

NRC INSPECTION MANUAL

IRIB

INSPECTION MANUAL CHAPTER 0335

CHANGES, TESTS, AND EXPERIMENTS

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ATTACHMENT 1 Revision History for IMC 0335

Att1-1

0335-01 PURPOSE

To provide the regulatory background of Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 50.59, “Changes, tests and experiments,” and 72.48, “Changes, tests, and experiments.” This guidance is intended to assist staff when reviewing licensee evaluations of changes in the facility or spent fuel storage cask design as described in the final safety analysis report (FSAR) (as updated), changes in the procedures as described in the FSAR (as updated), and tests or experiments not described in the FSAR (as updated), without obtaining a license amendment.

Inspectors should recognize the following regarding the content of this Inspection Manual Chapter (IMC):

- 10 CFR 50.59 uses the term “FSAR (as updated).” For simplicity in this IMC, the acronym “UFSAR,” which is synonymous with “FSAR (as updated),” will be used.
- The guidance in this IMC is based on underlying documents such as the regulations in 10 CFR 50.59 and 72.48, Statements of Consideration (SOCs) (specifically the 1999 final rule SOCs for 50.59 at 64 Fed. Reg. 53582, referred to herein as, “the SOCs”), Nuclear Energy Institute (NEI) 96-07, “Guidelines for 10 CFR 50.59 Evaluations,” Revision 1, etc. This IMC does not provide new guidance interpreting 10 CFR 50.59.
- All documents referenced in this IMC are listed in Section 9, “References.”

0335-02 OBJECTIVES

02.01 To provide inspectors guidance regarding the review of licensee or spent fuel storage cask certificate holder applicability determinations, screening, and evaluations of changes, tests, and experiments (CTEs),

02.02 To ensure inspectors review licensee CTE applicability determinations, screening, and evaluations consistently throughout the agency utilizing sound engineering practices, and

02.03 To provide inspectors references to guidance/documents available to aid when assessing licensee CTE applicability determinations, screening, and evaluations.

0335-03 APPLICABILITY

As described in 10 CFR 50.59(b), the requirements of 10 CFR 50.59 apply to holders of operating licenses under Part 50 and combined licenses under Part 52. Licensees are required to follow 10 CFR 50.59 when making changes to their facility as described in their UFSAR, making changes to procedures as described in their UFSAR, and when considering the conduct of tests or experiments not described in their facility UFSAR. 10 CFR 50.59 applies to power and non-power reactors that are authorized to operate and reactors (both power and non-power) that have permanently ceased operations.

10 CFR 72.48 provides parallel requirements applicable to Independent Spent Fuel Storage Installation (ISFSI) or monitored retrievable storage (MRS) license holders and holders of Nuclear Regulatory Commission (NRC) Certificates of Compliance (CoC) for a spent fuel storage cask design.

Licensees may also have procedures to implement the guidance of NEI 96-07, Revision 1, and NEI 12-04, "Guidelines for 10 CFR 72.48 Implementation," Revision 2.

0335-04 DEFINITIONS

04.01 Change: A modification or addition to, or removal from, the reactor/ISFSI/MRS facility, or spent fuel storage cask design, or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

04.02 Departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses: (1) Changing any of the elements of the method described in the UFSAR unless the results of the analysis are conservative or essentially the same; or (2) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Analytical results from changing any element of a method are "conservative" relative to results from the previous method if closer to the design basis limits or safety analyses limits. Results are "essentially the same" if they are within the margin of error needed for the type of analysis being performed, even if tending in the nonconservative direction.

04.03 Methods of evaluation: The calculational framework used for evaluating behavior or response of the reactor/ISFSI/MRS, cask design, or any structure, system, and component (SSC). This includes but isn't limited to the following elements of methodology (to the extent that they are described or applicable for a particular method):

- a. Data correlations,
- b. Means of data reduction,
- c. Physical constants or coefficients,
- d. Mathematical models,
- e. Specific assumptions in a computer program,
- f. Specified factors to account for uncertainty in measurements or data,
- g. Statistical treatment of results, and
- h. Dose conversion factors and assumed source term(s).

04.04 Input parameters: Those values derived directly from the physical characteristics of SSCs or processes in the facility/ISFSI/cask design. These would include such things as: flow rates, temperatures, pressures, dimensions or measurements (e.g., volume, weight, size), or system response times. Changes to input parameters described in the UFSAR are considered facility changes that would be evaluated under 10 CFR 50.59(c)(2)(i)-(vii), but not criterion (viii).

04.05 Facility or Spent Fuel Storage Cask Design as described in the UFSAR: (1) The SSCs that are described in the UFSAR, (2) the design and performance requirements for such SSCs described in the UFSAR, and (3) the evaluations or methods of evaluation (MOEs) included in the UFSAR for such SSCs which demonstrate that their intended function(s) will be accomplished.

Some SSCs or subcomponents may not be explicitly described in the FSAR, but they have the potential to affect the function of an SSC that is described. Some changes to a component or procedure could affect the SSC design functions. If a change to that (non-described) component could adversely affect any UFSAR-described design function or method of performing or controlling the design function, then that change requires evaluation under 10 CFR 50.59 or 72.48.

04.06 Facility as described in 10 CFR 72.48: Either an ISFSI or a MRS facility: For specific licensees, the “facility” is the ISFSI described in the Part 72 UFSAR. For general licensees, the “facility” is the ISFSI described in the evaluation report for 10 CFR 72.212 (212 Report) (see section 07.07 for further details on 212 Reports).

04.07 Final Safety Analysis Report (as updated): As used throughout this guidance document, UFSAR is synonymous with “FSAR (as updated).” For reactor licensees, the UFSAR (or Final Hazards Summary Report) submitted in accordance with 10 CFR 50.34, “Contents of applications; technical information,” as amended and supplemented, and as updated per the requirements of 10 CFR 50.71, “Maintenance of records, making of reports,” Section 50.71(e) or (f), as applicable.

For specific licensees and CoC holders, the FSAR submitted in accordance with 10 CFR 72.4 within 90 days after issuance of the license and after the spent fuel storage cask design approved pursuant to 10 CFR 72.238, respectively.

The UFSAR for specific licensees and CoC holders is always the latest revision updated thereafter, pursuant to 10 CFR 72.70 and 10 CFR 72.248, respectively, as supplemented by changes authorized under the provisions of 10 CFR 72.48. For general licensees, the CoC holder owns and maintains the UFSAR for the cask design(s) used at the ISFSI. The UFSAR for the general licensee is the UFSAR revision used for the specific loaded cask(s), and as revised by any applicable 10 CFR 72.48 changes made by the CoC holder and the general licensee.

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 incorporated by reference are not considered part of the UFSAR and therefore are not subject to control under 10 CFR 50.59 and 10 CFR 72.48.

04.08 Procedures as described in the UFSAR: Those procedures that contain information described in the UFSAR such as how SSCs are operated and controlled (including assumed operator actions and response times). See definition 04.06 for discussion on the scope of information that is the focus of 10 CFR 72.48.

For purposes of 10 CFR 50.59 and 10 CFR 72.48, “procedures” are not limited to plant procedures specifically identified in the UFSAR (e.g., operating and emergency procedures). Procedures include UFSAR descriptions of how actions related to system operation are to be performed and controls over the performance of design functions. This includes UFSAR descriptions of operator action sequencing or response times, certain descriptions (text or figure) of SSC operation and operating modes, operational and radiological controls, and similar information. If changes to these activities or controls are made, such changes are considered changes to procedures described in the UFSAR and are subject to 10 CFR 50.59 and/or 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 50.59 or 10 CFR 72.48.

04.09 Reference Bounds: 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.

04.10 Tests or experiments not described in the UFSAR: Any activity where any SSC is utilized or controlled in a manner which is either (1) outside the reference bounds of the design bases as described in the UFSAR, or (2) inconsistent with the analyses or descriptions in the UFSAR.

As stated in the 1999 SOCs, the intent of the requirement (i.e., 10 CFR 50.59) is that tests that put the facility/ISFSI/or cask design in a situation that has not previously been evaluated or that could affect the capability of SSC to perform their intended functions should be evaluated before they are conducted.

04.11 Design basis events: Conditions of normal operation, including anticipated operational occurrences, design basis accidents (DBAs), external events, and natural phenomena for which the plant/ISFSI has been designed to ensure the integrity of the pressure boundary, the capability to shutdown safely, and the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures.

04.12 Accident previously evaluated in the UFSAR: A DBA or event described in the UFSAR including accidents, transients and events the facility is required to withstand such as but not limited to floods, fires, earthquakes, other external hazards; reactor licensee's also include but are not limited to anticipated transients without scram, pressurized thermal shock events, and station blackout.

04.13 Design Function: 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.

04.14 Design bases functions: Functions performed by SSCs that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, orders or technical specifications (TS), or (2) credited in licensee safety analyses to meet NRC requirements.

04.15 Design Bases: Per 10 CFR 50.2, "Definitions," and 72.3, that information which identifies the specific functions to be performed by an SSC of a facility or storage cask and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or (2) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which an SSC must meet its functional goals.

04.16 Malfunction of SSCs important to safety: The failure of SSCs to perform their intended design functions described in the UFSAR. For reactor licensees, this means whether or not the SSC is classified as safety-related.

04.17 Screening: As discussed in NEI 96-07, Revision 1, and NEI 12-04, Revision 2, screening is a licensee process for determining whether a proposed activity requires a 10 CFR 50.59 or 10 CFR 72.48 evaluation.

The definitions of "change," "facility as described in the UFSAR (as updated)," "procedures as described in the FSAR (as updated)" and "test or experiment not described in the FSAR (as updated)" constitute criteria for the licensee's screening process, and is used to determine the need for a 10 CFR 50.59 or 10 CFR 72.48 evaluation. Activities that do not meet these criteria are said to "screen out" from further review under 10 CFR 50.59 or 10 CFR 72.48, i.e., the activities may be implemented without a 10 CFR 50.59 or 10 CFR 72.48 evaluation.

0335-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director/Deputy Director, Division of Reactor Oversight (DRO), Office of Nuclear Reactor Regulation (NRR)

- a. Coordinates development and revision preparation to the manual chapter,
- b. Serves as the NRR contact with the regional offices for guidance development and implementation.

05.02 Branch Chief, Reactor Inspection Branch (NRR/DRO/IRIB)

- a. Reviews and approves the technical content of periodic revisions to the content contained in the manual chapter.
- b. Serves as the program owner for 10 CFR 50.59 inspection issues.

05.03 Director/Deputy Director, Division of Fuel Management (DFM), Office of Nuclear Material Safety and Safeguards (NMSS)

- a. Directs the activities of the DFM and is responsible for their implementation.
- b. Approves the inspection program and procedures for activities.

05.04 Branch Chief, Inspection and Oversight Branch (NMSS/DFM/IOB)

- a. Reviews and approves the technical content of periodic revisions to the content contained in the manual chapter.
- b. Serves as the program owner for 10 CFR 72.48 inspection issues.

The requirements allowing licensees to make changes to their facilities and procedures or to conduct tests or experiments without prior NRC approval are contained in 10 CFR 50.59. Comparable provisions exist in 10 CFR 72.48 for licensees of facilities for the independent storage of spent nuclear fuel and high-level radioactive waste and are discussed in Section 0335-07 of this IMC. Licensees apply the 10 CFR 50.59 process to determine if a license amendment is required prior to implementing the CTE. 10 CFR 50.59 applies to (1) changes to facilities or procedures as described in the UFSAR, or (2) conduct of tests or experiments not described in the UFSAR in accordance with 10 CFR 50.59. Through the 10 CFR 50.59 process, a licensee determines when a license amendment pursuant to 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit," is required prior to a licensee implementing changes to the facility or procedures described in the UFSAR or tests and experiments not described in the UFSAR.

As stated in the 1999 SOCs for 10 CFR 50.59, the intent of 10 CFR 50.59 process is to permit licensees to make changes to the facility, provided the changes maintain acceptable levels of safety as documented in the safety analysis report. The process was structured around the licensing approach of design basis events (anticipated operational occurrences and accidents), safety-related mitigation systems, and consequence calculations for the DBAs. The purpose of the evaluation required by 10 CFR 50.59 is to identify possible changes that might affect the basis for licensing the facility so that any changes that might pose a safety concern are reviewed by NRC in a license amendment request to confirm their safety before implementation.

Inspectors should understand the basis for the NRC's approval of the license in order to perform an independent review of the licensee's evaluated CTE.

For each individual plant, the basis of the NRC's approval is provided in the Safety Evaluation Report (SER), supplements to the SER, and safety evaluations for license amendment requests. To aid understanding of the licensing bases, inspectors can review the applicable sections of NUREG-0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [light water reactor] Edition," as applicable, and Regulatory Guide (RG) 1.70, Revision 3, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants LWR Edition." NUREG-0800 identifies the specific areas of review and the associated acceptance criteria used by the NRC staff when a Safety Analysis Report is reviewed, and RG 1.70 provides guidance on what information should be included in the Safety Analysis Report.

The SRP and the RG are not requirements for the licensee unless the licensee committed to an SRP or RG as a method of complying with a regulation, therefore making it part of the licensing basis.

06.01 Relationship Between 10 CFR 50.59 and Fire Protection

If the licensee's fire protection program is required by a specific license condition or is not part of the UFSAR for the facility, the provisions of 10 CFR 50.59 cannot be applied to make changes without prior NRC approval. Some licensees have a license condition that specifically permits changes to the NRC-approved fire protection program. For those licensees with the standard license condition (stated in Generic Letter (GL) 86-10, "Implementation for Fire

Protection Requirements,") allowing changes that do not "adversely affect the ability to achieve and maintain safe shutdown in the event of a fire," the changes are controlled under the license condition and 10 CFR 50.59 does not apply.

06.02 Relationship Between 10 CFR 50.59 and Technical Specification Bases

Generally, 10 CFR 50.59 does not apply to changes made to the TS bases because TS bases are not part of the UFSAR. However, as part of improved Standard Technical Specifications conversion, many licensees have a TS section that specifies the requirements of 10 CFR 50.59 are applicable to changes affecting the TS bases.

06.03 Relationship Between 10 CFR 50.59 and 10 CFR 50.2 Design Bases

10 CFR 50.59 controls changes to both 10 CFR 50.2 design bases and supporting design information contained in the UFSAR. Section 06.20 of this IMC provides further information regarding the design basis limits for fission product barriers that are subject to 10 CFR 50.59(c)(2)(vii) and Section 06.21 provides guidance on the scope of methods of evaluation used in establishing design bases or in the safety analyses that are subject to 10 CFR 50.59(c)(2)(viii). RG 1.186, "Guidance and Examples for Identifying 10 CFR 50.2 Design Bases," December 2000, provides clarification of the term design bases in connection with the NRC's regulations that use this term.

06.04 Relationship Between 10 CFR 50.59 and 10 CFR 50.69

As stated in the 2004 SOCs for 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," no change was made to 10 CFR 50.59 as a result of 10 CFR 50.69; however, the Commission does not believe that a 10 CFR 50.59 evaluation need be performed when a licensee initially implements 10 CFR 50.69 and thereby changes the special treatment requirements applied to risk-informed safety class (RISC) categories 3 and 4 SSCs. Accordingly, 10 CFR 50.69(f) contains language that removes the requirement for licensees to perform 10 CFR 50.59 evaluations for the changes in special treatment that stem from 10 CFR 50.69 implementation.

The process of adjusting treatment for RISC-3 and RISC-4 SSCs does not need to be subject to 10 CFR 50.59 because 10 CFR 50.69 provides the decision process for categorization and determination of revision to requirements resulting from the categorization. Because it is only in the area of treatment for RISC-3 and RISC-4 SSCs that might be viewed as involving a reduction in requirements, these are the only aspects for which 10 CFR 50.69 provision applies. As required by 10 CFR 50.69(f), the licensee or applicant will be required to update the FSAR appropriately to reflect incorporation of its treatment processes into the FSAR. However, it is important to recognize that changes that may affect any nontreatment aspects of an SSC (e.g., changes to the SSC design basis functional requirements) are required to be evaluated in accordance with the requirements of 10 CFR 50.59.

The Commission, while developing 10 CFR 50.69, drew a distinction between treatment (managed through 10 CFR 50.69) and design changes (managed through other processes such as 10 CFR 50.59). 10 CFR 50.69 only risk-informs the scope of special treatment

requirements. The process and requirements established in 10 CFR 50.69 do not extend to making changes to the non-treatment portion of the design basis of SSCs. Section 50.69(f)(3) specifies that for initial implementation of the rule, changes to the UFSAR for implementation of this rule need not include a supporting 10 CFR 50.59 evaluation of changes directly related to implementation. Future changes to the treatment processes and procedures for 10 CFR 50.69 implementation may be made provided the requirements of 10 CFR 50.69 and 10 CFR 50.59 continue to be met.

06.05 Relationship Between 10 CFR 50.59 and 10 CFR 72.48

As a part of rulemaking in 1999, the staff revised the regulations in 10 CFR 72.48 to conform with the revised 10 CFR 50.59 rule in order to provide consistent implementation of these two regulations.

Other sections of this IMC discuss key definitions, provide guidance for reviewing the licensee's and CoC holder's processes for applicability and screening, and performing an assessment of 10 CFR 72.48 evaluations. Inspectors should be aware that changes in the ISFSI and spent fuel storage cask design may affect the Part 50 license if co-located and may require analyses in 10 CFR 50.59 and 10 CFR 72.48.

06.06 Relationship Between 10 CFR 50.59, Regulatory Commitments, and Surveillance Frequency Control Program

By letter dated September 28, 2006, the NRC found NEI 04-10, Revision 0, "Risk-Informed Technical Specification Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies," acceptable for referencing by licensees proposing to amend their Technical Specifications (TS) to establish a Surveillance Frequency Control Program (SFCP), for boiling water reactors to the extent specified and under the limitations delineated in NEI 04-10, Revision 0, and in the final SE. Subsequently, by letter dated September 19, 2007, the NRC found NEI 04-10, Revision 1, acceptable for referencing by licensees proposing to amend their TS to establish a SFCP to the extent specified and under the limitations delineated in NEI 04-10, Risk-Informed Method for Control of Surveillance Frequencies," Revision 1, and in the final safety evaluation.

The SFCP allows a licensee to change the frequency at which certain TS surveillance requirements are performed using the process in NEI 04-10, Revision 1. If a licensee determines that the change to the surveillance frequency is acceptable per the NEI 04-10 methodology, then the licensee must make appropriate changes to procedures, the UFSAR, and other documents in order to implement the revised surveillance frequency.

Licensees are required by 10 CFR 50.71(e) to update their UFSAR to include the effects of approved license amendments. Following NRC approval of an SFCP amendment, the licensee must update its UFSAR to describe the program within its UFSAR and how future changes to surveillance frequencies in the SFCP will be addressed. Changes to the SFCP are controlled in accordance with the requirements of 10 CFR 50.59. However, 10 CFR 50.59 is not applicable to changes to the specific surveillance frequencies in accordance with an approved SFCP.

The guidance for the SFCP in NEI 04-10, refers to the commitment change process, which is addressed in NEI 99-04, Revision 0, "Guidelines for Managing NRC Commitment Changes" (endorsed Regulatory Information Summary 00-017, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff"). Specifically, NEI 04-10 instructs licensee to review "regulatory commitments," which are defined in NEI 99-04 as "an explicit statement to take a specific action agreed to, or volunteered by, a licensee and submitted in writing on the docket to the NRC." The commitment change process described in NEI 99-04 would result in a 10 CFR 50.59 review only if the regulatory commitment is captured in the facility UFSAR or if a station procedure is changed. These types of changes to the facility or procedures are discussed in Section 06.10.

06.07 Relationship Between 10 CFR 50.59 and 10 CFR 50.155

10 CFR 50.155, "Mitigation of beyond-design-basis events," establishes the regulatory requirements for nuclear power reactor applicants and licensees to mitigate beyond-design-basis events (MBDBE). 10 CFR 50.155(f) allows a licensee to make changes in the implementation of the requirements in the MBDBE rule without NRC approval, provided that before implementing each such change the licensee demonstrates that the provisions of the 10 CFR 50.155 continue to be met and maintains documentation of changes until the requirements of 10 CFR 50.155 no longer apply. As stated in the 2019 SOCs for the MBDBE rule establishing 10 CFR 50.155, a licensee may intend to change its facility, procedures, or guideline sets to revise some aspect of beyond-design basis mitigation governed by the MBDBE rule in a manner that can impact multiple aspects of the facility, including design basis aspects of the facility subject to other regulations and change control processes. This same change also could impact safety-related SSCs, either directly (e.g., a proposed change that impacts a physical connection of mitigation strategies equipment to a safety-related component or system) or indirectly (e.g., a proposed change that involves the physical location of mitigation equipment in the vicinity of safety-related equipment that presents a potential for adverse physical/spatial interactions with safety-related components). As a result, 10 CFR 50.59 and other change control processes, as appropriate, need to be applied to evaluate the acceptability of the proposed change.

10 CFR 50.155(f)(2) serves to identify that other change control requirements such as those in 10 CFR 50.59, 10 CFR 50.54(p), 10 CFR 50.54(q), 10 CFR 73.58 (within 10 CFR 73, "Physical protection of plants and materials,") and fire protection change controls may apply depending on the extent of the change and the aspects of the facility that are impacted. As the 2019 SOCs explain, the MBDBE rule includes a provision intended to supplement the existing change control processes and focus on the beyond-design-basis aspects of proposed changes. For example, a change to an SSC having both a beyond-design-basis function and a design-basis function would have the aspects of the change involving its beyond-design-basis functions addressed under 10 CFR 50.155(f) and the aspects of the change involving the design-basis functions addressed under 10 CFR 50.59 or any other applicable change control requirement.

06.08 Applicability Determination

Licensees may perform applicability determinations to ascertain whether a 10 CFR 50.59 evaluation is required for a proposed CTE. Note that 10 CFR 50.59 does not require the licensee to perform an applicability determination for the proposed CTE. For example, as stated in 10 CFR 50.59(c)(4), an evaluation in accordance with 10 CFR 50.59(c)(2) is not

required when other applicable regulations establish more specific criteria for accomplishing a proposed CTE. In some instances, depending upon the nature of the proposed CTE, more than one regulation may apply to different aspects of the proposed CTE. Licensees are responsible for determining if a change control process in another regulation other than 10 CFR 50.59 is applicable to the CTEs at issue.

Regulations that contain change control processes include but are not limited to:

- a. 10 CFR Part 20, Standards for protection against radiation,
- b. 10 CFR 50.12, Specific exemptions,
- c. 10 CFR 50.46, Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors,
- d. 10 CFR 50.54, Conditions of licenses,
- e. 10 CFR 50.55a, Codes and standards, and
- f. 10 CFR 50.65, requirements for monitoring the effectiveness of maintenance at nuclear power plants.

A few examples of the above-mentioned change control processes that may govern the CTE include:

- changes to procedures involved with the quality assurance plan that may be described in the UFSAR, but where 10 CFR 50.54(a) establishes criteria and reporting requirements for such changes,
- changes to physical security plan or guard training and qualification plan covered by 10 CFR 50.54(p),
- changes to emergency response facilities covered by 10 CFR 50.54(q), and
- loss-of-coolant accident evaluation methods covered by 10 CFR 50.46.

06.09 Screening

Once a licensee determines that 10 CFR 50.59 is applicable (e.g., change control process in another regulation does not fully encompass the proposed CTE), the licensee may perform screening to determine if the proposed activity requires evaluation against the criteria in 10 CFR 50.59(c)(2). Note that 10 CFR 50.59 does not require the licensee to screen the proposed CTE. However, it does require the licensee to obtain a license amendment pursuant to 10 CFR 50.90 prior to implementing a proposed CTE if any of the criteria in 10 CFR 50.59(c)(2) are met. The licensee may forgo screening the proposed CTE and perform an evaluation of the criteria in 10 CFR 50.59(c)(2).

As described in NEI 96-07, Revision 1, and endorsed in RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," for licensees that choose to implement a 10 CFR 50.59 screening procedure, licensees should screen each element of a proposed CTE separately and independently of each other, unless they are interdependent; that is, linked to each other and not separable for functional reasons. Generally, the licensee's screening determinations for 10 CFR 50.59 are available as quality assurance records. When a licensee determined that a proposed CTE screened out, the inspector's independent review of the screening documentation and the licensee's basis for the screening should confirm that evaluation against the eight criteria in 10 CFR 50.59(c)(2) was not necessary. See Sections 06.15 through 06.21 of this IMC for discussions on the eight criteria in 10 CFR 50.59(c)(2).

Equivalent replacement is a type of change to the facility that does not alter the design functions of SSCs. Licensee equivalence assessments, e.g., consideration of performance/operating characteristics and other factors, may form the basis for screening determinations that no 10 CFR 50.59 evaluation is required.

06.10 Changes To The Facility Or Procedures

See Sections 04.01, 04.05, and 04.08 of this IMC for the definition of “change,” “facility as described in the UFSAR,” and “procedures as described in the UFSAR,” respectively. Inspectors should be aware that the 1999 SOCs for 10 CFR 50.59 state that the definitions of “change” and “facility as described in the UFSAR” explicitly establish that evaluation is required for changes to the analyses and bases for the facility as well as for physical or hardware changes to the facility, and that any additions are considered “changes.”

Inspectors should be aware that changes to information in the UFSAR that provide (1) performance or qualification requirements; (2) methods of operation; (3) the bases upon which the requirements have been established, or (4) the analyses and evaluations that demonstrate that the facility meets requirements may also satisfy the criteria in 10 CFR 50.59. As described in the 1999 SOCs for 10 CFR 50.59, the definition of change allows licensees to eliminate the need to further assess specific changes against the criteria in 10 CFR 50.59 because the nature of the change may not meet the criteria and require prior NRC review before implementation.

Inspectors should verify that the change did not affect any design functions, methods of performing or controlling functions, or methods of evaluation when a licensee’s screening determination concluded that a change is administrative, or descriptive only, or does not adversely affect the functions such that a 10 CFR 50.59 evaluation is not required. Proposed changes that might involve any of the evaluation criteria are subject to the 10 CFR 50.59 evaluation process and should be evaluated by the licensee. If a change has no effect or has only beneficial effects, it does not satisfy any of the evaluation criteria concerning more than minimal increase in frequency or occurrence of malfunction or higher consequences, etc. If the licensee cannot conclude that there is no adverse effect, a 10 CFR 50.59 evaluation is required.

As described in NEI 96-07, Revision 1, if the change has both beneficial and adverse effects, then the change should be screened in and a 10 CFR 50.59 evaluation is required. A 10 CFR 50.59 evaluation is required for changes that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished (i.e., “adverse changes”). Changes reducing the SSC capability, performance, qualification, or reliability are adverse. Being outside the bounds of existing safety analyses or ranges described in the UFSAR is adverse. NEI 96-07, Revision 1, states that the magnitude of the adverse effects is irrelevant for the screening process. Licensees should screen in and evaluate any change that adversely affects a UFSAR-described design function, method of performing or controlling functions, or method of evaluation that demonstrates that intended design functions will be accomplished.

The functions affected by a change might be for an SSC other than the one to which the change is being made because of indirect effects. As defined in NEI 96-07, Revision 1, indirect effects are those where the proposed CTE affects one SSC and this SSC affects the capability of another SSC to perform its design function. Indirect effects include such items as

environmental conditions, physical interactions, etc. The inspector should recognize that a word search of the UFSAR might miss such effects.

Two examples of “indirect effects” are as stated in the 1999 SOCs for 10 CFR 50.59. For a change that affects post-accident containment conditions, although 10 CFR 50.49 may be the applicable regulation for equipment qualification, other aspects such as containment pressure would need to be evaluated under 10 CFR 50.59 because containment pressure would be considered an indirect effect. Additionally, the bearings on a pump may not be specifically mentioned or described in the UFSAR; however, the pump function and performance requirement is described. A change being made to the bearings needs to be evaluated to determine if it affects the function or performance requirements of the pump, and if so, whether the criteria in 10 CFR 50.59 are met.

Licensees should not have excluded evaluation of changes solely on the basis that the SSCs or procedures that are described in the UFSAR are not safety related. In addition, an inspector should recognize that a facility also contains many SSCs not described in the UFSAR. As described in NEI 96-07, Revision 1, changes affecting SSCs that are not explicitly described in the UFSAR can have the potential to adversely affect other SSC design functions that are described in the UFSAR and may require a licensee 10 CFR 50.59 evaluation. In such cases, the licensee should consider the larger, UFSAR-described SSC of which the SSC being modified is a part. If for the larger SSC, the change adversely affects a UFSAR described design function, method of performing or controlling the function, or a method of evaluation demonstrating that intended design functions will be accomplished, then the licensee should have performed a 10 CFR 50.59 evaluation.

Licensees should have reviewed all CTEs, temporary and otherwise, in accordance with 10 CFR 50.59. See Section 06.22 of this IMC for further discussion on temporary alterations.

An unintended change of the facility or procedures from that described in the UFSAR, whether in existence since initial licensing, or as the result of an error in a subsequent facility/procedure change or other activity that is not restored must be reviewed by the licensee pursuant to 10 CFR 50.59 to determine whether the unintended change requires NRC approval. For unintended changes which rise to the level of requiring NRC approval, the NRC approval prior to implementation refers to the approval of the corrective action (i.e., of the change to the licensing basis as described in the UFSAR) before the condition is resolved.

06.11 Tests or Experiments Not Described in the UFSAR

Section 04.10 of this IMC defines tests or experiments not described in the UFSAR. Inspectors should be aware that the SOCs for 10 CFR 50.59 state that the intent of the requirement is that tests that put the facility in a situation that has not previously been evaluated or that could affect the capability of SSCs to perform their intended functions should be evaluated before they are conducted. The definition focuses upon the facility being outside its design basis values or inconsistent with the safety analyses in the UFSAR.

Inspectors should be aware that modifications to tests or experiments described in the UFSAR are reviewed as a change to procedures. However, (1) testing that removes an SSC from service for maintenance, if it is not a prolonged removal, (2) temporary alterations in place less than 90 days (including those affecting operator actions and procedures as described in the

UFSAR) in support of maintenance, and (3) post-modification testing is considered a maintenance activity, and does not require a 10 CFR 50.59 evaluation because they are controlled by 10 CFR 50.65(a)(4). See Section 06.22 of this IMC for further discussion on temporary alterations.

06.12 Evaluation Process

Licenses evaluate the eight criteria in 10 CFR 50.59 to determine if obtaining a license amendment is required for proposed CTEs. If the CTE involves a change to the TS, licenses do not need to perform an evaluation of the eight criteria in 10 CFR 50.59 and must apply for a license amendment in accordance with 10 CFR 50.90.

Areas inspectors should consider when reviewing licenses' 10 CFR 50.59 evaluations include but are not limited to:

- SSCs directly and indirectly affected by the change (e.g., does the change affect the capability of the SSCs at issue, or another SSC, to perform the intended design function(s)?);
- changes to any elements of a method of evaluation described in the UFSAR, which includes changes from a method described in the UFSAR;
- parameters of the accident analysis affected by the change (e.g., are all the relevant DBAs and transients identified in licensee evaluations?);
- potential effects of SSC failures (e.g., licenses explored and answered the question, "what would happen if..." in the evaluation); and
- how the evaluation criteria are met.

Each element of a CTE should be separately evaluated against each of the 10 CFR 50.59(c)(2) criteria unless the elements of a CTE are interdependent, that is, linked to each other and not separable for functional reasons. If concurrent changes are being made that are not linked, inspectors should expect licenses to evaluate each criterion separately and independently. One change (that might add conservatism) should not be used to preclude NRC review of another change that would, on its own, meet any of the evaluation criteria. Each criterion must be satisfied on its own. A reduction in consequences cannot offset an increase in likelihood for a given change as a basis for meeting 10 CFR 50.59.

Licensee evaluations that concluded that any of the 10 CFR 50.59(c)(2) criteria are met must obtain a license amendment per 10 CFR 50.90 prior to implementation of the CTE.

06.13 Minimal Increase Principle

Inspectors should be aware that the 1999 SOCs for 10 CFR 50.59 state that, in consideration of the conservatisms in NRC design and analysis requirements and acceptance criteria, "minimal" variations in probability of occurrence or consequences of accidents and malfunctions should not affect the basis for the previous licensing decision. During the plant licensing process, accident probabilities were assessed in relative frequencies (such as likely to occur more than once, likely to occur once during the life of the plant or limiting fault that is not likely to occur during the life of the plant). System train and equipment failures were generally postulated to gauge the robustness of the design, without estimating their likelihood of occurrence.

In this light, minimal increases in probability do not significantly change the licensing basis of the facility and do not impact the conclusions reached about acceptability of the facility design.

Further, the limits for radiological consequences established in the regulations and in the SRP are conservatively chosen, so that minimal increases also do not impact the safety determination if demonstrated by a suitably conservative analysis. The 10 CFR 50.59 criteria provide some degree of flexibility for licensees to make changes with smaller impacts without the need to obtain a license amendment.

Although 10 CFR 50.59 allows minimal increases, licensees still must meet applicable regulatory limits and other acceptance criteria to which licensees are committed (such as are contained in RGs and nationally recognized industry consensus standards, e.g., the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code and Institute of Electrical and Electronic Engineers Standards) for the CTE to be a minimal increase. Inspectors should verify that licensees continue to meet applicable regulatory limits and other acceptance criteria to which they are committed.

As 10 CFR 50.59 provides a qualitative standard of “no more than minimal,” quantitative calculations are not required except for those instances in which a licensee decided to offer quantitative arguments as part of its evaluation. This is expected to occur for some instances involving increases in consequences, where licensees may have performed calculations of the predicted radiological dose consequences from postulated accidents.

06.14 Probabilistic Risk Assessment and Risk Insights

Inspectors should be aware that the 1999 final rule SOCs for 10 CFR 50.59 include discussion on the use of probabilistic risk assessment (PRA) in 10 CFR 50.59 evaluations. In response to public comments on the proposed rule discussing the use of risk insights and PRA to determine when a more than minimal increase in probability has occurred, the Commission stated:

For instance, commenters thought that the values for changes in core damage frequency [CDF] or large early release frequency [LERF] in Regulatory Guide (RG) 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk Informed Decisions on Plant-Specific Changes to the Licensing Basis,” might be used. However, this RG was developed for the purpose of guiding changes to the licensing basis where the staff was reviewing and approving the change, not for changes made under § 50.59. The Commission concludes that if use is to be made of PRA in § 50.59, more fundamental changes to the rule would be necessary to provide a coherent set of requirements, in that § 50.59 deals with design basis events, and RG 1.174 deals with risk including that from severe accidents beyond the design basis.

Consistent with the Commission’s statements supporting the final 10 CFR 50.59 rule, inspectors should verify that licensees did not use the values for change in CDF and/or LERF in RG 1.174 as the basis for 10 CFR 50.59 evaluations. In addition, each criterion must be satisfied on its own. As a result, for a given change, a reduction in consequences cannot “offset” an increase in likelihood. For example, a licensee’s proposed CTE evaluation might both lower an initiating event frequency (i.e., frequency of an accident) but at the same time raise an SSC’s probability of failure (i.e., likelihood of occurrence of a malfunction) or vice versa, and result in “more than a minimal increase.” In this case, the 10 CFR 50.59 criteria would not be met even though the

CDF and LERF values were unchanged because the frequency could offset the likelihood thereby masking the consequences. For these reasons, consistent with the Commission's position in the SOCs (i.e., that use of CDF and LERF values in RG 1.174 are not appropriate for 10 CFR 50.59 evaluations), the resultant CDF and LERF from the PRA cannot be the basis for the licensee's evaluation.

However, while the resultant CDF and LERF from the PRA are not acceptable as the sole basis to inform the licensee's 10 CFR 50.59 evaluation, it is acceptable for licensees to use reasonable engineering practices, engineering judgement, and PRA techniques, as appropriate, to inform 10 CFR 50.59 evaluations with respect to "more than a minimal increase." Such PRA techniques may include but are not limited to initiating event analysis, common cause failure analysis, human reliability analysis, parameter estimation, and systems modeling via event and fault tree analysis.

Inspectors should review the licensee's application of the PRA technique to determine its applicability and adequacy for the specific deterministic evaluation at issue and whether it has been applied correctly. If the inspector cannot determine the adequacy or application of the PRA technique, then the inspector should request assistance from the regional Senior Reactor Analysts and/or the Division of Risk Assessment (DRA) in the Office of Nuclear Reactor Regulation (NRR).

06.15 Review Licensee Evaluation of Criterion (c)(2)(i)

10 CFR 50.59(c)(2)(i) focuses on whether the CTE would result in a more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR. See Section 04.12 of this IMC for the definition of accident previously evaluated in the UFSAR.

Inspectors should recognize that the SOCs for 10 CFR 50.59 emphasize that, for this criterion, what is of interest is whether the proposed CTE has the effect of making the accident occur more often.

The inspector should also be aware that the SOCs for 10 CFR 50.59 state that the effect of the change on the frequency of the accident must be discernible and attributable to the change in order to exceed the "more than minimal" increase standard as compared to uncertainty about the existing frequency value and how it might be quantified. Additionally, for a CTE to be considered a minimal increase, the resulting frequency of occurrence (considering the proposed CTE) must still satisfy the event frequency classification provided in the licensee's UFSAR. CTEs that result in a change in event frequency classification meet this criterion and 10 CFR 50.59 requires a licensee to obtain a license amendment prior to implementation of the CTE. However, remaining within the classification is not sufficient for a licensee to conclude that no more than a minimal increase has occurred because qualitative judgments are not as rigorous as quantitative assessments, and the accident categories and their uncertainties may be large.

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed. When the General Design Criteria (GDC) have been incorporated into the licensing basis, departures from the design, fabrication, construction, testing, and performance requirements in the GDC as incorporated into the licensing basis are not compatible with a "no more than minimal increase" standard.

As stated in NEI 96-07, Revision 1, licensees may use reasonable engineering practices, engineering judgment and PRA techniques, as appropriate, to determine whether the frequency of occurrence of an accident more than minimally increases as a result of implementing a CTE. See Section 06.14 of this IMC for further discussion on PRA and PRA techniques.

06.16 Review Licensee Evaluation of Criterion (c)(2)(ii)

10 CFR 50.59(c)(2)(ii) focuses on whether the CTE would result in more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety previously evaluated in the UFSAR. See Section 04.16 of this IMC for the definition of malfunction of SSCs important to safety.

Inspectors should recognize that the SOCs for 10 CFR 50.59 state that 10 CFR 50.59 provides a qualitative standard of “no more than minimal” and that quantitative calculations are not required except for those instances in which a licensee decides to offer quantitative arguments as part of their evaluation.

As stated in the SOCs for 10 CFR 50.59, the likelihood of malfunction of SSC important to safety previously evaluated in the UFSAR is a minimal increase if “design bases” assumptions and requirements are still satisfied (i.e., the seismic or wind loadings, qualification specifications, etc.) For instance, a change that causes piping stresses to exceed their code allowable values is more than a minimal increase in likelihood of malfunction. CTEs that invalidate specific commitments made for redundancy, diversity, separation, and other such design characteristics, are considered as “more than a minimal increase in likelihood of malfunction,” and require prior NRC approval via a license amendment.

Additions of components to a system (e.g., cabling, manual valves, protective features) is not generally viewed as more than a minimal increase in likelihood of malfunction, provided that applicable design and quality standards are followed. For example, adding protective devices to breakers or installing an additional drain line (with appropriate isolation capability) is not an increase in likelihood of malfunction. However, there may be situations where such additions impact how a system performs its functions and does not satisfy the 10 CFR 50.59 criteria (for example, a cross-connect between trains that is not suitably isolated).

Substitution of one type of component for another (as for instance, an air operated valve for a motor-operated valve) is also viewed as no more than a minimal increase in likelihood of malfunction provided requirements for redundant motive force, quality, and other requirements are met (and of course that any new failure modes are already bounded by the analysis).

When the GDC have been incorporated into the licensing basis, departures from the design, fabrication, construction, testing, and performance requirements in the GDC as incorporated into the licensing basis, are not compatible with a “no more than minimal increase” standard.

Similar to the guidance in IMC Section 06.13, a licensee’s CTE evaluations should consider the effects of the CTE on performance of all affected SSCs, decide as to whether there has been a more than minimal increase, and provide a basis for the determination. Licensees should consider both direct and indirect effects as discussed above in Section 06.10 of this IMC.

As stated in NEI 96-07, Revision 1, licensees typically will use qualitative engineering judgment and/or an industry precedent to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. See Section 06.14 of this IMC for further discussion on PRA and PRA techniques.

06.17 Review Licensee Evaluation of Criteria (c)(2)(iii) and (c)(2)(iv)

10 CFR 50.59(c)(2)(iii) focuses on whether the CTE would result in a more than a minimal increase in the consequences of an accident previously evaluated in the UFSAR.

10 CFR 50.59(c)(2)(iv) focuses on whether the CTE would result in a more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the UFSAR.

As stated in the SOCs for 10 CFR 50.59, the reference to consequences is intended to relate directly to radiological consequences (i.e., dose), and not to other outcomes that are covered by the remaining criteria. Also, “consequences of accidents” includes not only offsite exposure, but also dose to operators in the control room (in accordance with GDC 19 of Appendix A to 10 CFR Part 50) or other onsite personnel, resulting from accidents and malfunctions previously evaluated in the UFSAR.

A change involves no more than a minimal increase in consequences if the increase is less than or equal to the more limiting of either 10 percent of the difference between the licensee’s existing calculated value and the regulatory guideline value (10 CFR Part 100, 10 CFR 50.67, or GDC 19 as applicable), or has reached the SRP guideline value for the particular design basis event/accident, regardless of how the plant was specifically licensed using the SRP.

Criteria (iii) and (iv) cover CTEs that arise from malfunctions (such as failure of a waste tank or filter systems), and others that might arise from changes in source term or timing of mitigation systems, that are more pertinent to “accidents.” Changes in consequences that are 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 toward increasing the consequences), need not be considered an increase in consequences.

For cases where a licensee is licensed with calculated consequences in excess of the established SRP guidelines, only limited flexibility under this criterion exists for changes that increased the calculated radiological consequences of accidents. In this regard, differences of about 0.1 rem are viewed as being within the error or uncertainty of design basis-type radiological consequences analysis such that NRC review of such changes is not needed.

If a licensee performed an analysis with certain bounding assumptions, and the change increases a specific parameter from its present value to a different value that is still bounded by the value assumed in the analysis, the NRC concluded in the 50.59 SOCs that the change satisfies the criterion of “no more than a minimal increase in consequences.” In fact, this is no increase in consequences, because the bounding analysis is what determines the value from which a change is being judged. If a licensee needs to change its design basis assumptions or analytical methods, or both, to demonstrate that the change in consequences satisfies this

guidance [SOCs], then the NRC does not view the change as minimal and expects the licensee to submit a license amendment for such a change.

The 50.59 SOC provides several examples to illustrate the implementation of criteria (iii) and (iv). In each example, the calculated consequences do not include changes in methodology. Changes in methodology used to calculate radiological consequences would fail criterion (viii) of 10 CFR 50.59 and require prior NRC review regardless of how small the increase is in the calculated radiological consequences.

Example 1: A licensee has a calculated fuel handling accident (FHA) dose of 50 rem to the thyroid at the exclusion area boundary. Because of some change in the facility, the calculated FHA dose increases to 70 rem. Under 10 CFR 50.59, ten percent of the difference between the calculated value (50 rem) and the regulatory limit (300 rem) is 25 rem (10% of 250). The SRP acceptance guideline for FHA is 75 rem. Since the calculated increase (20 rem) is less than 25 rem and the total (70 rem) is less than the SRP acceptance guideline, then the 10 CFR 50.59 consequence criterion does not trigger the need for a prior NRC review and a licensee can make the change to the facility.

Example 2: The calculated consequences for a steam generator tube rupture accident are 25 rem to the thyroid at the exclusion area boundary. Because of a change in the plant, the calculated thyroid consequences increase to 29 rem. 10 CFR 50.59 permits this change to occur because the new calculated dose does not exceed the established SRP acceptance criteria (30 rem) nor does the incremental change in consequences (4 rem) exceed 10 percent of the difference between the previous calculated value and the regulatory limit of 300 rem. Ten percent of the difference between the acceptance criteria (300 rem) and the calculated value (25) is 27.5 rem (10% of 275); since 4 rem is less than 27.5 rem, this change satisfies the criterion and does not trigger the need for a prior NRC review. Because of this, a licensee can make the change to the facility.

Example 3: The calculated consequences of an FHA are 25 rem to the thyroid at the exclusion area boundary. Because of a proposed change in the facility, the calculated thyroid consequences increase to 65 rem. For this case, the revised calculated consequences are still less than the SRP acceptance guidelines of 75 rem; however, the incremental increase in consequences (40 rem) exceeds the 10 percent of the difference to the regulatory limit of 300 rem (which would be 27.5 rem). For this example, the change results in more than a minimal increase in consequences and requires NRC approval pursuant to 10 CFR 50.59(c)(2)(iii).

Example 4: The calculated dose to the control room operators following a loss of coolant accident is 4 rem whole body. A change is made to the control room ventilation system such that the calculated dose increases to 4.5 rem. The regulations dictate that the control room doses are to be controlled to less than 5 rem by GDC 19. Although the new calculated doses are less than the regulatory limits for the operators, the incremental increase in dose (0.5 rem) exceeds the value of 10 percent of the difference between the previously calculated value and the regulatory value (10% of 1 rem = 0.1 rem). This change requires prior NRC review before the licensee implements the change.

Typically, differences of about 0.1 rem are consistent with the "minimal" concept and are viewed to be within the error or uncertainty of design basis-type radiological consequences analysis such that NRC review of such changes is not needed. Below is an example of the "calculational error" concept.

Example 5: Suppose the existing approved analysis for an FHA at a plant predicts an offsite dose to the thyroid of 77 rem. The SRP acceptance guideline for this event is 75 rem. The change that a licensee wishes to make predicts an increase in the calculated dose from 77 to 77.1 rem. In this case, the proposed change can be made under 10 CFR 50.59 because the calculated value, even though greater than the SRP value, is satisfied within the level of uncertainty specified above. However, for this example, increases in consequences that would increase the calculated consequences to 77.2 rem would require prior NRC review before the specific change is implemented.

06.18 Review Licensee Evaluation of Criterion (c)(2)(v)

10 CFR 50.59(c)(2)(v) focuses on whether the CTE would create a possibility for an accident of a different type than any previously evaluated in the UFSAR.

Inspectors should recognize that the SOCs for 10 CFR 50.59 state that a licensee does not have to prove that an accident had not been created; rather, a licensee needs to request a license amendment only if it could be reasonably concluded that the possibility of an accident of a different type is created by the proposed CTE.

The accident must be credible in the sense of having been created within the range of assumptions previously considered (e.g., random single failure, loss of offsite power, no reliance on non-safety-grade equipment, etc.), and that a new initiator of the same accident is not a “different type” (but may affect the frequency of that accident under 10 CFR 50.59(c)(2)(i)).

Licensees are responsible for evaluating whether the CTE creates an accident of a different type. However, inspectors should be aware of the following useful considerations when reviewing a licensee 50.59 evaluation of criterion (v):

- Does the accident result in a new or greater release path than originally considered?
- Does the accident result in a new fission product barrier failure mode?
- Does the accident create a new sequence of events that results in significant cladding failure?
- Would the accident be included if the UFSAR were being written today?

As stated in NEI 96-07, Revision 1, certain accidents are not discussed in the UFSAR because their effects are bounded by other related events that are analyzed. For example, a postulated pipe break in a small line may not be specifically evaluated in the UFSAR because it has been determined to be less limiting than a pipe break in a larger line in the same area. Therefore, if a CTE introduces a small high energy line break into this area and a larger high energy line break into this area is already analyzed in the UFSAR, then postulated breaks in the smaller line are not considered an accident of a different type.

06.19 Review Licensee Evaluation of Criterion (c)(2)(vi)

10 CFR 50.59(c)(2)(vi) focuses on whether the CTE would create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the UFSAR. This criterion focuses on the result of the CTE and the licensee’s determination that

the possibility has been created rather than the cause/type of malfunction. See Section 04.16 of this IMC for definition of malfunction of SSCs important to safety.

Inspectors should recognize that the proposed rule SOCs for 10 CFR 50.59 discussion states that the determination for criterion (vi) is made either at the component level, or consistent with the failure modes and effects analyses, taking into account single failure assumptions and the level of the change being made. In the final rule SOCs, the Commission explained that several commenters on the proposed rule stated that this should be revised to refer only to the failure modes and effects analysis in the FSAR, and not to specify the component level. The Commission agreed that this criterion should be considered with respect to the failure modes and effects analyses (FMEA), but also noted that certain changes may require a new FMEA, which needs to be evaluated as to whether the effects of the malfunctions are bounding.

Note that the likelihood of malfunction may be increased if new failure modes are introduced (even if the effects have been previously evaluated in the FSAR (as updated)), and this situation would have to be evaluated under criterion (ii).

06.20 Review Licensee Evaluation of Criterion (c)(2)(vii)

10 CFR 50.59(c)(2)(vii) focuses on whether the CTE would result in a design basis limit for a fission product barrier as described in the UFSAR being exceeded or altered.

Inspectors should recognize that the final rule SOCs for 10 CFR 50.59 state that 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 a barrier. Typically, the controlling value for the parameter is set at a point far enough away from failure that there is confidence in the integrity of the barrier.

The 50.59 SOCs further state that licensees must evaluate all CTEs that affect the design basis limits, including changes to parameters within mitigation and support systems for their effects upon the design basis limits for the barriers. Depending upon the type of facility and its operational status, the fission product barriers and design bases limits vary but should be evident from the safety analyses presented in the UFSAR.

Inspectors should be able to ascertain from a review of the UFSAR the parameters applicable to a specific facility. As described in the SOCs, for operating power reactors, the barriers are generally limited to the fuel cladding, reactor coolant system boundary, and containment. As presented in the UFSAR, there is a design basis (functions and controlling values of parameters) that determines the minimum performance requirements for SSCs. The controlling value for a parameter is the point at which confidence in the capability of the SSCs to perform their intended safety functions begins to decrease. For a reactor undergoing decommissioning where the fuel is stored in the spent fuel pool, the barrier is the fuel cladding. For non-power reactors, the fission product barriers would include, as applicable to the specific reactor, the fuel cladding, the reactor tank, and the reactor room, building, confinement, or containment.

Although the list of fission product barriers includes containment and other features that prevent the release of radiation, the design basis limits for these barriers are parameters such as pressure. The licensee determination of resultant radiological consequences from leakage

through or breach of these barriers is the subject of 10 CFR 50.59(c)(2)(iii) and (iv) rather than 10 CFR 50.59(c)(2)(vii).

Inspectors should note that the minimal change concept does not apply to criterion (vii), and criterion (vii) does not permit small changes beyond the design basis limits without NRC review and approval. With respect to changes relating to the design basis capability of SSCs to perform their functions in those circumstances in which the change does not cause any design basis limits to be exceeded or altered, the other evaluation criteria provide the standards for prior NRC approval of such changes.

Alteration of a design basis limit is not allowed. Changes that involve alteration of the design basis limit for a fission product barrier involve such a fundamental alteration of the facility design that a change, even in the conservative direction, requires prior NRC review and approval via license amendment.

To satisfy criterion (vii), licensees must determine the parameters that are affected by the proposed CTE. The affected parameters are not limited to the specific parameters in the system in which the change is being made or to parameters that are only directly linked to the actual fission product barrier. Rather, the design parameters must include an assessment of all affected parameters, including design parameters of mitigation and support systems. Once the parameters are identified, the licensee must establish whether the parameters have values established in the UFSAR, whether the parameters are controlling parameters that are reference bounds for the design, and whether the parameter has the potential to affect the performance of the fission product barrier. If the specific parameter values are already subject to controls established by the TS or other rules or regulation, those requirements shall be followed.

After a licensee assesses the information discussed above, identification of the specific design basis limits that are affected for each of the identified parameters is necessary. After the licensee completes its assessment of the change against each design basis limit, if no design basis limit is altered or exceeded, 10 CFR 50.59(c)(2)(vii) is satisfied, and the licensee can make the change without prior NRC review.

Several examples from the 50.59 final rule SOCs to illustrate the implementation of this criterion are included below. In each example, it is assumed that NRC approval is not required because of other reasons, such as need for a TS change, 10 CFR 50.55a requirements, etc.

Example 1: A plant UFSAR states that the function of the auxiliary feedwater system (AFW) is to provide feed water flow to the steam generators following postulated accidents (e.g., main steam line break, feed line break, small break loss-of-coolant accident), or when a reactor trip occurs coincident with a loss-of-offsite power. The UFSAR states that 700 gallons per minute (gpm) will be delivered to the steam generators. The licensee's accident analyses used 700 gpm to assess the acceptability of the plant to respond to the accidents and concluded that no safety limits were challenged if 500 gpm were supplied. As a result of recent testing of the AFW system, the licensee determines that the pumps can no longer deliver 700 gpm. The licensee determines that the AFW pumps can deliver only 500 gpm at the required pressure and temperature. The licensee performs the necessary safety analyses and confirms that 500 gpm is sufficient to meet all necessary functions and that no safety limits would be challenged as a result of the flow reduction. The licensee decides to leave the pumps in the plant as is rather than replace the pumps to restore the originally stated capability. The licensee revises the

UFSAR to state that the AFW system will deliver 500 gpm during postulated accidents or for transients involving a loss-of-offsite power.

Under 10 CFR 50.59(c)(2)(vii), the licensee has to assess the impact of the reduced flow rate on the design limits of the fission product barriers. The licensee has to identify the system parameters that vary as a result of the changes in AFW system performance, identify the specific design limits that have the potential to affect the fission product barrier performance, and complete the analyses to determine whether the specific design limits for the fission product barriers are challenged. In this example, it is assumed that the licensee did not change the method of evaluation for the safety analyses. If the licensee had used a different methodology from that used initially in establishing that the limits were met, then, the licensee may have to submit the revised analyses under 10 CFR 50.59(c)(2)(viii) of the revised rule. For this example, the licensee has to complete the evaluations required by 10 CFR 50.59 but does not have to submit a license amendment request to lower the expected flow rate of the AFW system, from that stated in the UFSAR, to the lower as-found value, nor would a licensee have to request an amendment to remove the old pumps and replace the pumps with new pumps that provide the lower capacity assumed in this example. The basis for this conclusion is that the licensee analyses determined that the design limits of the fission product barriers are not challenged and, therefore, that the fundamental basis for the NRC staff's initial safety conclusion is maintained.

Example 2: A facility UFSAR states that some of the functions of the component cooling water (CCW) system are to provide cooling water flow to the reactor coolant pump seals and to the shell side of the residual heat removal system (RHR) heat exchangers. The UFSAR states that the CCW system provides 400 gpm, 100 gpm for the seals and 300 gpm for the RHR heat exchanger. The licensee has recently obtained a new reactor coolant pump seal which requires an additional 25 gpm of cooling flow. The licensee plans to revise the flow distribution such that 125 gpm is directed to the seals, and 275 gpm to the RHR heat exchangers. The licensee performs analyses to determine that with the reduced CCW flow to the RHR heat exchangers, the RHR system can still perform its required functions with required limits, as for example, removing sufficient decay heat to cool down within required time frames, keeping post-accident temperatures within required limits, etc. The licensee would satisfy 10 CFR 50.59(c)(2)(vii) and be able to make this change under 10 CFR 50.59.

Example 3: A licensee discovers an error in the primary system pressure boundary piping fatigue calculation performed to demonstrate compliance with the ASME Code requirements. A corrected calculation shows that the fatigue criterion is exceeded (for the postulated UFSAR events). A change to the licensing basis to accept revised fatigue criteria requires review under 10 CFR 50.59(c)(2)(vii) because the design basis limit for one of the fission product barriers (reactor coolant system piping) is exceeded or altered. (This change also does not meet 10 CFR 50.59(c)(2)(i), "minimal increase in frequency of occurrence of an accident" because of potential failure of piping due to fatigue cracking, leading to loss of piping system integrity.)

06.21 Review Licensee Evaluation of Criterion (c)(2)(viii)

10 CFR 50.59(c)(2)(viii) focuses on whether the CTE would result in a departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses. See Section 04.02 of this IMC for definition of departure from a method of evaluation described in the UFSAR.

Inspectors should recognize that the SOCs for 10 CFR 50.59 state this criterion is specifically used for changes to methods of evaluation. Unless the methods are used in FSAR safety analyses, as demonstrating that the facility performance continues to meet requirements, or to verify conformance with the design bases, they would not meet the rule requirements for approval. For example, if a licensee chose to perform sensitivity studies or to examine alternative approaches for a change being contemplated or included other analyses in the UFSAR for reference purposes, these methods are not subject to 10 CFR 50.59. It is at the

point in time that the revised method becomes the means used for purposes of satisfying UFSAR safety analysis or design bases requirements that NRC approval becomes necessary.

If the result from the revised method is further from the established limit than under the previous method, the revised method is in the nonconservative direction. When judging conservatism of a change in methods, a predicted result closer to an established limit is conservative, in that there is less opportunity for other changes without triggering the need for NRC review and approval. (In contrast, a facility change, which when evaluated (with no change in methods) results in a value further from the limit, is a "conservative" facility change. The difference is that it is the facility change that causes "more margin" in the actual expected result, as contrasted to an analytical result arising from a change to methodology).

Licensees' results are "essentially the same" if they are within the margin of error needed for the type of analysis being performed even if trending in the nonconservative direction. Licensees' results are essentially the same if the variation in results due to the change to the method is explainable as routine analysis sensitivities, and the differences in the results are not a factor in determining whether any limits or criteria are satisfied. The licensee's determination can be made through benchmarking (e.g., new versus old method), or may be apparent from the nature of the changes between the methods. When licensees benchmark a method to determine how it compares to the previous one, the analyses that are done must be for the same set of plant conditions; otherwise, the results are not comparable. Approval for intended application includes the licensee assuring that the approved method is approved for the type of analysis being conducted, generically approved for the type of facility using it, and that all terms and conditions for use of the method are satisfied. The intent of this criterion is to limit the need for review to those changes to methods that could impact upon the acceptability of performance were the results to be at the limiting values.

Design bases, as used in this criterion, is the definition contained in 10 CFR 50.2 and in particular those controlling values that are restraints derived from generally accepted practices for achieving functional goals or requirements derived from analysis of the effects of a postulated accident for which a SSC must meet its functional goals, or requirements derived from analysis of the effects of a postulated accident for which a SSC must meet its functional goals. Safety analyses are those evaluations that demonstrate that acceptance criteria for the facility's capability to withstand or to respond to postulated events are met.

This criterion applies to those methods of evaluation used for demonstrating that design basis limits for fission product barriers are met for other analyses (such as radiological consequences) that are part of the safety analyses and for analyses that demonstrate that functional goals for SSC are met. Included are those analyses that show that the SSC will function under limiting conditions such as natural phenomena, environmental conditions, dynamic effects, and so forth.

However, only those methods that are used in establishing the design bases or in the safety analyses fall within this criterion.

In addition, changes to time-limited aging analyses and evaluations of aging management programs required by 10 CFR 54.21(d) and 10 CFR 54.37(b) require licensee evaluation with respect to criterion (viii), to the extent that evaluation methods for these analyses are described in the UFSAR supplement.

The SOCs further state that, to assure consistent implementation of this criterion, it is important for licensees to clearly distinguish between methods of evaluation and input parameters to the methods. See Sections 04.03 and 04.04 of this IMC for definitions of methods of evaluation and input parameters, respectively. The SOCs also state that licensees may use generic topical reports and not consider them a “departure” from a method of evaluation provided that the topical report is applicable to the licensee’s facility and is used by the licensee within the terms and conditions specified in the NRC-approved topical report.

As clarified in RG 1.187, Rev. 2, 10 CFR 50.59 allows licensees to document a methodology revision either (1) as a change to any of the elements of the methodology described in the UFSAR (i.e., paragraph (i) of the departure definition (Section 04.02)), or (2) as a change from the method described in the UFSAR to another method (i.e., paragraph (ii) of the departure definition (Section 04.02)). If a methodology revision is documented as a change from the method described in the UFSAR to another method using paragraph (ii) of the departure definition, then “the results of the analysis are conservative or essentially the same” of paragraph (i) of the departure definition is not applicable.

Several examples from the 50.59 final rule SOCs to illustrate the implementation of this criterion include:

Example 1: The UFSAR states that a damping value of 0.5 percent is used in the seismic analysis of safety-related piping. The licensee wishes to change this value to 2 percent to reanalyze the seismic loads for the piping. Using a higher damping value to represent the response of the piping to the acceleration from the postulated earthquake in the analysis results in lower calculated stresses because the increased damping reduces the loads. Since this analysis is used in establishing the seismic design bases for the piping, and since this is a change to an element of the method that is not conservative and is not essentially the same, the NRC concludes that this change meets criterion (viii) and requires prior NRC approval before implementation.

On the other hand, had NRC already approved an alternate method of seismic analysis that allowed 2 percent damping provided certain other assumptions were made, and the licensee used the complete set of assumptions to perform its analysis, then the use of the 2 percent damping under these circumstances is not a departure, under the second part of the departure definition (i.e., approved by NRC for the intended application).

Example 2: The licensee wishes to use an inelastic analysis procedure, not previously used in its seismic analyses as described in the UFSAR, to demonstrate that the structural acceptance criteria are met for cable trays. The NRC concludes that this is a departure from the methods of evaluation and that it is not essentially the same because the revised analysis predicts greater capacity than the previous analysis. Therefore, this change requires prior NRC approval.

Example 3: The licensee wishes to change a non-LOCA UFSAR Chapter 15 transient methodology. The methodology is being changed to a different vendor's NRC approved method. The new vendor's method is approved generically for the particular reactor type (e.g., 2 loop PWR) and for the particular transient being analyzed. The analysis is being performed in accordance with all the applicable limitations and restrictions. The licensee can make this change without prior NRC approval because the use of a generically approved method for the purpose it was approved, while meeting all the limitations and restrictions, is not considered a "departure." Subsequent plant changes can then be evaluated by the licensee using this new method and the other seven criteria in 10 CFR 50.59.

Example 4: The licensee wishes to change an analysis described in the UFSAR, which states that adequate net positive suction head (NPSH) is verified by analysis without crediting containment overpressure. The new analysis assumes that five pounds of overpressure is credited in calculation of available NPSH. The revised analysis predicts more (five additional pounds of) available NPSH for the pumps, a result further from the limit (the required NPSH) for an analysis that establishes part of the design bases for the pumps as being capable of performing their required function under the range of expected conditions. This change cannot be made without prior NRC approval because a change in an element of a method described in the UFSAR that is used to establish the design basis, that is not conservative or essentially the same, is considered a "departure."

Example 5: The licensee wishes to change an evaluation method described or incorporated by reference in the UFSAR Chapter 15 transient analysis. To remove some of the conservatism associated with the analysis, the change the licensee is contemplating is removal from the analysis of consideration of certain instrument uncertainties for a few parameters, by assuming nominal values instead. By not accounting for the greater range of the parameter (including the uncertainties), the analysis predicts response further from the limit to be satisfied. The treatment of uncertainties was an element of the method described in the UFSAR, and, therefore, this change cannot be made without prior NRC approval because a change in an element of a method described in the UFSAR, used in the safety analysis, that is not essentially the same is a "departure."

On the other hand, if an instrument in the plant were replaced with a different one, the assumed uncertainty in the analysis for that instrument can be used in the analysis without prior NRC review and approval using the other seven 10 CFR 50.59 criteria rather than criterion (viii) because this is an input change rather than a model change. How the uncertainties are treated in the analysis is part of the method. The range of values of the uncertainties associated with particular instruments is a characteristic of the facility and is an input parameter.

06.22 Maintenance Activities

Inspectors should be aware that the SOCs for 10 CFR 50.59 state that simply removing a component from service for maintenance does not require a 10 CFR 50.59 evaluation. Rather, maintenance activities, including associated temporary changes, can be assessed and managed in accordance with the Maintenance Rule, 10 CFR 50.65. However, prolonged removal from service appears indistinguishable in its effect from a change that removes the component from the facility. Further, there may be circumstances under which maintenance activities would place the facility in a configuration not previously considered or require disabling of barriers or movement of heavy loads to accomplish.

Removing equipment from service (making it inoperable) for maintenance during the technical specification (TS) allowed outage time does not require application of 10 CFR 50.59. Removing non-TS equipment from service is covered by the requirements of the maintenance rule (10 CFR 50.65). 10 CFR 50.59 does not need to be applied. One way to decide if a particular activity is "maintenance" or a "change" is to determine if the plant will be returned to its as-design condition following the activity.

Regarding maintenance, when reviewing a licensee's evaluated CTE, inspectors should consider whether the plant will return to the same configuration following the activity. Licensee reliance upon the 10 CFR 50.65(a)(4) assessment in lieu of a 10 CFR 50.59 evaluation also extends to temporary alterations (or test activities) to the facility or procedures that directly relate to and are required in support of specific maintenance activities. If a licensee completed a 10 CFR 50.65(a)(4) assessment, then temporary alterations in support of implementation of a modification are not subject to 10 CFR 50.59 evaluation (the modification itself is subject to 10 CFR 50.59 with respect to operation following installation). However, if the temporary alterations (including those affecting operator actions and procedures as described in the UFSAR) are not in support of maintenance, or are expected to remain in place for more than 90 days at power, licensees should perform a 10 CFR 50.59 review in addition to the 10 CFR 50.65(a)(4) assessment.

06.23 Compensatory Actions

Licensee compensatory actions and/or measures are temporary in nature and are subject to 10 CFR 50.59 in the same manner as those CTEs that are permanent. If a compensatory action and/or measure involves a facility or procedure change, then the licensee is responsible to determine whether the compensatory action and/or measure itself (not the condition) impacts other aspects of the facility or procedures described in the UFSAR. IMC 0326, "Operability Determinations," contains additional guidance on compensatory measures. Evaluation against the criteria in 10 CFR 50.59 of such compensatory actions and/or measures is the responsibility of the licensee. Inspectors should be mindful of whether a temporary change impacts other aspect of the facility, and pay particular attention to ancillary aspects of the temporary change that result from actions taken to directly compensate for the condition. See Sections 06.15 through 06.21 of this IMC for discussion of the criteria in 10 CFR 50.59.

06.24 Guidance for Digital Modifications

NEI 96-07, Appendix D, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications," provides focused application of the 10 CFR 50.59 guidance contained in NEI 96-07, Revision 1, to activities involving digital modifications. RG 1.187, Revision 2, endorses NEI 96-07, Appendix D, Revision 1, as a means for complying with the requirements of 10 CFR 50.59 when conducting digital I&C modifications, subject to the clarifications in RG 1.187, Revision 2. Additionally, Regulatory Issue Summary (RIS) 2002-22, Supplement 1, "Clarification on Endorsement of Nuclear Energy Institute Guidance in Designing Digital Upgrades in Instrumentation and Control Systems" clarifies the guidance for preparing and documenting "qualitative assessments" that can be used to evaluate the likelihood of failure of a proposed digital modification, including the likelihood of failure due to a common cause (i.e., common-cause failure (CCF)). The guidance in NEI 96-07, Appendix D may be used in conjunction with the 10 CFR 50.59-related guidance contained in RIS 2002-22, Supplement 1.

Inspectors should refer to the guidance in RG 1.187; NEI 96-07, Appendix D; and RIS 2002-22, Supplement 1 when inspecting digital modifications.

06.25 Documentation and Reporting

10 CFR 50.59(d)(1) requires licensees to maintain records of changes in the facility, of changes in procedures, and of tests and experiments made in accordance with 10 CFR 50.59 without NRC approval. It also requires that these records include a written evaluation which provides the bases for the determination that the CTE does not require a license amendment.

10 CFR 50.59(d)(2) requires that the licensee submit, as specified by 10 CFR 50.4 and 52.3, a report containing a brief description of each CTE, including a summary of its supporting evaluation, implemented without prior NRC approval. The reporting frequency is not to exceed 24 months, but reports may be filed more frequently if a licensee so chooses. Reports are required by 10 CFR 50.59 only for those CTEs for which evaluations against the criteria were required and not for CTEs that screened out (for those licensees who employ a screening process).

10 CFR 50.59(d)(3) requires that records of changes to the facility be maintained until the date of termination of the license (either the Part 50 license, combined license issued under Part 52, or any license issued under Part 54), and that records of changes to the procedures and records of tests and experiments be maintained for a period of 5 years.

The NRC staff does not consider a checklist to be sufficient to meet the requirement for a written evaluation. However, depending upon the significance of the change, the 10 CFR 50.59 evaluation can be quite brief. As described in NEI 96-07, Revision 1, 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 50.59, these explanations should be complete in the sense that another knowledgeable reviewer could draw the same conclusion. Restatement of the criteria in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. It is recognized, however, that for certain very simple activities, a statement of the conclusion with identification of references consulted to support the conclusion would be adequate and the 10 CFR 50.59 evaluation could be very brief.

0335-07 10 CFR 72.48 PROCESS

The existing requirements contained in 10 CFR 72.48 allow an ISFSI licensee, a MRS licensee, or a spent fuel storage cask CoC holder to make changes to their facilities, spent fuel storage cask, procedures, and to conduct tests or experiments without prior NRC review and approval. Comparable provisions exist in 10 CFR 50.59 for power reactor licensees, as described in Section 0355-06 of this IMC. Additionally, prior to implementing a CTE, a licensee or a cask CoC holder would use the 10 CFR 72.48 process to determine whether prior NRC approval through a license amendment under (1) 10 CFR 72.56 (for specific licensees) or (2) 10 CFR 72.244 (for general licensees and storage cask certificate holders) is required.

Furthermore, licensees and CoC holders should apply the 10 CFR 72.48 process after determining that a proposed activity is safe and effective through appropriate engineering and

technical evaluations. The licensee's and CoC holder's process may involve the following steps:

- a. **Applicability and Screening:** Licensees and CoC holders may follow these processes, as described in the licensee's or CoC holder's procedures to determine if another process governs the CTE or if the licensee or CoC holder may need to perform a 10 CFR 72.48 evaluation. The applicability determination also decides whether there is no regulatory review required at all (i.e., for editorial or administrative changes).
- b. **Evaluation:** The licensee or CoC holder applies the evaluation criteria delineated in 10 CFR 72.48(c)(2) to determine if prior NRC review and approval through a license amendment is required, pursuant to (1) 10 CFR 72.56 (for specific licensees) or (2) a CoC amendment is required under 10 CFR 72.244 (for general licensees and certificate holders).
- c. **Documentation and Reporting:** Document and report to the NRC and to the appropriate licensee's or certificate holder's activities implemented under 10 CFR 72.48.

07.01 Relationship Between 10 CFR 50.59 and 10 CFR 72.48

As a part of rulemaking in 1999, the staff revised the regulations in 10 CFR 72.48 to conform with the revised 10 CFR 50.59 rule in order to provide consistent implementation of these two regulations. The rule change in 1999 gave CoC holders the authority to use 10 CFR 72.48 for the first time. Therefore, the inspection staff may apply applicable guidance in Section 0335-06 of this IMC to support the implementation of 10 CFR 72.48.

Other sections of this IMC discuss key definitions, provide guidance for reviewing the licensee's and CoC holder's processes for applicability and screening, and performing an assessment of 10 CFR 72.48 evaluations. Inspectors should be aware that changes in the ISFSI and spent fuel storage cask design may affect the Part 50 license if co-located and may require analyses in 10 CFR 50.59 and 10 CFR 72.48.

07.02 Relationship Between 10 CFR 72.48 and Quality Assurance Program Requirements

Prior to the NRC issuing an ISFSI license or a CoC for a spent fuel storage cask, the NRC staff will review Quality Assurance Programs (QAPs) applications such as 10 CFR Part 72, Subpart G, 10 CFR Part 71, Subpart H and 10 CFR Part 50, Appendix B. The implementation of the QAPs ensures that the ISFSI and spent fuel storage cask design and construction meet applicable requirements, codes, and standards in accordance with the safety classification of SSCs. The design control provisions of Part 72, Subpart G, Part 71, Subpart H, and 10 CFR Part 50, Appendix B ensure that changes under 10 CFR 72.48 will continue to meet applicable design and quality requirements. The QAP and 10 CFR 72.48 requirements are applicable after the issuance of an ISFSI license or a spent fuel storage cask CoC or implementation of a 10 CFR Part 72 general license. The review of 10 CFR 72.48 changes is exclusively a regulatory assessment to determine if a licensee or CoC holder requires prior NRC review and approval before they implemented the change.

QAP requirements are also applicable to corrective actions. Section 07.21 of this IMC describes how to address degraded and nonconforming conditions and the application of 10 CFR 72.48 to compensatory measures.

07.03 Relationship Between 10 CFR 72.48 and Transportation (10 CFR Part 71)

Some CoC holders designed spent fuel dry cask storage systems as dual purpose cask systems for storage and transportation. These systems may have separate UFSARs for the Part 72 certification of compliance and the Part 71 certification of compliance. 10 CFR 72.48 controls changes to activities in the UFSAR, only with respect to the design and licensing bases of the cask storage system certified under Part 72. When licensees or CoC holders propose changes for a dual-purpose cask, this could affect the Part 71 transportation design and licensing bases. Inspectors should be aware of changes to activities that affect Part 71 design and licensing bases and will need to be assessed and controlled under Part 71 requirements when the casks are ready for transport. Such changes are outside the scope of this document because Part 71 does not have a change control process, similar to 10 CFR 72.48.

07.04 Relationship Between 10 CFR 72.48 and Maintenance (10 CFR 50.65)

Inspectors should recognize maintenance activities affecting the ISFSI or storage cask are subject to the 10 CFR 72.48 process. Maintenance activities are activities that may restore SSCs to their as-designed condition including activities that implement approved design changes. These maintenance activities may include troubleshooting, calibration, refurbishment, maintenance-related testing, like-for-like replacements, housekeeping and similar activities that do not permanently alter the design, performance requirements, operation, or control of SSCs.

Inspectors should be aware that maintenance activities also include temporary alterations to the ISFSI, cask design, or procedures that directly relate to and are necessary to support the maintenance. Examples of temporary alterations that support maintenance include placing temporary lead shielding on casks, removal of barriers, and use of scaffolding and supports.

Inspectors should be aware that 10 CFR 50.65 does not apply to an ISFSI or a spent fuel storage cask licensed or certified under 10 CFR Part 72. Additionally, as discussed in Section 07.21 of this IMC, 10 CFR 72.48 applies to temporary changes and proposed compensatory measures for degraded or non-conforming conditions.

07.05 Relationship Between 10 CFR 72.48 and 10 CFR 72.212 Evaluation Report

Inspectors should understand the relationship between the requirements described in 10 CFR 72.48 and 10 CFR 72.212 evaluation reports. An evaluation report for 10 CFR 72.212 (212 Report) for a general licensee contains written evaluations required under the provisions of 10 CFR 72.212 (b)(5), (b)(6), and (b)(8). A general licensee creates these evaluation reports as a part of a review of activities prior to the first use of a cask system or applying the changes of an amended CoC to cask loaded under the initial or an earlier amended CoC.

10 CFR 72.212(b)(7) requires a general licensee to evaluate any changes to these written evaluations required by paragraphs (b)(5) and (b)(6) of 10 CFR 72.212 using the requirements of 10 CFR 72.48. Section 72.212(b)(5) requires the general licensee to perform a written evaluation before using a cask and before applying the changes authorized by an amended CoC to a previously loaded cask. Section 72.212(b)(6) requires the general licensee to review the Safety Analysis Report referenced in the CoC or amended CoC and the related NRC Safety Evaluation Report, prior to use of the general license, to determine whether or not the reactor site parameters, including analyses of earthquake intensity and tornado missiles, are enveloped by the cask design bases considered in these reports. This includes the written evaluations described in the initial 212 Report that deviate from information in the cask UFSAR.

If the initial issuance of the 212 Report contains no deviations from the cask UFSAR, then there is no 10 CFR 72.48 review required. Thereafter, other than editorial or administrative corrections, any alterations made to the 212 Report require a 10 CFR 72.48 review pursuant to 10 CFR 72.212(b)(7) as applicable. When there are deviations from the cask UFSAR, then the inspectors should verify that the general licensee has performed a review of the deviations under the 10 CFR 72.48 process.

The modification to the 212 Report may identify the need to perform additional reviews under 10 CFR 72.48 for modifications to the cask UFSAR. The NRC Regulatory Issue Summary 2015-05 provides additional information on the relationship between 10 CFR 212 and 10 CFR 72.48 evaluations.

07.06 Applicability Determination

10 CFR 72.48 applies to each holder of (1) a general or specific license issued under Part 72, and (2) a CoC issued under Part 72.

Inspectors should recognize that similar to the 10 CFR 50.59 process and as discussed in the 1999 SOCs of the final rule, the Commission excluded specific types of changes established by other provisions and regulations from the scope of 10 CFR 72.48 review. Examples of these regulations that contain a change control process in Part 72 regulations, include, but are not limited to the following:

- 10 CFR 72.7, Specific exemptions,
- 10 CFR 72.44, License conditions,
- 10 CFR 72.56, Application for amendment of license, and
- 10 CFR 72.244, Application for amendment of a certificate of compliance.

Inspectors should also recognize that there may be certain activities for which a licensee or storage cask CoC holder may need to apply the requirements of 10 CFR 72.48 and another regulation.

07.07 Screening

NEI 12-04, Revision 2, provides guidance related to the 10 CFR 72.48 process including the licensee's and CoC holder's processes for applicability and screening. These controlled processes may be part of the licensee's or CoC holder's administrative procedures that may determine if the CTE warrants a 10 CFR 72.48 evaluation. The screening process follows the

licensee's or CoC holder's applicability process which determines that another change control process in other regulations does not apply to a proposed change.

Inspectors should review the results of the screening process to understand how the licensee or CoC holder answered the screening questions for the proposed CTE. As stated in NEI 12-04, Revision 2, the licensees or CoC holders should consider four possible aspects of a proposed CTE:

1. Impact(s) on the facility or storage design functions,
2. Impact(s) on procedures for performing or controlling SSC design functions,
3. Impact(s) on Methods of Evaluation, and
4. Impact(s) on Tests or Experiments.

07.08 Changes to the Facility or to Procedures

Inspectors should understand the change(s) to the ISFSI or MRS facility, storage cask, or procedures. The definitions of change, a facility as described in the UFSAR, and procedures as described in the UFSAR are in Sections 04.01, 04.05 and 04.08 of this IMC, respectively. Inspectors should recognize that the definitions described in those sections establishes that changes to analyses, as well as physical or hardware changes to the facility, and to the licensing bases of the facility require an evaluation.

Additionally, changes to information in the UFSAR that provide performance or qualification requirements, methods of operation, and the bases on how the licensee and CoC holders established those requirements to the analyses and evaluations in the UFSAR, which demonstrate that the facility meets requirements may also satisfy the licensee's and CoC holders' screening criteria.

NEI 12-04, Revision 2, provides guidance for licensees and CoC holders on how to use the screening determination process to assess whether changes are administrative, only descriptive, or do not adversely affect the functions of the SSC. Changes such as these do not require a 10 CFR 72.48 evaluation.

NEI 12-04, Revision 2, states that if a change has no effect or has only beneficial effects, it does not trigger any of the evaluation criteria concerning more than minimal increase in frequency or occurrence of malfunction or higher consequences, etc. If the licensee cannot conclude that there is no adverse effect, a 10 CFR 72.48 evaluation is required.

Inspectors should recognize that changes reducing an SSC's capability, performance, qualification, or reliability are adverse. Inspectors should recognize that changes reducing an SSC's capability, performance, qualification, or reliability in the accomplishment of its as-credited design function is adverse.

The functions being affected by a change might cause indirect effects on an SSC including environmental conditions and physical interactions. For these reasons, the inspectors should be mindful of how the licensees address indirect effects.

SSCs or procedures that are described in the UFSAR but are not important-to-safety or safety-related should not be excluded from evaluation in accordance with 10 CFR 72.48. If the 10 CFR 72.48 screening criteria is satisfied, then a 10 CFR 72.48 evaluation is required.

Each element of a CTE should be separately evaluated against each of the 10 CFR 72.48(c)(2) criteria unless the elements of a CTE are interdependent, that is, linked to each other and not separable for functional reasons. If concurrent changes are being made that are not linked, inspectors should expect licensees to evaluate each criterion separately and independently. One change (that might add conservatism) should not be used to preclude NRC review of another change that would, on its own, meet any of the evaluation criteria. Each criterion must be satisfied on its own, and a reduction in consequences cannot offset an increase in likelihood for a given change as a basis for meeting 10 CFR 72.48.

An unintended change of the ISFSI or MRS facility, spent fuel storage cask design or procedures from that described in the UFSAR, whether in existence since initial licensing, or as the result of an error in a subsequent facility/procedure change or other activity that is not restored must be reviewed by the licensee pursuant to 10 CFR 72.48 to determine whether the unintended change required NRC approval. For unintended changes which rise to the level of requiring NRC approval, the NRC approval prior to implementation refers to the approval of the corrective action (i.e., of the change to the licensing basis as described in the UFSAR) before the condition is resolved.

07.09 Tests or Experiments Not Described in the UFSAR

The SOC for the 10 CFR 72.48 rule states that tests and experiments that have not been previously evaluated or could affect the capability of SSCs to perform their intended functions, those tests and experiments should be evaluated under 10 CFR 72.48 before implementation. Additionally, 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.

07.10 Evaluation Process

During the 10 CFR 72.48 evaluation process, inspectors should expect the licensee or CoC holder to review the eight evaluation criteria of 10 CFR 72.48(c)(2) to determine if the CTE requires prior NRC approval. Inspectors should recognize that a 10 CFR 72.48 evaluation would not be required if the CTE to the ISFSI or MRS facility, storage cask, or procedure involves a change to the TS. If the CTE involves a TS change, then the specific licensee must apply for and obtain a license amendment in accordance with 10 CFR 72.56 and a CoC holder must apply for and obtain a CoC amendment under 10 CFR 72.244 (for itself or for a general licensee) before implementing the CTE.

The SOCs for the final rules for 10 CFR Parts 50 and 72 state the evaluation process permits licensees and CoC holders to make changes to the facility and storage casks provided the changes maintain acceptable levels of safety as documented in the safety analysis report. The Commission structured the evaluation process around the licensing approach of design basis events (e.g., anticipated operational occurrences, off-normal and accidents), safety-related mitigation systems, and consequence calculations for the DBAs. The purpose is to identify possible changes that might affect the basis for licensing the facility or storage cask design so that any changes that might pose a safety concern the NRC would review to confirm their safety before implementation.

The NRC provides the basis for its approval of a license and CoC in the SER, supplements to the SER, and SERs for amendments to the license or CoC. Inspectors should consider the

bases presented in a SER and perform an independent review of the licensee's evaluated CTE against the criteria described in 10 CFR 72.48(c)(2). Inspectors should also review the SRP applicable to the storage design to understand the licensing basis of the approval. The SRP identifies the specific areas of review and the associated acceptance criteria the NRC staff used to review the licensee's or CoC holder's Safety Analysis Report.

Inspectors should understand that the SRP does not provide requirements for the licensee unless the licensee committed to an SRP method of complying with a regulation or a code alternative which may make it part of the licensing basis.

The areas that the inspectors should consider when reviewing licensees' or CoC holders 10 CFR 72.48 evaluations include but are not limited to the following:

- SSCs directly and indirectly affected by the change (e.g., does the change affect the capability of the SSCs, or another SSC, to perform the intended design function(s)?);
- A change to any element of a method described in the UFSAR or 2) a change from a method described in the UFSAR to another method;
- parameters of the accident analysis affected by the change (e.g., are all the relevant DBAs and transients identified in licensee evaluations?);
- potential effects of SSC failures (e.g., licensees explored and answered the question, "what would happen if..." in the evaluation); and
- how the evaluation criteria are met.

Each element of a CTE should be separately evaluated against each of the 10 CFR 72.48(c)(2) criteria unless the elements of a CTE are interdependent, that is, linked to each other and not separable for functional reasons. If concurrent changes are being made that are not linked, inspectors should expect licensees to evaluate each criterion separately and independently. One change (that might add conservatism) should not be used to preclude NRC review of another change that would, on its own, meet any of the evaluation criteria. Each criterion must be satisfied on its own, and a reduction in consequences cannot offset an increase in likelihood for a given change as a basis for meeting 10 CFR 72.48.

Licensee evaluations that concluded that any of the 10 CFR 72.48(c)(2) criteria are met must obtain a license amendment prior to implementation of the CTE.

07.11 Minimal Increase Principle

The "minimal increase" principle is described in Section 06.13 of this IMC. Additionally, ISFSI design basis events and equipment failures were generally postulated to gauge the robustness of the design, without estimating their likelihood of occurrence.

The inspector may reference the applicable SRP for spent fuel dry storage systems and facilities for additional insight related to the minimal increase principle.

07.12 Probabilistic Risk Assessment and Risk Insights

For licensees committed to RG 3.72, Revision 0, the use of PRA and risk insights is described in Section 06.14 of this IMC.

For licensees committed to RG 3.72, Revision 1, NEI 12-04, Revision 2, provides guidance explaining that the use of PRA is inapplicable to 10 CFR 72.48.

For licensees that have not committed to either version of RG 3.72, then an inspector should confirm whether the licensee has followed its current licensing basis with regard to use of PRA and whether the licensee evaluations comply with the regulations in 10 CFR 72.48.

07.13 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(i)

10 CFR 72.48(c)(2)(i) focuses on whether the CTE would result in a more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR.

As described in NEI 12-04, Revision 2, ISFSI design events have been divided into categories based upon a qualitative assessment of frequency. The frequency categories for design events, as discussed in NUREG-2215 and ANSI/ANS-57.9, "Design Criteria for an Independent Spent Fuel Storage Installation (Dry Type)," 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 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.

The SOCs for the final rule considered accident frequencies broadly. Inspectors should recognize that a change from one frequency category to a more frequent category is 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, inspectors should base their review of licensee determinations of frequency increase on a qualitative assessment using engineering evaluations consistent with the UFSAR analysis assumptions. However, as stated in NEI 12-04, Revision 2, an ISFSI or spent fuel storage cask specific accident frequency calculation may be used to evaluate a proposed activity in a quantitative sense.

NEI 12-04, Revision 2, and Appendix B of NEI 96-07, Revision 1, provide guidance for licensees or CoC holders on the use of reasonable engineering practices, engineering judgment and PRA techniques, as appropriate, to determine whether the frequency of occurrence of an accident more than minimally increases as a result of implementing a CTE. Section 06.14 of this IMC discusses PRA and PRA techniques for licensees committed to RG 3.72, Revision 0.

Inspectors should be aware that licensees or CoC holders do not need to provide quantitative calculations to meet the standard of "no more than minimal," unless when the licensee or CoC holder offers quantitative arguments as part of its evaluation.

However, as discussed in the SOC for the final rule, departures from the design basis, design, fabrication, construction, testing, and performance standards as outlined in the GDC (Subpart F to Part 72), Spent Fuel Storage Casks Approval (Subpart L), and as specified in the licensing basis, those are not compatible with a "no more than minimal increase" standard.

Inspectors should recognize that frequencies of occurrence of natural phenomena used to establish the initial licensing basis for specific licensees also apply to general licensees. However, frequencies of occurrence of natural phenomena were not established as part of the generic storage cask certification because there was no geographic location 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 site-specific. The frequency of occurrence of environmental phenomena at any site are not expected to change, unless the ISFSI owner specifically updates the information pertaining to meteorological or seismic event occurrence that forms the design basis for the facility. The changes in design requirements for natural phenomena, such as earthquakes, tornadoes, snow, flooding, and lightning strikes, etc. should be treated as potentially affecting the likelihood of a malfunction (see Section 07.14) rather than the frequency of occurrence of an accident.

07.14 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(ii)

10 CFR 72.48(c)(2)(ii) focuses on whether the CTE would result in a more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety previously evaluated in the UFSAR. See Section 04.16 of this IMC for the definition of malfunction of SSCs important to safety.

Inspectors should consider the cause and mode of a malfunction in determining whether there is a change in the likelihood of a malfunction. Inspectors should also consider the effect or result of a malfunction in determining whether a malfunction with a different result is involved per Section 7.18. Inspectors should recognize that in determining whether there is more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC to perform its design function as described in the UFSAR, the inspector should consider what SSCs does the CTE affect. The inspector should also consider what the effects of the proposed CTE have on the affected SSCs. This independent evaluation should include both direct and indirect effects.

Direct effects are those where the proposed CTE affects the SSCs. Indirect effects are those where the proposed CTE 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 CTE 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 the design. Certain design functions, while not specifically identified in the safety analysis, are credited in an indirect sense. After determining the effect of the proposed CTE on the important-to-safety SSCs, the inspectors should consider whether the likelihood of a malfunction of the important-to-safety SSCs has increased more than minimally.

As discussed in NEI 12-04, Revision 2, the licensee or CoC holder may use qualitative engineering judgment and/or an industry precedent 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. See Section 06.14 of this IMC for further discussion on PRA and PRA techniques.

Inspectors should consider whether the likelihood of malfunction is more than minimally increased at a level consistent with existing UFSAR-described failure modes and effects analyses, as applicable. If, for example, in support of the evaluation the licensee or CoC holder calculates the change in likelihood of occurrence of a malfunction, and the result is less than two times, than this would not exceed the “more than a minimal increase” standard and would not require prior NRC approval. Additionally, design requirements for earthquakes, tornadoes, and other natural phenomena should be evaluated as potentially affecting the likelihood of malfunction.

Further, departures from the design, fabrication, construction, testing, and performance standards as outlined in the GDC (Subpart F to Part 72) are not compatible with a “no more than minimal increase” standard because such departures would be non-compliant with the regulations. When the GDC has been incorporated into the licensing basis, departures from the design, fabrication, construction, testing, and performance requirements in the GDC as incorporated into the licensing basis, are not compatible with a “no more than minimal increase” standard.

07.15 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(iii)

10 CFR 72.48(c)(2)(iii) focuses on whether the CTE would result in a more than a minimal increase in the consequences of an accident previously evaluated in the UFSAR.

Inspectors should recognize that the term “consequences” refers to radiological consequences, and includes not only offsite exposure, but also dose to operators in the control room or other onsite personnel resulting from accidents and malfunctions or off-normal events previously evaluated in the UFSAR. As described in the SOCs for the final rule, this criterion uses a graduated approach, consistent with the concept of “minimal” being small enough so as not to impact the basis for the acceptability of the previous licensing decision.

A change involves no more than a minimal increase in consequences if the increase is less than or equal to the more limiting of either 10 percent of the difference between the licensee’s existing calculated value and the regulatory guideline value (10 CFR 72.104, 10 CFR 72.106, or GDC 19 as applicable), or has reached the SRP guideline value for the particular design basis event/accident.

Inspectors should consider the applicability with respect to the accident, not whether the plant was specifically licensed using the SRP. Inspectors should recognize that this criterion covers proposed CTE that affect source terms, credited mitigation systems or actions which is pertinent to accidents.

If a licensee or CoC holder has performed an analysis with certain bounding assumptions, and the proposed CTE would increase a specific parameter from its present value to a different value that is still bounded by the value assumed in the analysis, the proposed CTE satisfies the criterion of “no more than a minimal increase in consequences,” because the bounding analysis is what determines the value from which a change is being judged. If a licensee needs to change its design basis assumptions or analytical methods, or both, to demonstrate that the change in consequences satisfies this criterion, then the change is not minimal, and a license amendment request is required.

Inspectors can find examples which illustrate the implementation of this criterion in Section 06.17 of this IMC.

07.16 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(iv)

10 CFR 72.48(c)(2)(iv) focuses on whether the CTE would result in a more than a minimal increase in the consequences of a malfunctions evaluated in the UFSAR. See Section 04.16 of this IMC for definition of malfunction of SSCs important to safety.

Inspectors should verify which malfunctions evaluated in the UFSAR are associated with the proposed CTE. The guidance for determining whether a proposed CTE results in more than a minimal increase in the consequences of a malfunction is the same as that for accidents.

Operation of an ISFSI, including cask loading and unloading, must not result in doses exceeding the limits of 10 CFR 72.104, 10 CFR 72.106, or GDC 19 as a result of a proposed CTE.

07.17 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(v)

10 CFR 72.48(c)(2)(v) focuses on whether the CTE would create a possibility for an accident of a different type than any previously evaluated in the UFSAR.

Inspectors should verify the DBAs and off-normal events evaluated in the UFSAR and potentially affected by the proposed change. Inspectors should verify these accidents and off-normal events to determine if a licensee or CoC holder needs to request a license amendment if it could be reasonably concluded that the licensee or CoC holder created a possibility of an accident of a different type based on the proposed CTE. However, inspectors should verify the following when determining whether a proposed CTE results in an accident of a different type:

- Does the accident result in a new or greater release path than originally considered?
- Does the accident result in a new fission product barrier failure mode?
- Does the accident create a new sequence of events that results in significant cladding failure?
- Would the accident be included if the UFSAR were being written today?

As stated in the SOC for the final rule “accidents” that would require multiple independent failures or other circumstances in order to “be created” would not fall within this criterion. The accident must be credible in the sense, of having been created within the range of assumptions previously considered and that a new initiator of the same accident is not a “different type” (but may affect the frequency of that accident under 10 CFR 72.48(c)(2)(i).

Additionally, NEI 12-04, Revision 2, states, in part, that certain accidents are not discussed in the UFSAR because their effects are bounded by other related accidents and 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 CTE introduces a cask drop of a distance less than the evaluated cask drop then the postulated cask drop does not need to be considered an accident of a different type.

07.18 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(vi)

10 CFR 72.48(c)(2)(vi) focuses on whether a CTE would create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the UFSAR. See Section 04.16 of this IMC for definition of malfunction of SSCs important to safety.

As described in NEI 12-04, Revision 2, and discussed in the SOC for the final rule, this criterion focuses upon the “effect” of the proposed CTE and whether the result of any malfunctions that might have been created by the proposed CTE has already been analyzed or bounded by the analyses in the UFSAR. Only if the effect is different from those already considered would this criterion require prior NRC approval for a proposed CTE involving a new type of malfunction. Note that the likelihood of malfunction may be increased if new failure modes are introduced (even if the effects have been previously evaluated in the UFSAR), and this situation would have to be evaluated under 10 CFR 72.48(c)(2)(ii). However, a proposed CTE 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.

The determination for this criterion should be made either at the component level, or consistent with the FMEA, considering single failure assumptions, and the level of the change being made. Certain changes may require a new FMEA, which would then need to be evaluated as to whether the effects of the malfunctions are bounding.

07.19 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(vii)

10 CFR 72.48(c)(2)(vii) focuses on whether a CTE would result in a design basis limit for a fission product barrier as described in the UFSAR being exceeded or altered.

Inspectors should recognize that this criterion would require a license amendment prior to implementation if the CTE results in exceeding or altering a design bases limit, established in the UFSAR, which has the potential to affect the performance of a fission product barrier. As discussed in the SOC for the final rule, affected parameters are not limited to specific parameters in the system in which the CTE is being made or to parameters that are only directly linked to the actual fission product barrier. Rather, the design parameters must include an assessment of all affected parameters, including design parameters of mitigation and support systems.

Inspectors should verify all the affected parameters identified by the licensee and determine whether the parameters have values established in the UFSAR, whether the parameters are controlling parameters that are reference bounds for the design, and whether the parameter has the potential to affect the performance of the fission product barrier. Inspectors should recognize that if the specific parameter values are already subject to controls established by the TS or other rules or regulation then those requirements shall be followed.

As described in NEI 12-04, Revision 2, for the purposes of 10 CFR 72.48 considerations, the fission product barriers for a spent fuel storage cask system would include the fuel cladding and the confinement boundary for the storage system. Dry spent fuel storage systems are designed in accordance with NRC requirements to preserve both fuel cladding integrity and

confinement capability during all credible normal, off-normal, and accident events. Integrity of the fuel cladding is required to maintain retrievability and sub-criticality of the stored spent fuel. Even if the cladding is not explicitly credited in the UFSAR as a fission product boundary, such as when damaged fuel is stored in a cask, effects of a proposed activity on cladding should still be considered when answering this 72.48(c)(2)(vii) criteria because the cladding integrity would continue to be important to maintain retrievability and sub-criticality (fuel configuration).

Proposed CTEs are judged in terms of whether the analysis results meet the acceptance criteria, such as not exceeding a design basis limit for any fission product barrier. Effects under this criterion are to be judged using the methods described in the UFSAR; methodology changes are evaluated using 10 CFR 72.48(c)(2)(viii). This criterion ensures that the margin that exists in the limits continues to be met. A design basis limit may not be altered. Changes that involve alteration of the design basis limit for a fission product barrier involve such a fundamental alteration of the facility design that a change, even in the conservative direction, need prior NRC approval via a license amendment.

Several examples from the final rule SOCs meant to illustrate the concepts for the implementation of this criterion are described in Section 6.18.

07.20 Review Licensee or CoC Holder Evaluation of Criterion (c)(2)(viii)

10 CFR 72.48(c)(2)(viii) focuses on whether a CTE would result in a departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses.

As discussed in NEI 12-04, Revision 2, the ISFSI or cask UFSAR contains design and licensing basis information for an ISFSI or spent fuel storage cask design, including descriptions of how regulatory requirements for design are met (such as the requirements governing normal operations and off-normal operations), and the adequacy of SSCs 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's or cask's response to accidents and events is acceptable. As such, in cases where the analytical methodology was an important part of the conclusion that the ISFSI 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.

Inspectors should have awareness of the definition of design bases as used in 10 CFR 72.48(c)(2)(viii) and contained in 10 CFR 72.3, and in particular, those controlling values that are restraints derived from generally accepted practices for achieving functional goals, or requirements derived from analysis of the effects of a postulated accident for which a SSC must meet its functional goals. Safety analyses are those evaluations that demonstrate that acceptance criteria for the facility or of a spent fuel storage cask's capability to withstand or to respond to postulated events are met. Therefore, 10 CFR 72.48(c)(2)(viii) applies to those methods of evaluation used for demonstrating that design basis limits for fission product barriers are met, for other analyses such as radiological consequences that are part of the safety analyses, and for analyses that demonstrate that functional goals for SSC are met. These would include those analyses that show that SSC will function under limiting conditions such as natural phenomena, environmental conditions, dynamic effects, and so forth. However, only those methods that are used in establishing the design bases or in the safety analyses fall

within 10 CFR 72.48(c)(2)(viii). In addition, changes to time-limited aging analyses and evaluations of aging management programs required by 10 CFR 72.42(a) and 10 CFR 72.240(c), require evaluation with respect to 10 CFR 72.48(c)(2)(viii) to the extent that evaluation methods for these analyses are described in the UFSAR supplement.

Because 10 CFR 72.48 provides a process for determining if prior NRC approval is required before making changes to the ISFSI or spent fuel storage cask design as described in the UFSAR, changes to MOEs described in the UFSAR also fall under the provisions of the 10 CFR 72.48 process, specifically criterion (c)(2)(viii). In general, licensees or CoC holders can make changes to MOEs without first obtaining a license amendment or cask CoC amendment in two ways:

1. Changing one or more elements of the MOE, provided the results are essentially the same as, or more conservative than, previous results or
2. Using a new or different MOE, if the MOE has been approved by the NRC for the intended application.

The responsibility and authority for performing the 10 CFR 72.48 review for a cask design approved under a CoC can be either the general licensee or the CoC holder. 10 CFR 72.48 responsibility and authority for a specific license are solely the specific licensees. In both cases, however, it is typically the cask designer (i.e., the MOE owner) that utilizes MOEs to perform the safety analyses or establish the cask design basis and would have the need to modify an element of an MOE or use a new or different MOE. As such, the licensee and MOE owner must coordinate efforts to ensure roles and responsibilities are clearly delineated and information is shared appropriately to ensure that a complete and comprehensive 10 CFR 72.48 review is performed for any change to an MOE.

If a proposed activity (e.g., a physical modification or procedure change) also involves a modified MOE element or a new or different MOE to analyze that physical modification or procedure change, the MOE change should be evaluated first against 10 CFR 72.48(c)(2)(viii), before the physical modification or procedure change is evaluated against 10 CFR 72.48(c)(2)(i) through (vii). If the MOE change is determined not to require NRC approval, these two separate evaluations may be documented in the same, or separate overall 10 CFR 72.48 reviews, at the discretion of the licensee or CoC holder.

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 a MOE described in the UFSAR, unless the results of the analysis are conservative or essentially the same
- Changes from a MOE in the FSAR to another method unless that method has been approved by NRC for the intended application.

See Section 04.02 of this IMC for definition of departure from an MOE described in the UFSAR.

To assure consistent implementation of the rules in 10 CFR 72.48 and 10 CFR 50.59(c)(2)(viii), it is important to clearly distinguish between elements and input parameters to the methods. See Sections 04.03 and 04.04 of this IMC for definitions of methods of evaluation and input parameters, respectively.

As stated in NEI 12-04, Revision 2, the 10 CFR 72.48(c)(2)(viii) requirements for evaluation methods allow for use of generic topical reports as not being a “departure,” provided that the topical report is applicable to the facility and is used within the terms and conditions specified in the approved topical report.

All CTEs are reviewed to determine if there is a departure from the method as described in the UFSAR. A departure occurs if any of the elements of the method are changed, such that the result of the analysis using that method is not conservative or essentially the same.

“Conservative” is judged with respect to the results obtained from the previous method. If the result from the changed method is further from the established limit than under the previous method, the changed method is in the nonconservative direction. When judging conservatism of a change in methods, a result closer to an established limit or values is conservative, in that there is less opportunity for other changes without triggering the need for NRC review and approval.

Results are “essentially the same” if they are within the margin of error needed for the type of analysis being performed, even if tending in the nonconservative direction. Results are essentially the same if the variation in results because of the change to the method is explainable as routine analysis sensitivities, and the differences in the results are not a factor in determining whether any limits or criteria are satisfied. The determination can be made through benchmarking (new vs. old method) or may be apparent from the nature of the changes between the methods. When benchmarking a method to determine how it compares to the previous one, the analyses that are done must be for the same set of plant conditions, otherwise, the results are not comparable. Approval for intended application includes assuring that the approved method is approved for the type of analysis being conducted, generically approved for the type of facility using it, and that all terms and conditions for use of the method are satisfied.

10 CFR 72.48 allows licensees to document a methodology revision either (1) as a change to any of the elements of the methodology described in the UFSAR (i.e., part 1 of the departure definition (Section 04.02), or (2) as a change from the method described in the UFSAR to another method (i.e., part 2 of the departure definition (Section 04.02)). If a methodology revision is documented as a change from the method described in the UFSAR to another method using part 2 of the departure definition, then “the results of the analysis are conservative or essentially the same” of part 1 of the departure definition is not applicable.

10 CFR 72.48(c)(2)(viii) ensures that the margin that exists from the conservatisms included in the methods used to demonstrate that requirements continues to be met.

Additionally, it is incumbent upon the user of a new or different MOE - even one generically approved by the NRC - to ensure that 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 or different 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 that it is approved for use in the intended application, the licensee or CoC holder 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.

The 10 CFR 72.48 evaluation documentation should provide a technical justification to demonstrate that the new or different MOE is technically applicable. This should include describing the MOE, conditions of applicability, limitations, restrictions, etc. If adequate information cannot be found on which to base the intended application of the MOE and described in the 10 CFR 72.48 evaluation, the MOE should not be considered “approved by the NRC for the intended application.”

When considering the application of an 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 or different and existing MOEs is considered when deciding whether to apply it to a different ISFSI or cask design. The new or different MOE must be used only by the same entity as the originally approved MOE or a successor entity who has become the CoC holder for that cask design.

Several examples from the final rule SOCs meant to illustrate the concepts for the implementation of this criterion are described in Section 6.19.

07.21 Compensatory Actions

General and specific licensees, and CoC holders have three ways to treat or consider non-conforming and degraded conditions, when determining whether to conduct a 72.48 evaluation, as discussed below:

- If the licensee or cask CoC holder intends to restore the SSC back to its as-designed condition, then the corrective action should be performed in accordance with 10 CFR 72, Subpart G, in a timely manner commensurate with safety. The corrective action activity is not subject to 10 CFR 72.48.
- If an interim compensatory action to address the non-conforming and degraded condition requires a temporary procedure or a change to the ISFSI or the cask design, 10 CFR 72.48 is applicable to the temporary change. The intent is to determine whether the temporary change/compensatory action itself (not the degraded condition) impacts other aspects of the ISFSI, cask design, or procedures described in the UFSAR.
- If the licensee or cask CoC holder implements a corrective action that (1) accepts the non-conforming or degraded condition “as-is,” thereby accepting a condition outside the as-designed condition, or (2) implements a corrective action that changes the ISFSI, the cask design, or the procedures, then 10 CFR 72.48 will be applicable to the corrective action. In these situations, the final corrective action is a CTE subject to 10 CFR 72.48.

07.22 Documentation and Reporting

Inspectors should recognize that the documentation and reporting requirements of 10 CFR 72.48(d) apply to activities that require an evaluation under the criteria of 10 CFR 72.48(c) and are determined to not require prior NRC review and approval. The documentation and reporting regulations in 10 CFR 72.48 do not apply to the licensee’s and CoC holder’s screening process as discussed in Section 07.08 of this IMC. Generally, the licensee’s and CoC holder’s screening determinations for 10 CFR 72.48 are available as quality assurance records.

0335-08 ISSUE RESOLUTION AND INTERNAL ALIGNMENT

If an inspector disagrees with a licensee's conclusion and results made in a 10 CFR 50.59 or 10 CFR 72.48 evaluation, the inspector should work with the licensee's management to resolve the issue expeditiously. A good practice is to make sure that licensee management is aware of potential 10 CFR 50.59 or 10 CFR 72.48 issues while the inspector is still evaluating the issue. Once the inspector concludes there is disagreement with the licensee, then the inspector should brief his/her NRC supervisor as soon as possible and work with NRC management to identify appropriate means to resolve the issue with the licensee.

Inspectors may consult with NRR/NMSS/DSS technical experts regarding a plant-specific CTE issue as part of the inspector's review of the licensee's 10 CFR 50.59 or 10 CFR 72.48 evaluation. This consultation may be informal (phone, email, etc.) or may be formalized using; COM-106 "Technical Assistance Request (TAR) Process," for reactors or NMSS Policy and Procedure 7-05 "Procedures for Processing of Technical Assistance Requests," for materials. In cases where there is a disagreement between the NRR/NMSS/DSS and the regional office staff regarding the 10 CFR 50.59 or 10 CFR 72.48 evaluation conclusion, the deciding authority shall be the appropriate Regional Administrator, or his/her delegate. Regarding the deciding authority, inspectors may utilize Management Directive (MD) 9.29, "Organization and Functions, Regional Office" and MD 9.27, "Organization and Functions, Office of Nuclear Reactor Regulation."

If the inspector believes the issue may impact other facilities, then the inspector should contact the appropriate NRR and NMSS technical staff through their Division of Operating Reactor Licensing (DORL) Project Manager and NMSS generic communication coordinator for evaluation as to the generic applicability of the issue. If the Region and/or NRR determines the issue is generic, then NRR should take the lead in developing a plan for addressing the issue through NRR's generic issue process. NMSS should follow NMSS Policy and Procedure 2-06 or NRR may also implement the LIC-504, "Integrated Risk-Informed Decision-Making," process which provides a risk-informed method for evaluating the safety significance of the issue and for deciding on the path forward for resolution. As NRR proceeds through developing and implementing a plan for resolution, the regional offices should be kept informed of the issue status and progress through regular communication paths.

0335-09 REFERENCES

- 10 CFR 20, "Standards for protection against radiation"
- 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
- 10 CFR 50.2, "Definitions"
- 10 CFR 50.12, "Specific exemptions"
- 10 CFR 50.34, "Contents of applications; technical information"
- 10 CFR 50.36, "Technical specifications"
- 10 CFR 50.46, "Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors"
- 10 CFR 50.54, "Conditions of licenses"

- 10 CFR 50.55, “Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses”
- 10 CFR 50.59, “Changes, tests and experiments”
- 10 CFR 50.65, “Requirements for monitoring the effectiveness of maintenance at nuclear power plants”
- 10 CFR 50.69, “Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors”
- 10 CFR 50.71, “Maintenance of records, making of reports”
- 10 CFR 50.90, “Application for amendment of license, construction permit, or early site permit”
- 10 CFR 50.155, “Mitigation of beyond-design-basis events”
- 10 CFR 72, “Licensing requirements for the independent storage of spent nuclear fuel and high-level radioactive waste, and reactor-related greater than Class C waste”
- 10 CFR 73, “Physical protection of plants and materials”
- 10 CFR 100, “Reactor site criteria”
- 1999 10 CFR 50.59 Statements of Consideration (64 FR 53582)
- 1999 10 CFR 50.59 Statements of Consideration (64 FR 53589)
- 2004 10 CFR 50.69 Statements of Consideration (69 FR 68007)
- 2019 10 CFR 50,155 Statements of Consideration (84 FR 39684)
- ANSI/ANS-57.9, “Design Criteria for an Independent Spent Fuel Storage Installation (Dry Type)”
- ASME Boiler and Pressure Vessel Code
- COM-106, “Technical Assistance Request (TAR) Process”
- GDC 19, “Control Room”
- GL 86-10, “Implementation for Fire Protection Requirements”
- GL 95-02, “Use of NUMARC/EPRI TR-102348, Guideline on Licensing Digital Upgrades, in Determining the Acceptability of Performing Analog-To-Digital Replacements Under 10 CFR 50.59”
- IMC 0326, “Operability Determinations”
- LIC-504, “Integrated Risk-Informed Decision-Making Process for Emergent Issues”
- MD 9.27, “Organization and Functions, Office of Nuclear Reactor Regulation”
- MD 9.29, “Organization and Functions, Regional Office”
- NEI 04-10, Revision 0, “Risk-Informed Technical Specification Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies,”
- NEI 04-10, Risk-Informed Method for Control of Surveillance Frequencies,” Revision 1
- NEI 12-04, Rev 2, “Guidelines for 10 CFR 72.48 Implementation”
- NEI 96-07, Rev 1, “Guidelines for 10 CFR 50.59 Evaluations”
- NEI 96-07, Appendix B, “Guidelines for 10 CFR 72.48 Implementation”
- NEI 97-04, rev. 1 Appendix B, “Guidance and Examples for Identifying 10 CFR 50.2 Design Bases”
- NMSS Policy and Procedure 2-06, “Overview of Generic Communications Coordination and Processing,” Revision 1
- NMSS Policy and Procedure 7-05, “Procedures for Processing of Technical Assistance Request,” Revision 1
- NUREG-0800, “Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [light water reactor] Edition”
- NUREG 1430, “Standard Technical Specifications — Babcock and Wilcox Plants”
- NUREG 1431, “Standard Technical Specifications — Westinghouse Plants”

- NUREG 1432, “Standard Technical Specifications — Combustion Engineering Plants”
- NUREG 1433, “Standard Technical Specifications — General Electric Plants (BWR/4)”
- NUREG 1434, “Standard Technical Specifications — General Electric Plants (BWR/6)”
- NUREG 1536, “Standard Review Plan for Spent Fuel Dry Storage Systems at a General License Facility – Final Report”
- NUREG 1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors
- NUREG 1567, “Standard Review Plan for Spent Fuel Dry Storage Facilities”
- NUREG 2194, “Standard Technical Specifications, Westinghouse Advanced Passive 1000 (AP 1000) Plants”
- NUREG 2215, Standard Review Plan for Spent Fuel Dry Storage Systems and Facilities”
- RG 1.70, Rev 3, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants LWR Edition”
- RG 1.174, Rev 3, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions of Plant-Specific Changes to the Licensing Basis”
- RG 1.186, “Guidance and Examples for Identifying 10 CFR 50.2 Design Bases”
- RG 1.187, “Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments”
- RG 3.72, “Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments”
- RIS 2012-05, “Clarifying the Relationship Between 10 CFR 72.212 and 10 CFR 72.48 Evaluations”
- SECY 99-07, “Recommendations for Reactor Oversight Process Improvements”

END

Attachment 1 - Revision History for IMC 0335, "Changes, Tests, and Experiments"

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
	ML20325A150 DRAFT CN	Made publicly available to discuss at the December 1, 2020, public meeting.	N/A	N/A
	ML20325A180 01/29/21 CN 21-007	Initial issuance. IMC 0335 has been created to update the guidance associated with TG 50.59 - 10 CFR 50.59, Changes, Tests, and Experiments.	Regional/HQ training to be performed in February/March 2021	ML20325A172