reinforcing bar, etc. remain the same. Structurally the modified cask meets all acceptance criteria for normal, off-normal, and accident conditions (e.g., cask drop and tipover). All other technical evaluations remain unaffected.

The shielding calculations for the proposed modification to the concrete cask indicate that if the current design basis fuel assembly is used in all storage locations, the dose rate limit specified in the CoC cannot be met. The CoC holder revises its shielding calculation for the proposed modification to change the design basis fuel assembly to reflect only the limiting combinations of cooling time and burnup permitted for loading in the cask (5 years & 35,000 MWd/MTU; 10 years & 50,000 MWd/MTU; and 15 years & 65,000 MWd/MTU), rather than the conservative 5 years cooled, 65,000 MWd/MTU burned assembly. A sufficient number of cooling time/burnup combinations are analyzed to ensure the CoC dose rate limit is not exceeded. In fact, across the board, the calculated dose rates are less than the CoC limit for all cooling time/burnup combinations.

Performing the shielding analysis for the reduced diameter cask yields surface dose rates within the CoC/TS limits for all selected cooling time/burnup combinations when applying the same method as used for the original diameter cask.

### NRC-APPROVED LICENSING BASIS

The licensing basis for the cask system, comprised of the CoC (including Appendix A and Appendix B), the SER, and the FSAR (as updated) describe a canister-based, vertical storage cask system.

The CoC and TS are silent with respect to the diameter of the concrete cask. The description of the cask system in the SER and FSAR (including drawings), and the supporting structural, thermal and shielding analyses are more detailed.

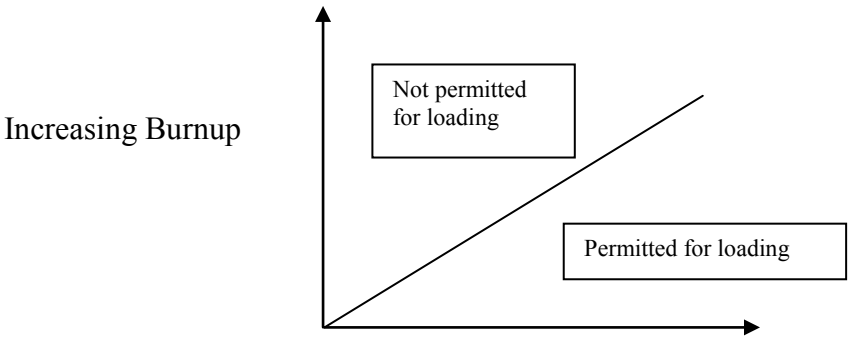
### CoC, TS and Approved Contents

*The CoC description states that the cask system consists of the canister, which contains the spent fuel, and the concrete cask, which contains the canister during storage. The CoC describes the concrete cask as the storage overpack which provides structural support, confinement, shielding, protection from environmental conditions, and natural convection*

*cooling of the canister during long term storage. It further describes the storage cask as a reinforced concrete structure with a carbon steel inner liner. The concrete cask has an annular air passage to allow passive convection air flow around the canister.*

*The CoC permits loading fuel cooled as little as five years and burned as high as 65,000 MWd/MTU, although not in that combination. The design basis shielding analysis uses a hypothetical 5-year cooled, 65,000 MWd/MTU fuel as the design basis assembly in all fuel storage locations. The NRC's SER does not discuss the choice to assume design basis assembly in all locations. The CoC includes a contact dose rate limit at the cask mid-plane that was determined by calculation, using the design-basis fuel assembly.*

*The CoC permits fuel to be loaded into the storage system in accordance with a burnup/cooling time graph as follows:*




*Limiting combinations of cooling time and burnup for fuel assemblies that are permitted for loading (i.e., they fall on the line in the graph) are:*

*5 years, 35,000 MWd/MTU*

*10 years, 50,000 MWd/MTU*

*15 years, 65,000 MWd/MTU*

*Thus, the design basis fuel assembly used in the shielding analysis, cooled 5 years and having a burnup of 65,000 MWd/MTU is clearly in the "Not Permitted for Loading" Zone of the CoC graph.*

*The CoC Appendix A, Design Features, includes a maximum surface dose rate for the concrete cask.*

**72.48 APPLICABILITY DETERMINATION**

*{72.48 applies unless "Yes" is answered to one or more of the three questions for <u>all</u> aspects of the proposed activity}*

[NEI 4.0.1]: Does the proposed activity involve a modification to the ISFSI, cask design or procedure in the ISFSI or cask FSAR or the 212 Report that is an editorial/administrative correction (4.3) or a modification to a managerial or administrative procedure governing the conduct of operations (4.4)?

Response: No. This modification involves a change to the concrete cask design as described in the cask FSAR. It also changes the depictions and description of the cask system in several figures, license drawings and text in the FSAR.

[NEI 4.0.2]: Does the proposed activity require a change to the ISFSI license or CoC, including appendices?

Response: No. Neither the CoC, nor the appendices, describe the diameter of the over-pack, or the conservative five-year burned 65,000 MWd/MTU design basis combination. The burnup-cooling time limits are not being changed in the CoC or appendices. Changes are only being made to the assumed burnup-cooling time limits assumed in the shielding analyses. No change to either of the CoC or the TS is required.

[NEI 4.0.3]: Does a different regulation provide more specific criteria for accomplishing the proposed activity?

Response: No.

Conclusion*: 72.48 applies,* and the proposed activity must be screened.

**72.48 SCREENING**

*{72.48 evaluation is required if "Yes" is answered to any of the following questions}*

1. [NEI 5.0, 1st Bullet, 5.1.1, 5.1.2, and 5.1.3]: Does the proposed activity involve a change to a UFSAR-described design function of an SSC or cask design?

Response: Yes. Because the effect of reducing the cask diameter is such that existing safety analyses (shielding analyses) are no longer bounding and therefore FSAR safety analyses must be re-run to demonstrate that all required safety functions and design requirements are met, the change is considered to be adverse. It is noted that the shielding analysis for the new configuration still comply with the TS limit. Structurally, the modified cask meets all acceptance criteria for normal, off-normal, and accident conditions. Structural, thermal,

criticality and confinement analyses remain unaffected as the results of the original analyses contained in the FSAR bound the new configuration.

2. [NEI 5.0, 2nd Bullet, 5.1.1, 5.1.2, and 5.1.4]: Does the proposed activity involve a change to a UFSAR-described method of performing or controlling a design function?

Response: No. Procedures performing or controlling FSAR described SSC design functions remain unchanged by the proposed modification. Reducing the diameter of the concrete cask does not alter any procedure that adversely affects how the design functions of the concrete cask are performed or controlled.

3. [NEI 5.0, 3rd Bullet, 5.1.1, 5.1.2, and 5.1.5]: Does the proposed activity involve 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?

Response: No. The change (i.e. cask diameter) is not an element of the method of evaluation, but rather it is an SSC, which is not part of the calculational framework. The method used is identical to that for the original configuration as described in the FSAR. The reduced diameter of the concrete cask is an input to the shielding analysis, not an element of the method of evaluation.

4. [NEI 5.0 and 5.2]: Does the proposed activity involve 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 cask FSAR?

Response: No. This change is not a test or experiment because it is intended to be a permanent modification for an alternate design that will perform in the same manner in which the cask provides for safe storage of the spent fuel as described in the FSAR (as updated).

Conclusion: *A 72.48 evaluation is required.* One or more "yes" answers to the screening questions indicates a 72.48 evaluation is required to be performed. In this case, only Screen question 1 was answered 'yes', therefore, only evaluation questions 72.48(c)(2)(i-vii) are applicable.

**72.48 EVALUATION**

{*Prior NRC approval is required if Yes is answered to any of the following questions*}

[NEI 6.0, 2nd para]: "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."

Since only Question 1 was answered 'yes', then only the first seven evaluation questions, 72.48(c)(2)(i—vii), are applicable.

Question 1 [NEI 6.1]: Does the activity result in more than a minimal increase in the frequency of occurrence of an accident?

Response: No. Reduction of the concrete cask diameter does not increase the likelihood of occurrence any of the accidents previously evaluated in the FSAR because the smaller cask diameter is not an accident initiator.

Question 2 [NEI 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?

Response: No. The affected design function is shielding of the spent fuel content. The modified cask meets all acceptance criteria for normal, off-normal and accident conditions. Shielding is provided by the concrete cask as a passive system. No malfunctions of passive systems are evaluated in the FSAR (as updated).

Question 3 [NEI 6.3]: Does the activity result in more than a minimal increase in the consequences of an accident?

Response: No. The radiological consequences of all accidents described in the FSAR remain the same as currently evaluated because loading of fuel in the modified cask system is limited to a combination of cooling time and burnup which meets the CoC limit for maximum surface dose rate.

Question 4 [NEI 6.4]: Does the activity result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety?

Response: No. The concrete cask storage system is a passive system. No malfunctions are described in the FSAR (as updated) for the passive storage system. Reducing the diameter of the concrete cask by 12 inches will not result in any increase in the radiological consequences of a malfunction of any SSC important to the safety of the storage system.

Question 5 [NEI 6.5]: Does the activity create a possibility for an accident of a different type?

Response: No. Reduction of the concrete cask diameter by 12 inches does not create the possibility of occurrence of a different accident previously not evaluated in the FSAR because the accidents for the reduced-diameter cask are bounded by the accidents for the original diameter cask.

Question 6 [NEI 6.6]: Does the activity create a possibility for a malfunction of an SSC important to safety with a different result?

Response: No. The concrete cask storage system is a passive system. No malfunctions are described in the FSAR (as updated) for the passive storage system. Reducing the diameter of

the concrete cask by 12 inches will not result in creating the possibility of a malfunction of any SSC important to safety of the storage system with a different result.

Question 7 [NEI 6.7]: Does the activity result in a design basis limit for a fission product barrier being exceeded or altered?

Response: No. The fission product barriers are the fuel cladding and the canister confinement boundary. Reducing the diameter of the concrete cask by 12 inches will not result in any change to these fission product barriers

Conclusion: *No prior approval from the NRC is required* for this change because questions 1-7 of the 72.48 evaluation are answered "no."

### ADDITIONAL CONSIDERATIONS

The following variations to the main example demonstrate how small changes in the specific conditions can result in different conclusions from the 72.48 review.

### Variant 1

The design basis in the cask FSAR includes fuel assemblies with 5-year cooling time and 65,000 MWd/MTU burnup. The SER recognizes the 5-year cooled, 65,000 MWd/MTU design basis fuel assembly was chosen conservatively, however this was the basis for the NRC approval of the cask design and contents.

The CoC holder re-performs its shielding calculation for the proposed modification to change the design basis fuel assembly to reflect only the limiting combinations of cooling time and burnup permitted for loading in the cask (5 years & 35,000 MWd/MTU; 10 years & 50,000 MWd/MTU; and 15 years & 65,000 MWd/MTU), rather than the conservative 5 years cooled, 65,000 MWd/MTU burned assembly. A sufficient number of cooling time/burnup combinations are analyzed to ensure the CoC dose rate limit is not exceeded. In fact, across the board, the calculated dose rates are less than the CoC limit for all cooling time/burnup combinations.

*Screening – Answer to Q- 3 is "Yes." Changing the design basis fuel assembly to reflect only the limiting combinations of cooling time and burnup permitted for loading in the cask has an adverse impact on the previously-approved user-inputs to the combination of cooling time/burnup, which represent an "element of the method." Use of the new combinations reduces the conservatism provided by this "element."*

*Evaluation – Answer to Q-8: Yes. Revision of the MOE (changing assumed fuel parameters) would have non-conservative results, i.e. further from design limit (for an equivalent cask diameter for the original design), therefore the results are not 'essentially the same' or 'conservative' and it is a departure from a MOE, which requires prior NRC approval.*

# EXAMPLE 6 – INSTALLATION OF AN ENCLOSURE STRUCTURE OVER THE CASKS

## PROPOSED ACTIVITY

The storage system is a canister-based system with a concrete outer structure (e.g., a ventilated vertical cask). A Part 72 specific licensee seeks to modify the ISFSI facility to include an enclosure structure with a roof and walls, open at the bottom and top approximately 6 inches, around the entire perimeter of the ISFSI, for aesthetic improvement. The structure includes vertical support posts at the corners and several intermediate locations anchored to the ISFSI pad to ensure it stays in place.

No modifications to the storage cask or canister are proposed. The structure design has been successfully analyzed to remain in place under all applicable design conditions, such as tornado winds and missiles, fire, and earthquake. The structure is located far enough away from the nearest cask that there will be no physical interaction between the casks and the structure under any normal, off-normal or accident condition.

The casks and enclosure structure are modeled using the thermal analysis computer code and version of record documented in the ISFSI FSAR. The results of the thermal analysis all show that the component and fuel cladding temperatures remain within applicable limits, although the margins to those limits are smaller due to the reduced rate of convection at the cask surface. Likewise, thermal stresses increase but remain within the code allowables for normal, off-normal, and accident conditions.

## NRC-APPROVED LICENSING BASIS

The current licensing basis (CLB) for the cask system, comprised of the ISFSI license, (including technical specifications (TS) Safety Evaluation Report (SER), and ISFSI FSAR describe a canister-based, vertical storage cask system.

### License and TS

> *The license and TS are silent with respect to the presence of a separate outer structure around the casks. The license description states that*[3] *"the cask system is comprised of the canister, which contains the spent fuel, the storage cask, which contains the canister during storage, and the transfer cask, which contains the canister during loading, transfer, and*

[3] Quotations represent "actual" language from a fictitious license approved by the NRC. The intent here is to provide a licensing basis that does not have language in the license/TS that immediately requires NRC approval for this modification. The exercise is intended to use the questions in 72.48(c) to determine whether NRC approval is required for the modification.

*unloading operations." It further describes the canister as "the confinement boundary" and describes how the "canister basket and neutron absorbers provide criticality control." It also describes the subcomponents of the canister closure system.*

*The license describes the storage cask as "the storage overpack which provides shielding, structural protection and natural convection cooling during storage operations." It further describes the storage cask as "a reinforced concrete structure with a steel inner wall to provide standoff to minimize impact loads on the canister and to provide an annular space for convection air cooling. The storage cask has air inlets and outlets to provide for cooling air flow past the canister."*

*Decay heat removal from the fuel is described in the license as follows: "The spent fuel decay heat is transferred from the fuel assemblies to the canister shell using pressurized helium circulated by natural convection through the fuel basket, conduction, and radiation heat transfer. Heat flows by convection from the canister shell to the circulating air and by radiation from the canister shell to the storage cask inner wall. The heated air, driven by buoyancy, is released from the air outlet vents at the top of the cask, which in turn draws cooler air into the inlet vents at the bottom of the cask. The top of the storage cask is closed by a bolted lid."*

*The design features in the TS include an ambient temperature limit for the ISFSI but otherwise do not address whether the cask surface is directly exposed to the ambient environment or if another structure may be in the intervening space.*

**SER**

*The SER essentially repeats the descriptive information from the license and finds the design acceptable. The technical specifications include a requirement to "inspect the air inlet and outlet screen to ensure no blockage exists."*

**FSAR**

Figures and text in the FSAR show the cask in storage in an open-air environment, without any surrounding structure. There is no minimum airflow requirement through the cask specified in the cask FSAR.

### 72.48 APPLICABILITY DETERMINATION

*{72.48 applies unless "Yes" is answered to one or more of the three questions for <u>all</u> aspects of the proposed activity}*

[NEI 4.0.1]: Does the proposed activity involve a modification to the ISFSI, cask design or procedure in the ISFSI or cask FSAR or the 212 Report that is an editorial/administrative

correction (4.3) or a modification to a managerial or administrative procedure governing the conduct of operations (4.4)?

Response: No. This modification involves a change to the ISFSI facility that affects cask decay heat removal system and associated thermal analysis as described in the ISFSI FSAR. It also changes the depictions of the ISFSI as shown in several figures in the FSAR.

[NEI 4.0.2]: Does the proposed activity require a change to the ISFSI license or CoC, including appendices?

Response: No. The change does not require a change to the ISFSI license or TS.

[NEI 4.0.3]: Does a different regulation provide more specific criteria for accomplishing the proposed activity?

Response: No.

Conclusion: *72.48 applies* and the proposed activity must be screened. The modification also requires review under plant programs governed by other regulations, including security, fire protection, and 50.59.

**72.48 SCREENING**

{*72.48 evaluation is required if "Yes" is answered to any of the following questions*}

1. [NEI 5.0, 1st Bullet, 5.1.1, 5.1.2, and 5.1.3]: Does the proposed activity involve a change to a UFSAR-described design function of an SSC or cask design?

Response: Yes. The modification adversely affects the conditions under which the heat transfer from the fuel is performed. Namely, the conditions no longer involve an "open-air" environment. The revised thermal analysis indicates decreased convection heat transfer from the surface of the cask due to the presence of the enclosure. Furthermore, the addition of an outer enclosure adversely affects the heat removal design function, and the analysis of the heat removal, because the heat must now be transferred through two regions to get to the ambient, rather than one: the current annular region inside the cask and the additional region between the cask and the enclosure. In addition, radiant heat results in an increase in average ambient temperature that surrounds the cask.

2. [NEI 5.0, 2nd Bullet, 5.1.1, 5.1.2, and 5.1.4]: Does the proposed activity involve a change to a UFSAR-described method of performing or controlling a design function?

Response: No. The proposed activity does not involve a change to a procedure that includes information on how SSCs are operated or controlled.

3. [NEI 5.0, 3rd Bullet, 5.1.1, 5.1.2, and 5.1.5]: Does the proposed activity involve 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?

Response: No. The thermal analysis for the modification was performed using the same thermal analysis computer code and version as previously used for analyzing the "open air" configuration of the ISFSI. The computer code includes tools and instructions for modeling both casks directly in the ambient environment and inside a structure with openings all around. All previously-approved user-inputs to the model that would qualify as "elements of the method" remain unchanged in modeling the structure.

4. [NEI 5.0 and 5.2]: Does the proposed activity involve 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 cask FSAR?

Response: No. This modification does not constitute a test or experiment because it is intended to be a permanent modification that maintains the manner in which the casks provide for safe storage of the fuel as described in the ISFSI FSAR.

Conclusion: A 72.48 evaluation is required. One or more "yes" answers to the screening questions indicates a 72.48 evaluation is required to be performed. In this case, only Screen question 1 was answered 'yes', therefore, only evaluation questions 72.48(c)(2)(i-vii) are applicable.

**72.48 EVALUATION**

{*Prior NRC approval is required if Yes is answered to any of the following questions*}

[NEI 6.0, 2nd para]: "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."

Since only Screen question 1 was answered "yes," then only the first seven evaluation questions, 72.48(c)(2)(i—vii), are applicable.

Question 1 [NEI 6.1]: Does the activity result in more than a minimal increase in the frequency of occurrence of an accident?

Response: No. The presence of a structure around the storage casks does not increase the frequency of occurrence of any of the accidents previously evaluated in the ISFSI FSAR because the structure has no physical connection to the casks and the structure. The structure does not affect the manner in which the casks are loaded, lifted, moved, placed in their designated storage locations at the ISFSI, or operate to store the spent fuel. Thus, this proposed change does not affect an accident initiator as described in the ISFSI FSAR.

Question 2 [NEI 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?

Response: No. The storage cask is a completely passive system. No malfunctions of passive equipment are evaluated in the ISFSI FSAR. The presence of the structure does not make the occurrence of any environmental events (extreme ambient temperature, earthquake, tornado) more likely than they currently are because they are driven by the geographic location of the ISFSI, which is not affected by the structure.

Question 3 [NEI 6.3]: Does the activity result in more than a minimal increase in the consequences of an accident?

Response: No. The radiological consequences of all accidents described in the ISFSI FSAR remain the same as currently evaluated because the canister confinement boundary remains intact under all normal, off-normal, and accident conditions with the structure in place. The structure provides additional shielding for direct radiation beyond that currently credited in the cask FSAR. The proposed change does not alter the contents approved for storage, thus the source term available for release remains the same are currently analyzed.

Question 4 [NEI 6.4]: Does the activity result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety?

Response: No. There are no radiological consequences of a malfunctions described in the ISFSI FSAR because there are no malfunctions of the cask described in the ISFSI FSAR for this completely passive system.

Question 5 [NEI 6.5]: Does the activity create a possibility for an accident of a different type?

Response: No. An analysis of the drop of the structure onto the casks during installation shows that the effects of the structure drop are bounded by the existing tornado missile analysis for the cask. Because the structure includes a continuous gap around the roof and walls to facilitate heat removal, the structure maintains cooling air flow in a passive manner with a large amount of unrestricted flow area into and out of the structure. The potential blockage of these gaps has been determined by analysis to be bounded by the previously evaluated accident postulating the blockage of the cask vents.

Question 6 [NEI 6.6]: Does the activity create a possibility for a malfunction of an SSC important to safety with a different result?

Response: No. The design function is the casks' ability to allow for natural circulation of air through the annulus between the fuel canister and the storage cask through the strategic locations of the air inlet and outlet vents. The result of any potential malfunction initiated by the failure of the structure are bounded by those described in the ISFSI FSAR. Therefore there is not a possibility of malfunction with a different result than previously evaluated in the ISFSI FSAR.

Question 7 [NEI 6.7]: Does the activity result in a design basis limit for a fission product barrier being exceeded or altered?

Response: No. The fission product barriers are the fuel cladding and the canister confinement boundary. The presence of the structure has been analyzed for normal, off-normal, and accident conditions and all component and fuel cladding temperatures remain within the existing design basis limits (i.e., code stresses, fuel cladding temperature less than 752$^{o}$F (normal) and 1058$^{o}$F (accident)).

Conclusion: *No prior approval from the NRC is required* for this change because questions 1-7 of the 72.48 evaluation are answered "no."

### ADDITIONAL CONSIDERATIONS

The following variations to the main example demonstrate how small changes in the specific conditions can result in different conclusions from the 72.48 review.

### Variant 1

A sun-cover structure with no walls is installed over the ISFSI, instead of the structure proposed in the original example.

Provided the elevation of the sun cover is high enough that its presence is inconsequential (or positive by reducing heat input via insolation) for the thermal analysis, this variant would screen out and not require a full 72.48 evaluation.

### Variant 2

A full structure with roof and walls extending the full height of the structure and having a sufficient number of louvered vents to permit adequate, but not unfettered air flow, requiring specific modeling of the louver size and pressure drop.

This would require prior NRC review and approval for one of two reasons:

1. Because the ISFSI TS currently require inspection of the cask vents to ensure they are not blocked, it could be concluded by the licensee that a similar TS would be required for the louvers in the structure because flow through the louvers is just as essential for heat removal as flow through the cask vents, or

2. This modification would require a full 72.48 evaluation for the same reason as the base case – it is an adverse change to the thermal performance of the cask. The answer to 72.48 Question 6 (malfunction with a different result) in this case would be "yes." The presence of the structure and blockage of some or all of the structure louvers would increase the ambient temperature inside the structure, potentially beyond that considered for the extreme ambient temperature condition currently analyzed in the ISFSI FSAR.