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Nuclear Energy Institute

GUIDELINES FOR 10 CFR 50.59 IMPLEMENTATION AT NON-POWER PRODUCTION OR UTILIZATION FACILITIES

Month 2021

ACKNOWLEDGMENTS

In 1996, NSAC-125, “Guidelines for 10 CFR 50.59 Safety Evaluations,” was transformed into Nuclear Energy Institute (NEI) 96-07 with minor changes to address specific NRC concerns. Much of this long-standing industry guidance continues to underlie the revised guidance presented in this document. We appreciate EPRI allowing NEI to use NSAC-125 in this manner and we recognize the efforts of the individuals who contributed to the development of NSAC-125.

In 1999, the NRC revised 10 CFR 50.59. In 2000, NEI 96-07, Revision 1, “Guidelines for 10 CFR 50.59 Implementation,” was issued that was developed with the invaluable assistance of the 10 CFR 50.59 Task Force and the Regulatory Process Working Group.

In 2021, this document was developed with the invaluable assistance of the Organization of Test, Research and Teaching Reactors task group on the subject.

Notice

Foreword

Under 10 CFR 50.59, licensees are allowed to make changes in the facility and procedures as described in the FSAR (as updated) and conduct tests or experiments not described in the FSAR (as updated), without obtaining a license amendment pursuant to 10 CFR 50.90 provided specific criteria are met. In 1999, the NRC revised 10 CFR 50.59. In 2000, NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," was issued to provide guidance for the revised 10 CFR 50.59 regulation.

In 2021, this document was developed to provide guidance on implementation of 10 CFR 50.59 at nuclear facilities other than power reactors, specifically non-power production or utilization facilities (NPUFs). This NPUF document was developed because most of the examples and specific discussion in NEI 96-07, Revision 1, focus on power reactors and some regulatory requirements that do not apply to NPUF licensees (e.g., Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"). Because of the intended consistency in applying 10 CFR 50.59 at power reactor licensees and NPUF licensees, this document was developed by adapting NEI 96-07, Revision 1, guidance.

Refer to the Foreword to NEI 96-07, Revision 1, for background information regarding the development of NEI 96-07, Revision 1.

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1.0 INTRODUCTION

1.1 PURPOSE

Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.59 establishes the conditions under which licensees may make changes to the facility or procedures and conduct tests or experiments without prior U.S. Nuclear Regulatory Commission (NRC) approval. Proposed changes, tests and experiments (hereafter referred to collectively as activities) that satisfy the definitions and one or more of the criteria in the rule must be reviewed and approved by the NRC before implementation. Thus 10 CFR 50.59 provides a threshold for regulatory review—not the final determination of safety—for proposed activities.

The purpose of this document is to provide guidance for developing effective and consistent 10 CFR 50.59 implementation processes at a "non-power production or utilization facility" (NPUF)[1]. NPUFs include non-power reactors, research reactors, testing facilities (also referred to as test reactors), critical assemblies, and training reactors, as well as, non-power production or utilization facilities that do not have a reactor (e.g., ~~for~~ medical radioisotope irradiation and processing facilities).

1.2 RELATIONSHIP OF 10 CFR 50.59 TO OTHER REGULATORY REQUIREMENTS AND CONTROLS

As the process for controlling a range of activities affecting equipment and procedures at NPUFs implementation of 10 CFR 50.59 interfaces with many other regulatory requirements and controls. To optimize the use of 10 CFR 50.59, the rule and this guidance should be understood in the context of the proper relationship with these other regulatory processes. These relationships are described below:

1.2.1 Relationship of 10 CFR 50.59 to Other Processes That Control Licensing Basis Activities

10 CFR 50.59 focuses on the effects of proposed activities on the safety analyses that are contained in the final safety analysis report (FSAR) (as updated) (also referred to as the updated final safety analysis report (UFSAR)) and are a cornerstone of each facility's licensing basis. In addition to 10 CFR 50.59 control of changes affecting the safety analyses, there are several other complementary processes for controlling activities that affect other aspects of the licensing basis, including:

- Amendments to the operating license (including the technical specifications) are sought and obtained under 10 CFR 50.90.

[1] NPUFs collectively refer to non-power reactors and certain other production or utilization facilities that are licensed under 10 CFR 50.21, "Class 104 licensees; for medical therapy and research and development facilities," paragraphs (a) and (c) or 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities." NPUFs do not include nuclear power reactors or production facilities as defined under paragraphs (1) and (2) of the definition of "production facility" in 10 CFR 50.2, "Definitions."

- Where changes to the facility or procedures are controlled by more specific regulations (e.g., ~~quality assurance,~~ security and emergency preparedness program changes controlled under 10 CFR 50.54 (p) and (q), respectively), 10 CFR 50.59 states that the more specific regulation applies.

- Changes that require an exemption from a regulation are processed in accordance with 10 CFR 50.12.

- Maintenance activities ~~are~~as discussed in Section 4.1.2.

Together with 10 CFR 50.59, these processes form a framework of complementary regulatory controls over the licensing basis. To optimize the effectiveness of these controls and minimize duplication and undue burden, it is important to understand the scope of each process within the regulatory framework. This guideline discusses the scope of 10 CFR 50.59 in relation to other processes, including circumstances under which different processes, e.g., 10 CFR 50.59 and 10 CFR 50.90, should be applied to different aspects of an activity.

In addition to controlling changes to the facility and procedures described in the UFSAR under 10 CFR 50.59 as required by the rule, some licensees also control changes to other licensing basis information using the 10 CFR 50.59 process. This may be in accordance with a requirement of the license or commitment to the NRC. The technical specifications bases are an example of documentation that may be outside the UFSAR but that is controlled via 10 CFR 50.59 by many licensees.

1.2.2 Relationship of 10 CFR 50.59 to the Quality Assurance Program

After the construction permit is issued and prior to the operating license, 10 CFR 50.59 does not apply and the NRC-approved quality assurance program required by 10 CFR 50.34(a)(7)[2] assures that the facility design and construction meet applicable requirements, codes and standards in accordance with the safety classification of structures, systems, and components (SSCs). During construction, the quality assurance program design control provisions that ensure that all changes continue to meet applicable design requirements. The design and licensing bases evolve during construction in accordance with the quality assurance program to the time that an operating license is received, and 10 CFR 50.59 is not applicable until after that time.

[2] 10 CFR 50.34(a)(7) requires that each application for a construction permit include a preliminary safety analysis report that includes a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Although a QA program is required, the regulations in 10 CFR Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, do not apply to NPUFs, and NPUF licensees are not required to comply with ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications." Although not a requirement, NPUF licensees typically commit to ANSI/ANS-15.8, "Quality Assurance Program Requirements for Research Reactors," as recommended in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors." This commitment, along with a commitment to implement their NRC reviewed and approved quality assurance program description during construction would be contained in the licensee's construction permit.

10 CFR 50.59 applies following receipt of an operating license and Section 50.34(b)(6)(ii) requires that a final safety analysis report include the managerial and administrative controls to be used to assure safe operation. The general requirements for establishing and executing a quality assurance program for the testing, modification, and maintenance of research reactors in ANSI/ANS-15.8, which is endorsed by RG 2.5, provide an acceptable method for complying with the quality requirements of 10 CFR 50.34. ANSI/ANS 15.8 recognizes that the described controls are integral to the management of a facility and that it is not necessary to establish a separate quality assurance (QA) program for changes to the facility and procedures. ANSI/ANS-15.1, "The Development of Technical Specifications for Research Reactors," provides guidance on documenting the managerial and administrative controls in the facility TSs (see NUREG-1537).

1.2.3 Relationship of 10 CFR 50.59 to the UFSAR

10 CFR 50.59 is the process that identifies when a license amendment is required prior to implementing changes to the facility or procedures described in the UFSAR or tests and experiments not described in the UFSAR. As such, it is important that the UFSAR be properly maintained and updated ~~in accordance with 10 CFR 50.71(e). Guidance for updating UFSARs to reflect activities implemented under 10 CFR 50.59 is provided by Regulatory Guide 2.7.~~

Commented [CN1]: To backout the NPUF rule.

1.2.4 Relationship of 10 CFR 50.59 to 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. In support of 10 CFR 50.59 implementation, Section 4.3.7 of this guideline defines the design basis limits for fission product barriers that are subject to control under 10 CFR 50.59(c)(2)(vii), and Section 4.3.8 provides guidance on the scope of methods of evaluation used in establishing design bases or in the safety analyses that are subject to control under 10 CFR 50.59(c)(2)(viii). Additional guidance for identifying 10 CFR 50.2 design bases is provided in NUREG-1537.

As discussed in Section 3.3, "design bases functions" are a subset of "design functions" for purposes of 10 CFR 50.59 screening.

1.3 10 CFR 50.59 PROCESS SUMMARY:

After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR 50.59 process is applied to determine if a license amendment is required prior to implementation. This process involves the following basic steps as depicted in Figure 1:

Applicability and Screening: Determine if a 10 CFR 50.59 evaluation is required.

Evaluation: Apply the eight evaluation criteria of 10 CFR 50.59(c)(2) to determine if a license amendment must be obtained from the NRC.

Documentation and reporting: Document and report to the NRC activities implemented under 10 CFR 50.59.

Later sections of this document discuss key definitions, provide guidance for determining applicability, screening, and performing 10 CFR 50.59 evaluations, and present examples to illustrate the application of the process.

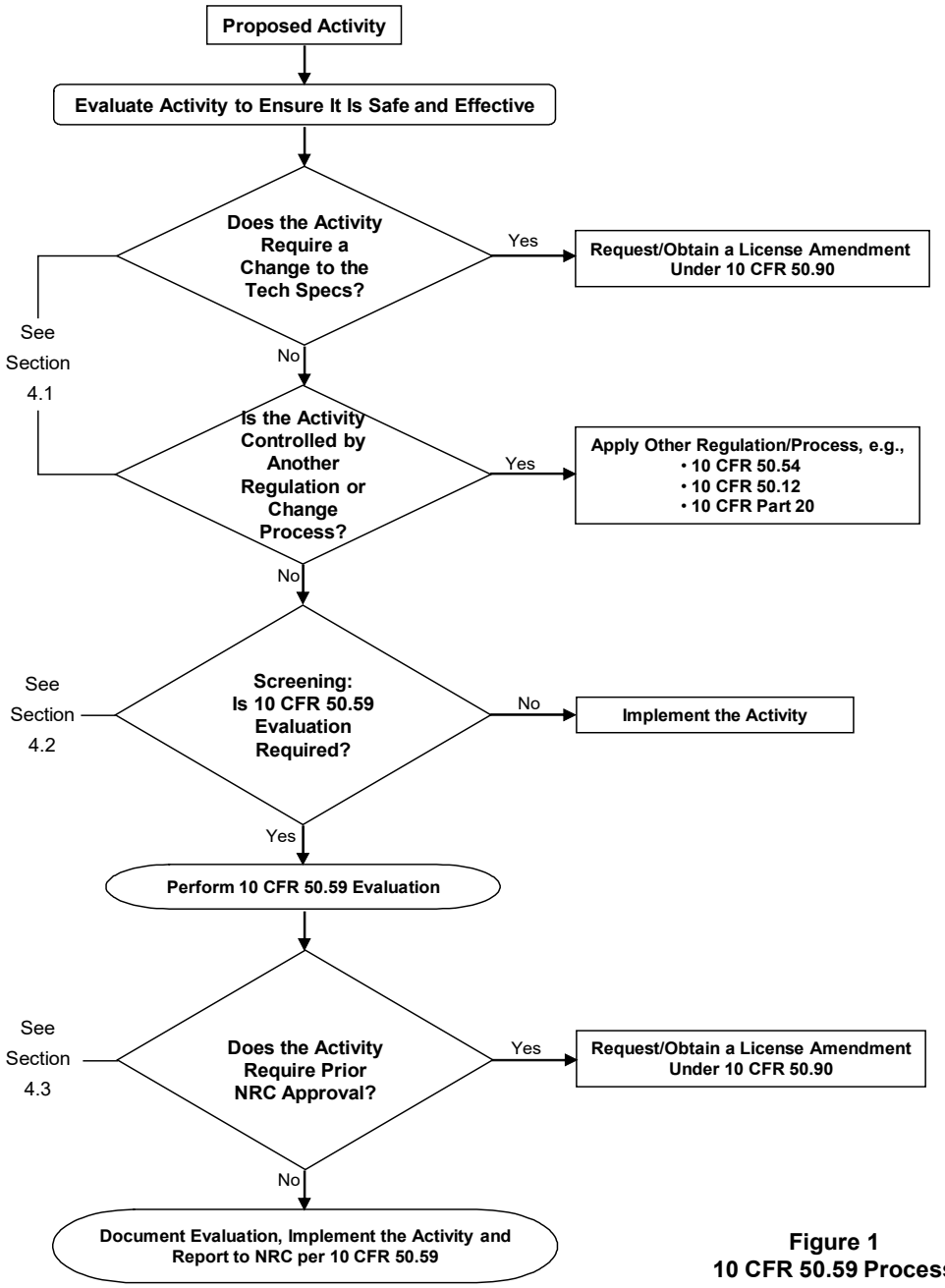

Figure 1
10 CFR 50.59 Process

1.4 RESERVED

1.5 CONTENT OF THIS GUIDANCE DOCUMENT

The NRC has established requirements for nuclear facility systems, structures and components to provide reasonable assurance of adequate protection of the public health and safety. Many of these requirements, and descriptions of how they are met, are documented in the UFSAR. 10 CFR 50.59 allows a licensee to make changes in the facility or procedures as described in the UFSAR, and to conduct tests or experiments not described in the UFSAR, unless the changes require a change in the technical specifications or otherwise require prior NRC approval. In order to perform 10 CFR 50.59 screenings and evaluations, an understanding of the design and licensing basis of the facility and of the specific requirements of the regulations is necessary. Individuals performing 10 CFR 50.59 screenings and evaluations should also understand the rule and concepts discussed in this guidance document.

In Section 2, the relationship between the principal design criteria for the facility, and 10 CFR 50.59 is discussed as background for applying the rule.

Section 3 presents definitions and discussion of key terms used in 10 CFR 50.59 and this guideline.

Section 4 discusses the application of the definitions and criteria presented in 10 CFR 50.59 to the process of changing the facility or procedures and the conduct of tests or experiments. This section includes guidance on the applicability requirements for the rule, the screening process for determining when a 10 CFR 50.59 evaluation must be performed and the eight evaluation criteria for determining if prior NRC approval is required. Examples are provided to reinforce the guidance. Guidance is also provided on addressing degraded and nonconforming conditions and on dispositioning 10 CFR 50.59 evaluations.

Section 5 provides guidance on documenting 10 CFR 50.59 evaluations and reporting to NRC.

2.0 DEFENSE-IN-DEPTH DESIGN PHILOSOPHY AND 10 CFR 50.59

One objective of Title 10 of the Code of Federal Regulations is to establish requirements directed toward protecting the health and safety of the public from the uncontrolled release of radioactivity. At the design stage, protection of public health and safety is ensured through the design of physical barriers to guard against the uncontrolled release of radioactivity. Other sources of radioactivity including radwaste systems are included. The defense-in-depth philosophy includes reliable design provisions to safely terminate accidents and provisions to mitigate the consequences of accidents.

Examples of physical barriers that provide defense-in-depth at NPUFs include, but are not limited to:

- Fuel Matrix
- Fuel Cladding
- Experiment Encapsulations

- Reaction Vessel (facilities with fission reactions in solution)
- Reactor Coolant System Boundary
- Containment or Confinement Boundary

These barriers perform a health and safety protection function. They are designed to reliably fulfill their operational function by meeting all criteria and standards applicable to mechanical components, pressure components and civil structures. These barriers are protected extensively by inherent safety features and through the implementation of engineered safety features. The public health and safety protection functions are analytically demonstrated and documented in the UFSAR. Analyses summarized in the UFSAR demonstrate that under the assumed accident conditions, the consequences of accidents challenging the integrity of the barriers will not exceed established dose guideline values~~limits based on the guidelines established in 10 CFR 100 for testing facilities or 10 CFR 50.34 for other NPUFs~~. Thus, the UFSAR analyses provide the final verification of the nuclear safety design phase by documenting facility performance in terms of public protection from uncontrolled releases of radiation. 10 CFR 50.59 addresses this aspect of design by requiring prior NRC approval of proposed activities that, although safe, require a technical specification change or meet specific threshold criteria for NRC review.

Commented [CN2]: To back out the NPUF rule.

This protection philosophy pervades the UFSAR accident analyses and Title 10 of the CFR. To understand and apply 10 CFR 50.59, it is necessary to understand this perspective of maintaining the integrity of the physical barriers designed to contain radioactivity. This is because:

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

The principal "consequences" that the physical barriers are designed to preclude is the uncontrolled release of radioactivity. Thus, for purposes of 10 CFR 50.59, the term "consequences" means dose.

The design effort and the operational controls necessary to ensure the required performance of the physical barriers during anticipated operational occurrences and postulated accidents are extensive. Because 10 CFR 50.59 provides a mechanism for determining if NRC approval is needed for activities affecting facility design and operation, it is helpful to review briefly the requirements and the objectives imposed by the CFR or license requirements on facility construction and operation. The review will define more clearly the extent of applicability of 10 CFR 50.59.

The UFSAR describes the principal design criteria[3] and design basis for the facility (see NUREG-1537 Part 1 Chapter 3) that were established initially during the original facility licensing that relate to the accident prevention or mitigation functions of SSCs that provide for protection by multiple fission product barriers. The UFSAR-described facility-

[3] 10 CFR 50.34(a)(3) requires that each application for a construction permit include a preliminary safety analysis report that describes the preliminary design of the facility including the principal design criteria for the facility. The regulations do not invoke 10 CFR Part 50 Appendix A, General Design Criteria for Nuclear Power Plants, requirements for NPUFs.

specific criteria establish requirements for inherent protection, reactor protection and reactivity control systems, instrumentation and control, reactor coolant boundary and reactor coolant system design, confinement or containment design, reactor rooms, and electric power systems. The criteria may address design, inspection, testing and operational requirements to ensure inherent and engineered protection of the fission product barriers. The criteria may also address the need to consider a single failure, redundancy, diversity and separation of mitigation and protection systems and may also address the conditions under which these systems must function such as natural phenomena, fire, operational and accident generated environmental conditions. All of these requirements concentrate on protecting fission product barriers either through inherent or mitigative means.

The implementation of this design philosophy requires extensive accident analyses to define the correct relationship among nominal operating conditions, limiting conditions for operations and limiting safety systems settings to prevent safety limits from being exceeded. The UFSAR presents the set of limiting analyses required by NRC which for NPUFs includes the analysis of a maximum hypothetical accident that typically assumes a failure that leads to breach of the fuel cladding or a fueled experiment encapsulation. The limiting analyses are used to confirm the systems and equipment design, to identify critical setpoints and operator actions, and to support the establishment of technical specifications. Therefore, the results of the UFSAR accident analyses reflect performance of equipment under the conditions specified by NRC regulations or requirements. Changes to facility design and operation and conduct of new tests and experiments have the potential to affect the probability and consequences of accidents, to create new accidents and to impact the integrity of fission product barriers. Therefore, these activities are subject to 10 CFR 50.59.

3.0 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

3.1 10 CFR 50.59 Evaluation
3.2 Accident Previously Evaluated in the UFSAR
3.3 Change
3.4 Departure from a Method of Evaluation Described in the UFSAR
3.5 Design Bases (Design Basis)
3.6 Facility as Described in the UFSAR
3.7 UFSAR
3.8 Input Parameters
3.9 Malfunction of an SSC Important to Safety
3.10 Methods of Evaluation
3.11 Procedures as Described in the UFSAR
3.12 Safety Analyses
3.13 Screening
3.14 Tests or Experiments Not Described in the UFSAR

3.1 10 CFR 50.59 EVALUATION

Definition:

A 10 CFR 50.59 evaluation is the documented evaluation against the eight criteria in 10 CFR 50.59(c)(2) to determine if a proposed change, test or experiment requires prior NRC approval via license amendment under 10 CFR 50.90.

Discussion:

It is important to establish common terminology for use relative to the 10 CFR 50.59 process. The definitions of 10 CFR 50.59 Evaluation and Screening are intended to clearly distinguish between the process and documentation of licensee screenings and the further evaluation that may be required of proposed activities against the eight criteria in 10 CFR 50.59(c)(2). Section 4.3 provides guidance for performing 10 CFR 50.59 evaluations. The screening process is discussed in Section 4.2.

The phrase "change made under 10 CFR 50.59" (or equivalent) refers to changes subject to the rule (see Section 4.1) that either screened out of the 10 CFR 50.59 process or did not require prior NRC approval based on the results of a 10 CFR 50.59 evaluation. Similarly, the phrases "10 CFR 50.59 applies [to an activity]" or "[an activity] is subject to 10 CFR 50.59" mean that screening and, if necessary, evaluation are required for the activity. The "10 CFR 50.59 process" may include screening, evaluation, documentation and reporting to NRC of activities subject to the rule.

3.2 ACCIDENT PREVIOUSLY EVALUATED IN THE UFSAR

Definition:

Accident previously evaluated in the UFSAR means a design basis accident or event described in the UFSAR including accidents, such as those typically analyzed in Chapter 13 of the UFSAR, and transients and events the facility is required to withstand such as floods, fires, earthquakes, other external hazards, and loss of all AC power.

Discussion:

The term "accidents" refers to the anticipated (or abnormal) operational transients and postulated design basis accidents that are analyzed to demonstrate that the facility can be operated without undue risk to the health and safety of the public. For purposes of 10 CFR 50.59, the term "accidents" encompasses other events for which the facility is required to cope and that are described in the UFSAR (e.g., fire, earthquakes and flooding).

Accidents also include new transients or postulated events added to the licensing basis based on new NRC requirements and reflected in the UFSAR ~~pursuant to 10 CFR 50.71(e)~~.

Commented [CN3]: To backout the NPUF rule.

Accidents at NPUFs assume failure of a major component such as the reactor coolant system boundary or a reactivity addition event. Because most NPUFs operate at atmospheric pressure, at relatively low power levels, and with conservative safety margins, few credible postulated accidents result in radiological risk to the public. NPUF licensees also analyze a limiting accident named the maximum hypothetical accident; the details of which are facility specific. Because the maximum hypothetical accident is not expected to occur, the scenario need not be entirely credible. The initiating event

and the scenario details need not be analyzed, but the potential consequences are analyzed and evaluated. The maximum hypothetical accident assumes a failure that leads to breach of the fuel cladding or a fueled experiment containment. These postulated accidents are compared with acceptance criteria such as the safety limits from the technical specifications or, where there are radiological consequences, to accepted accident criteria (i.e., Dose guideline values for testing facilities are based on 10 CFR Part 100. For NPUFs that are not testing facilities, the results of the accident analysis have generally been compared with 10 CFR Part 20~~e.g., the criteria in 10 CFR 100 for testing facilities or in 10 CFR 50.34 for other NPUFs~~). Meeting the design acceptance criteria demonstrates facility performance in terms of public protection from uncontrolled releases of radiation.

Commented [CN4]: The list of examples does not need to be complete.

The analyzed accident scenarios that NPUFs may present in UFSAR Chapter 13 include the following:

- loss of coolant
- loss of coolant flow
- insertion of excess reactivity (rapid or ramp)
- loss of fuel cladding integrity or mishandling of fuel
- failure or malfunction of an experiment
- other uncontrolled release of radioactive material
- loss of electric power
- external events such as floods and earthquakes

3.3 CHANGE

Definition:

Change means a modification or addition to, or removal from, the facility or procedures that affects: (1) a design function, (2) method of performing or controlling the function, or (3) an evaluation that demonstrates that intended functions will be accomplished.

Discussion:

Additions and removals to the facility or procedures can adversely impact the performance of SSCs and the bases for the acceptability of their design and operation. Thus, the definition of change includes modifications of an existing provision (e.g., SSC design requirement, analysis method or parameter), additions or removals (physical removals, abandonment or nonreliance on a system to meet a requirement) to the facility or procedures.

The definitions of “change…,” “facility…” (see Section 3.6), and “procedures…” (see Section 3.11) make clear that 10 CFR 50.59 applies to changes to underlying analytical bases for the facility design and operation as well as for changes to SSCs and procedures. Thus 10 CFR 50.59 should be applied to a change being made to an evaluation for demonstrating adequacy of the facility even if no physical change to the facility is involved. Further discussion of the terms in this definition is provided as follows:

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

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

UFSAR description of design functions may identify what SSCs are intended to do, when and how design functions are to be performed, and under what conditions. Design functions may be performed by SSCs and include functions that, if not performed, would initiate a transient or accident that the facility is required to withstand.

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

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

Evaluation that demonstrates that intended functions will be accomplished means the method(s) used to perform the evaluation (i.e., calculational framework as discussed in Section 3.10, "Method of Evaluation"). Example: an integrated leak rate calculation for a reactor containment structure that demonstrates radioactive releases to the unrestricted area are equal to or less than the releases analyzed in a postulated accident.

Temporary Changes

Temporary changes to the facility or procedures, such as jumpering terminals, lifting leads, placing temporary lead shielding on pipes and equipment, removal of barriers and use of temporary blocks, bypasses, scaffolding and supports, are made to facilitate a range of facility activities and are subject to 10 CFR 50.59 as follows:

- 10 CFR 50.59 should be applied to temporary changes proposed as compensatory actions to address degraded or nonconforming conditions as discussed in Section 4.4.
- Other temporary changes to the facility or procedures that are not associated with maintenance (see Section 4.1.2) are subject to 10 CFR 50.59 in the same manner as permanent changes, to determine if prior NRC approval is required. Screening and, as necessary, evaluation of such temporary changes may be considered as part of the screening/evaluation of the proposed permanent change.

3.4 DEPARTURE FROM A METHOD OF EVALUATION DESCRIBED IN THE UFSAR

Definition:

Departure from a method of evaluation described in the UFSAR means (i) 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 (ii) changing from a method described in the UFSAR to another method unless that method has been approved by NRC for the intended application.

Discussion:

The 10 CFR 50.59 definition of "departure …" provides licensees with flexibility to make changes in methods of evaluation that are "conservative" or that are not important with respect to demonstrating that SSCs can perform their intended design functions. See also the definition and discussion of "methods of evaluation" in Section 3.10. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR 50.59(c)(2)(viii) is provided in Section 4.3.8.

Conservative vs. Nonconservative Evaluation Results

Gaining margin by revising an element of a method of evaluation is considered to be a nonconservative change and thus a departure from a method of evaluation for purposes of 10 CFR 50.59. Such departures require prior NRC approval of the revised method. In other words, analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change in an element of a method of evaluation that changes the result of a fuel cladding temperature analysis from 1050 degrees Celsius to 1100 degrees Celsius (with a design basis limit of 1500 degrees Celsius) would be considered a conservative change for the purposes of 10 CFR 50.59(c)(2)(viii). This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making future physical or procedure changes without a license amendment.

If use of a modified method of evaluation resulted in a change in calculated in a change in calculated fuel cladding temperature from 1050 degrees Celsius to 1000 degrees Celsius, this would be nonconservative. This is because the change would result in more margin being available (to the design basis limit of 1500 degrees Celsius) for a licensee to make more significant future changes to the physical facility or procedures.

"Essentially the Same"

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

"Approved by the NRC for the Intended Application"

Rather than make a minor change to an existing method of evaluation, a licensee may also adopt completely new methodology without prior NRC approval provided the new method is approved by the NRC for the intended application. A new method is "approved by the NRC for the intended application" if it is approved for the type of analysis being conducted and the licensee satisfies applicable terms and conditions for its use. Specific guidance for making this determination is provided in Section 4.3.8.2.

3.5 DESIGN BASES (DESIGN BASIS)

Definition:

(10 CFR 50.2) Design bases means that information which identifies the specific functions to be performed by a structure, system, or component of a facility 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 a structure, system, or component must meet its functional goals.

Discussion

Guidance and examples for identifying 10 CFR 50.2 design bases for research reactors are provided in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," such as Part 1, Section 3.1, "Design Criteria," and Section 7.2, "Design of Instrumentation and Control Systems."

3.6 FACILITY AS DESCRIBED IN THE UFSAR

Definition:

Facility as described in the final safety analysis report (as updated) means:

- The structures, systems, and components (SSC) that are described in the UFSAR,
- The design and performance requirements for such SSCs described in the UFSAR, and

- The evaluations or methods of evaluation included in the UFSAR for such SSCs, which demonstrate that their intended function(s) will be accomplished.

Discussion:

The scope of information that is the focus of 10 CFR 50.59 is the information presented in the original ~~U~~FSAR to satisfy the requirements of 10 CFR 50.34(b) as well as updates as described in Section 3.7~~, as updated per the requirements of 10 CFR 50.71(e)~~. The definition of "facility as described in the UFSAR" follows from the requirement of 10 CFR 50.34(b) that the ~~U~~FSAR (and by extension, the UFSAR) contains "a description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the bases, with technical justification therefore, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished."

3.7 FINAL SAFETY ANALYSIS REPORT (AS UPDATED)

Definition (per 10 CFR 50.59(a)(4)):

Commented [CN5]: This is the definition in the rule, so we cannot change it. The "as applicable" handles the NPUFs.

Final Safety Analysis Report (as updated) means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with 10 CFR 50.34, as amended and supplemented, and as updated per the requirements of 10 CFR 50.71(e), as applicable.

Discussion:

In its statements of consideration for the final 10 CFR 50.59 rule (see 64 FR 53589 dated October 4, 1999), the Commission's intent in stating that for purposes of implementation of 10 CFR 50.59, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations of changes made since the FSAR update is to ensure that decisions about particular changes are made with the most complete and accurate information. For NPUFs, the FSAR update process is necessary because NPUFs are not required to submit updates to their safety analysis report. Nevertheless, they must ensure that proposed changes are judged with respect to the existing facility, not the facility as originally described in the FSAR at time of licensing. The intent of the requirement is that the changes that were the subject of these evaluations be considered in the process of determining what the "facility as described" now is such that the reference for subsequent evaluations is complete and accurate.

Per 10 CFR 50.59(c)(3), the "UFSAR," for purposes of 10 CFR 50.59, also includes UFSAR update pages approved by the licensee for incorporation in the UFSAR since the last submittal of the FSAR to the NRC ~~required update was submitted per 10 CFR 50.71(e)~~. The intent ~~of this requirement~~ is to ensure that decisions about proposed activities are made with the most complete and accurate information available. Pending UFSAR revisions may be relevant to a future activity that involves that part of the UFSAR. Therefore, pending UFSAR revisions to reflect completed activities that have received final licensee approval for incorporation into the next FSAR ~~required~~ update should be considered as part of the UFSAR for purposes of 10 CFR 50.59 screenings and evaluations, as appropriate. Appropriate configuration management mechanisms

Commented [CN6]: This paragraph was moved to here from below, and then changes tracked.

Commented [CN7]: To backout the NPUF rule.

should be in place to identify and assess interactions between concurrent changes affecting the same SSCs or the same portion of the UFSAR.

The scope of the UFSAR includes its text, tables, diagrams, etc., as well as supplemental information explicitly incorporated by reference. References that are merely listed in the UFSAR and documents that are not explicitly incorporated by reference are not considered part of the UFSAR and therefore are not subject to control under 10 CFR 50.59.

Per 10 CFR 50.59(c)(4), licensees are not required to apply 10 CFR 50.59 to UFSAR information that is subject to other specific change control regulations. For example, licensee emergency plans and security plans are controlled by 10 CFR 50.54(p) and (q), respectively.

~~Guidance on the required content of UFSAR updates is provided in Regulatory Guide 2.7, "Preparation of Updated Final Safety Analysis Reports for Non-Power Production or Utilization Facilities."~~

Commented [CN8]: To backout the NPUF rule.

3.8 INPUT PARAMETERS

Definition:

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

Discussion:

The principal intent of this definition is to distinguish methods of evaluation from evaluation input parameters. Changes to methods of evaluation described in the UFSAR (see Section 3.10) are evaluated under criterion 10 CFR 50.59(c)(2)(viii), whereas changes to input parameters described in the UFSAR are considered changes to the facility that would be evaluated under the other seven criteria of 10 CFR 50.59(c)(2), but not criterion (c)(2)(viii).

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

- The method of evaluation includes a methodology describing how to select the value of an input parameter to yield adequately conservative results. However, if a licensee opts to use a value more conservative than that required by the selection method, reduction in that conservatism should be evaluated as an input parameter change, not a change in methodology.

- The development or approval of a methodology was predicated on the degree of conservatism in a particular input parameter or set of input parameters. In other words, if certain elements of a methodology or model were accepted on the basis

of the conservatism of a selected input value, then that input value is considered an element of the methodology.

Examples illustrating the treatment of input parameters are provided in Section 4.2.1.3.

Section 4.3.8 provides guidance and examples to describe the specific elements of evaluation methodology that would require evaluation under 10 CFR 50.59(c)(2)(viii) and to clearly distinguish these from specific types of input parameters that are controlled by the other seven criteria of 10 CFR 50.59(c)(2).

3.9 MALFUNCTION OF AN SSC IMPORTANT TO SAFETY

Definition:

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

Discussion:

Guidance and examples for applying this definition are provided in Section 4.3.

3.10 METHODS OF EVALUATION

Definition:

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

Discussion:

Examples of methods of evaluation are presented below. Changes to such methods of evaluation require evaluation under 10 CFR 50.59(c)(2)(viii) only for evaluations used either in UFSAR safety analyses or in establishing the design bases, and only if the methods are described, outlined or summarized in the UFSAR. Methodology changes that are subject to 10 CFR 50.59 include changes to elements of existing methods described in the UFSAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies.

Elements of Methodology	Example
■ Data correlations	■ DNBR correlations
■ Means of data reduction	■ neutron cross section reduction methods
■ Physical constants or coefficients	■ Heat transfer coefficients
■ Mathematical models	■ neutronics models
■ Specific limitations of a computer program	■ bulk boiling in coupled point-kinetics programs

- Specified factors to account for uncertainty in measurements or data
- Statistical treatment of results
- Dose conversion factors and assumed source term(s)
- 120% of 1971 decay heat model
- Vendor-specific thermal design procedure
- ICRP factors

Methods of evaluation described in the UFSAR subject to criterion 10 CFR 50.59(c)(2)(viii) are:

- Methods of evaluation used in analyses that demonstrate that design basis limits of fission product barriers are met (i.e., for the parameters subject to criterion 10 CFR 50.59(c)(2)(vii))
- Methods of evaluation used in UFSAR safety analyses, including accident analyses typically presented in UFSAR Chapter 13
- to demonstrate that consequences of accidents do not exceed required dose criteria
- Methods of evaluation used in supporting UFSAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the facility is required to withstand, including natural phenomena, environmental conditions, and loss of normal AC electrical power.

3.11 PROCEDURES AS DESCRIBED IN THE UFSAR

Definition:

Procedures as described in the final safety analysis report (as updated) means those procedures that contain information described in the UFSAR such as how structures, systems, and components are operated and controlled (including assumed operator actions and response times, if applicable).

Discussion:

The scope of information that is the focus of 10 CFR 50.59 is the information presented in the original ~~U~~FSAR to satisfy the requirements of 10 CFR 50.34(b) as well as updates as described in Section 3.7~~, as updated per the requirements of 10 CFR 50.71(e)~~.

Commented [CN9]: To backout the NPUF rule..

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

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. Sections 4.1.2 and 4.1.4 identify examples of procedures that are not subject to 10 CFR 50.59.

10 CFR 50.59 screening of procedure changes is discussed in Section 4.2.1.2.

3.12 SAFETY ANALYSES

Definition:

Safety analyses are analyses performed pursuant to NRC requirements to demonstrate the integrity of the fission product boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential off-site exposures comparable to the guideline~~s~~ values (i.e., Dose guideline values for testing facilities are based on 10 CFR Part 100. For NPUFs that are not testing facilities, the results of the accident analysis have generally been compared with 10 CFR Part 20.) ~~in 10 CFR 50.34(a)(1)20 or 10 CFR 100.11, as applicable~~. Safety analyses are required to be presented in the UFSAR per 10 CFR 50.34(b) ~~and 10 CFR 50.71(e)~~ and include, but are not limited to, the accident analyses typically presented in Chapter 13 of the UFSAR.

Commented [CN10]: To backout the NPUF rule.

Commented [CN11]: To backout the NPUF rule.

Discussion:

Safety analyses are those analyses or evaluations that demonstrate that acceptance criteria for the facility's capability to withstand or respond to postulated events are met. Accident analyses typically presented in Chapter 13 of the UFSAR clearly fall within the meaning of "safety analyses" as defined above. Also, within the meaning of this definition for purposes of 50.59 are:

- Supporting UFSAR analyses that demonstrate that SSC design functions will be accomplished as credited in the accident analyses.
- UFSAR analyses of events that the facility is required to withstand such as fires, floods, earthquakes, and loss of normal electrical power.

3.13 SCREENING (I.E., 10 CFR 50.59 SCREENING)

Definition:

Screening is the process for determining whether a proposed activity requires a 10 CFR 50.59 evaluation to be performed.

Discussion:

Screening is that part of the 10 CFR 50.59 process that determines whether a 10 CFR 50.59 evaluation is required prior to implementing a proposed activity.

The definitions of "change," "facility as described…," "procedures as described…" and "test or experiment not described…" constitute criteria for the 10 CFR 50.59 screening process. Activities that do not meet these criteria are said to "screen out" from further

review under 10 CFR 50.59, i.e., may be implemented without a 10 CFR 50.59 evaluation.

Engineering and technical information concerning a proposed activity may be used along with other information as the basis for determining if the activity screens out or requires a 10 CFR 50.59 evaluation.

Further discussion and guidance on screening are provided in Section 4.2.

3.14 TESTS OR EXPERIMENTS NOT DESCRIBED IN THE UFSAR

Definition:

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

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

Discussion:

Experiments that exceed the bounding parameters in the TS require a license amendment (per 10 CFR 50.59(c)(1)).

Experimental programs and the range of experiments vary widely among non-power reactor facilities. Furthermore, as the licensee gains experience and as technology develops, the experimental program and many of the specific experiments may change over the life of the facility. This makes it very difficult and impractical for the licensee to describe specific experiments in the UFSAR. The licensee typically describes and analyzes in Chapter 10 of the UFSAR (per NUREG 1537) and incorporates into the facility technical specifications enveloping conditions of experiment attributes such as reactivity limits or material properties to allow flexibility in the experimental program. Potential experimental needs are typically considered when establishing these limiting safety aspects in the UFSAR. As such experiments described in Chapter 10 and controlled in technical specifications would not be expected to fall within the definition of "tests or experiments not described in the UFSAR," therefore, would not be expected to fall within the definition of "change."

10 CFR 50.59 is applied to tests or experiments not described in the UFSAR. The intent of the definition is to ensure that tests or experiments that put the facility in a situation that has not previously been evaluated (e.g., unanalyzed system alignments) or that could affect the capability of SSCs to perform their intended design functions (e.g., high flow rates, high temperatures) are evaluated before they are conducted to determine if prior NRC approval is required. For example, a proposed experiment specifies installing an electrical jumper that is not described in the UFSAR that connects the experiment equipment and an in-service system for purpose of supporting the experiment (e.g., using a reactor protection system scram signal as input to the experiment equipment to start measuring time). This experiment meets 10 CFR 50.59 definition of "tests or

experiments not described in the UFSAR" because the experiment is an activity where an in-service SSC (the reactor protection system) is utilized in a manner which inconsistent with the analyses or descriptions in the UFSAR.

Maintenance-related testing is discussed in Section 4.1.2. 10 CFR 50.59 screening of tests and experiments unrelated to maintenance is discussed in Section 4.2.2. Examples of tests unrelated to maintenance and thus subject to 10 CFR 50.59 include (1) core physics testing outside of usual configurations, and (2) testing to help determine which of two redesign alternatives to pursue.

4.0 IMPLEMENTATION GUIDANCE

Licensees may determine applicability and screen activities to determine if 10 CFR 50.59 evaluations are required as described in Sections 4.1 and 4.2, or equivalent manner.

4.1 APPLICABILITY

As stated in Section (b) of 10 CFR 50.59, the rule applies to each holder of a license authorizing operation of a production or utilization facility, including a non-power production or utilization facility that has permanently ceased operations.

4.1.1 Applicability to Licensee Activities

10 CFR 50.59 is applicable to tests or experiments not described in the UFSAR[4] and to changes to the facility or procedures as described in the UFSAR, including changes made in response to new requirements or generic communications, except as noted below:

Per 10 CFR 50.59(c)(1)(i), proposed activities that require a change to the technical specifications must be made via the license amendment process, 10 CFR 50.90. Aspects of proposed activities that are not directly related to the required technical specification change are subject to 10 CFR 50.59.[5]

Commented [CN12]: Deleted the footnote as part of backing out the NPUF rule.

[4] ~~The primary purpose of preparing the UFSAR and subsequent UFSAR updates is to ensure that the UFSAR contains a description and analysis of the NPUF that reflect the current licensing basis. Under 10 CFR 50.71(e), the NRC requires the licensee to submit an updated UFSAR and subsequent UFSAR updates at intervals not to exceed 5 years to provide a common reference for the licensee and the NRC. In contrast, the UFSAR defined in 10 CFR 50.59(a)(4) serves as an up-to-date reference for the NPUF licensee to use in its activities between submittals required by 10 CFR 50.71(e) or by NRC inspectors and reactor operator licensing examiners when they are on site. In the case of changes made under 10 CFR 50.59 and 10 CFR 50.90, use of the UFSAR may be required to take into account changes since the last submission of the UFSAR under 10 CFR 50.71(e).~~

[5] For every licensee, legally binding obligations are explicitly stated in the license which includes specific parts of 10 CFR as well as TS. For example, if the license incorporates TS as an appendix and the NPUF TS includes the Bases, then the license includes the Bases. 10 CFR 50.59(c)(1)(i), allows licensees to make changes without an amendment provided, "(i) A change to the technical specifications incorporated in the license is not required." Therefore, changes to NPUF TS Bases would require prior NRC approval per 10 CFR 50.59(c)(1)(i) since 10 CFR 50.59(c)(1)(i) requires prior NRC approval for changes to the TS Bases IF it involves a "A change to the technical specifications incorporated in the license."

To reduce duplication of effort, 10 CFR 50.59(c)(4) specifically excludes from the scope of 10 CFR 50.59 changes to the facility or procedures that are controlled by other more specific requirements and criteria established by regulation. For example, 10 CFR 50.54, which was promulgated after 10 CFR 50.59, specifies criteria and reporting requirements for changing physical security and emergency plans.

In addition to 50.90 and 50.54(p) & (q), the following include change control requirements that meet the intent of 50.59(c)(4) and may take precedence over 50.59 for control of specific changes:

- 10 CFR 50.12, (Specific Exemptions)
- 10 CFR Part 20 (Standards for Radiation Protection).

Activities controlled and implemented under other regulations may require related information in the UFSAR to be updated. To the extent the UFSAR changes are directly related to the activity implemented via another regulation, applying 10 CFR 50.59 is not required. ~~UFSAR changes should be identified to the NRC as part of the required UFSAR update, per 10 CFR 50.71(e).~~ However, there may be certain activities for which a licensee would need to apply both the requirements of 10 CFR 50.59 and that of another regulation. For example, a modification to a facility involves additional components and substantial piping reconfigurations as well as changes to protection system setpoints. The protection system setpoints are contained in the facility technical specifications. Thus, a license amendment to revise the technical specifications under 10 CFR 50.90 is required to implement the new system setpoints. 10 CFR 50.59 should be applied to the balance of the modification, including impacts on required operator actions, if applicable.

Commented [CN13]: To backout the NPUF rule.

4.1.2 Maintenance Activities

Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. For example, a change to the facility occurs during a maintenance activity in which a valve is disassembled, repaired, and reassembled but the valve returned to its original as-designed condition upon completion of the maintenance activity. Maintenance activities are not subject to 10 CFR 50.59, but are subject to technical specifications. Technical specifications may contain action statements which are required actions when a system is temporarily taken off-line for the purpose of performing activities designed to ensure long-term operability of the system (i.e., maintenance). The technical specification may also have requirements for the system to be operable when returned to service. For example, some NPUFs have provisions for taking a measuring channel off-line (i.e., rendering it inoperable) for the purpose of calibrating the systems as long as all other monitoring and safety channels are operable during the calibration.

Maintenance activities include troubleshooting, calibration, refurbishment, maintenance-related testing, identical replacements, housekeeping and similar activities that do not permanently alter the design, performance requirements, operation or control of SSCs. Maintenance activities also include temporary alterations to the facility or procedures that directly relate to and are necessary to support the maintenance. Examples of

temporary alterations that support maintenance include jumpering terminals, lifting leads, placing temporary shielding, removal of barriers, and use of temporary blocks, bypasses, scaffolding and supports.

10 CFR 50.59 should be applied in the following case:

- The facility is not restored to its original condition upon completion of the maintenance activity (e.g., if SSCs are removed, the design, function or operation is altered, or if temporary alteration in support of the maintenance is not removed). In this case, 10 CFR 50.59 would be applied to the change to the facility.

Installation and post-modification testing of approved facility changes are indistinguishable, in terms of their impact on the facility, from maintenance activities that restore SSCs to their as-designed condition. As such, installation and testing of approved facility changes are maintenance activities. 10 CFR 50.59 addresses the effect, following implementation, of proposed facility changes to determine if prior NRC approval is required.

10 CFR 50.59 should be applied to temporary changes proposed as compensatory actions for degraded or nonconforming conditions, as discussed in Section 4.4.

Control of Maintenance Procedures

Changes to procedures for performing maintenance are made in accordance with any applicable facility requirements (e.g., managerial and administrative controls in the technical specifications) and licensee procedures. Licensee processes should ensure that changes to facility configurations called for by procedures are consistent with the technical specifications. Unless required by technical specifications, 10 CFR 50.59 does not apply to such changes because, like the maintenance activities themselves, changes to procedures for performing maintenance do not permanently alter the design, performance requirements, operation or control of SSCs. For example, technical specifications may explicitly require that 10 CFR 50.59 be applied to written procedures for maintenance of components that have nuclear safety significance and for technical specification required surveillance and testing.

Certain maintenance procedures, including those for technical specification required surveillance and inspection, may contain important information concerning SSC design, performance, operation or control. Examples include acceptance criteria for ventilation damper actuation times or other SSC functions, torque values, and types of materials (e.g., gaskets, elastomers, lubricants, etc.). Licensee design and/or configuration control processes should ensure that 10 CFR 50.59 is applied to changes in such information and that maintenance procedure changes do not inadvertently alter the design, performance requirements, operation or control of SSCs.

If a change to a maintenance procedure affects information in the UFSAR (e.g., a specific test or maintenance frequency), the affected information should be updated ~~in accordance with 10 CFR 50.71(e)~~.

Commented [CN14]: To backout the NPUF rule.

4.1.3 UFSAR Modifications

~~Guidance for UFSAR modifications can be found in Regulatory Guide 2.7.~~ Modifications to the UFSAR that are not the result of activities performed under 10 CFR 50.59 are not subject to control under 10 CFR 50.59. Such modifications include reformatting and simplification of UFSAR information and removal of obsolete or redundant information and excessive detail.

Commented [CN15]: To backout the NPUF rule.

Similarly, 10 CFR 50.59 need not be applied to the following types of activities:

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

4.1.4 Changes to Procedures Governing the Conduct of Operations

Even if described in the UFSAR, changes to managerial and administrative procedures governing the conduct of facility operations are not subject to control under 10 CFR 50.59. These include, but are not limited to, procedures in the following areas (provided they are not governed by the technical specifications or the license):

- Operations and work process procedures such as control of equipment status (tag outs)
- Administrative controls for Shift staffing
- Administrative controls for creating or modifying procedures such as maintenance procedures or operating procedures
- Facility modification process

Example

The individual who is designated as the reactor manager/supervisor is typically responsible for day-to-day facility operations. The designation of the manager/supervisor is an administrative requirement on the conduct of facility operations. Thus, assigning this function to another individual would not be subject to 10 CFR 50.59 but would be done in accordance with managerial and administrative controls in the facility technical specifications and any applicable quality assurance requirements and licensee procedures.

4.1.5 Changes to Fire Protection Systems and Programs

For NPUFs, changes to fire protection systems and program as described in the UFSAR are subject to 10 CFR 50.59.

4.2 SCREENING

Once it has been determined that 10 CFR 50.59 is applicable to a proposed activity, screening is performed to determine if the activity should be evaluated against the evaluation criteria of 10 CFR 50.59(c)(2).

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

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

Sections 4.2.1 and 4.2.2 provide guidance and examples for determining whether an activity is (1) a change to the facility or procedures as described in the UFSAR or (2) a test or experiment not described in the UFSAR. If an activity is determined to be neither, then it screens out and may be implemented without further evaluation under 10 CFR 50.59. Activities that are screened out from further evaluation under 10 CFR 50.59 should be documented as discussed in Section 4.2.3.

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

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

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

Activities that screen out may ~~nonetheless require~~ call for UFSAR information to be updated. ~~Licensees should provide updated UFSAR information to the NRC in accordance with 10 CFR 50.71(e).~~

Commented [CN16]: To backout the NPUF rule.

Specific guidance for applying 10 CFR 50.59 to temporary changes proposed as compensatory actions for degraded or nonconforming conditions is provided in Section 4.4.

4.2.1 Is the Activity a Change to the Facility or Procedures as Described in the UFSAR?

To determine whether or not a proposed activity affects a design function, method of performing or controlling a design function or an evaluation that demonstrates that design functions will be accomplished, a thorough understanding of the proposed activity is essential. A given activity may have both direct and indirect effects that the screening review must consider. The following questions illustrate a range of effects that may stem from a proposed activity:

- Does the activity decrease the reliability of an SSC design function, including either functions whose failure would initiate a transient/ accident or functions that are relied upon for mitigation?
- Does the activity reduce existing redundancy, diversity or defense-in-depth?
- Does the activity add or delete an automatic or manual design function of the SSC?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system or materials interaction?
- Does the activity adversely affect the ability or response time to perform required actions, e.g., alter equipment access or add steps necessary for performing tasks?
- Does the activity degrade the seismic or equipment environmental qualification of the SSC (if applicable)?
- Does the activity affect a method of evaluation used in establishing the design bases or in the safety analyses?
- For activities affecting SSCs, procedures, or methods of evaluation that are not described in the UFSAR, does the change have an indirect effect on electrical distribution, structural integrity, environmental conditions or other UFSAR-described design functions?

Per the definition of "change" discussed in Section 3.3, 10 CFR 50.59 is applicable to additions as well as to changes to and removals from the facility or procedures. Additions should be screened for their effects on the existing facility and procedures as described in the UFSAR and, if required, a 10 CFR 50.59 evaluation should be performed. ~~NRC Regulatory Guide 2.7 provides guidance for determining whether additions to the facility and procedures should be reflected in the UFSAR per 10 CFR 50.71(e).~~

Commented [CN17]: To backout the NPUF rule.

Changes affecting SSCs or functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions. A 10 CFR 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.

Screening for Adverse Effects

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"). The plain language definition of "adverse" is preventing success, harmful; or unfavorable. Changes that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new accidents or otherwise meet the 10 CFR 50.59 evaluation criteria.[6]

Per the definition of "design function" (see Section 3.3), SSCs may have preventive, as well as mitigative, design functions. Adverse changes to either must be screened in. Thus, a change that decreases the reliability of a function whose failure could initiate an accident would be considered to adversely affect a design function and would screen in. In this regard, changes that would relax the manner in which UFSAR- specified industry consensus standards are met for certain SSCs should be screened for adverse effects on design function. Similarly, changes that would introduce a new type of accident or malfunction would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and 10 CFR 50.59. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

If a change has both positive and adverse effects, the change should be screened in. The 10 CFR 50.59 evaluation should focus on the adverse effects.

The screening process is not concerned with the magnitude of adverse effects that are identified. Any change that adversely affects a UFSAR-described design function, method of performing or controlling design functions, or evaluation that demonstrates that intended design functions will be accomplished is screened in. The magnitude of the adverse effect (e.g., is the minimal increase standard met?) is the focus of the 10 CFR 50.59 evaluation process.

Screening determinations are made based on the engineering/technical information supporting the change. The screening focus on design functions, etc., ensures the essential distinction between (1) 10 CFR 50.59 screenings, and (2) 10 CFR 50.59 evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR 50.59(c)(2). Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse effect on UFSAR-described design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished may be used as basis for screening out the change. If the effect of a change is such that existing safety analyses would no longer be bounding and therefore UFSAR safety analyses must be re-run to demonstrate that all required safety functions and design requirements are met, the change is considered to be adverse and must be screened in. The revised safety

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

analyses may be used in support of the required 10 CFR 50.59 evaluation of such changes.

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

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a damper actuation relay that delays the building ventilation damper closure time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the analyses is for the building ventilation dampers close within 12 seconds of detecting abnormal effluent activity such that the activity is not released. This change would screen out because it is apparent that the change will not adversely affect the building isolation design function credited in the accident analyses.

However, a change that would delay the building ventilation isolation time to 13 seconds would screen in because the change adversely effects the design function (dampers to close within in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the ventilation dampers, e.g., building isolation, is satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in support of the 10 CFR 50.59 evaluation to determine whether any of the evaluation criteria are met such that prior NRC approval is required for the change. Additional specific guidance for identifying adverse effects due to a procedure or methodology change is provided in subsections 4.2.1.2 and 4.2.1.3, respectively.

4.2.1.1 Screening of Changes to the Facility as Described in the UFSAR

Screening to determine that a 10 CFR 50.59 evaluation is required is straightforward when a change adversely affects an SSC design function, method of performing or controlling a design function, or evaluation that demonstrates intended design functions will be accomplished as described in the UFSAR.

However, a facility also contains many SSCs not described in the UFSAR. These can be components, subcomponents of larger components or even entire systems. Changes affecting SSCs that are not explicitly described in the UFSAR can have the

potential to adversely affect SSC design functions that are described and thus may require a 10 CFR 50.59 evaluation. In such cases, the approach for determining whether a change involves a change to the facility as described in the UFSAR is to consider the larger, UFSAR-described SSC of which the SSC being modified is a part. If for the larger SSC, the change adversely affects a UFSAR-described design function, method of performing or controlling the design function, or an evaluation demonstrating that intended design functions will be accomplished, then a 10 CFR 50.59 evaluation is required.

Another important consideration is that a change to SSCs not described in the UFSAR can indirectly affect the capability of SSCs to perform their UFSAR-described design function(s). For example, increasing the heat load on a nonsafety-related heat exchanger could compromise the cooling system's ability to cool safety-related equipment.

Seismic qualification, flooding protection, fire protection, environmental qualification, and masonry block walls are some of the areas where changes to nonsafety-related SSCs, whether or not described in the UFSAR, can affect the UFSAR-described design function of SSCs through indirect or secondary effects.

Equivalent replacement is a type of change to the facility that does not alter the design functions of SSCs. Licensee technical evaluations should determine whether the proposed alternate replacement item is equivalent to the original in its ability to perform its required design functions, e.g., consideration of performance/operating characteristics and other factors, may thus form the basis for screening determinations that no 10 CFR 50.59 evaluation is required.

As discussed in Section 4.2.1, only proposed changes to SSCs that would, based on supporting engineering and technical information, have adverse effects on design functions require evaluation under 10 CFR 50.59. Changes that have positive or no effect on design functions may generally be screened out. In addition, any change to a design bases limit for a fission product barrier must be considered adverse and screened in. This is because 10 CFR 50.59(c)(2)(vii) requires prior NRC approval any time a proposed change would "exceed or alter" a design bases limit for a fission product barrier.

The following examples illustrate the 10 CFR 50.59 screening process as applied to proposed facility changes:

Example 1

A licensee proposes to replace the relays for the reactor pool level alarm circuits with a nonequivalent relay. These relays are not described in the UFSAR, but the design function of the reactor pool level alarm is described. Based on engineering/ technical information supporting the change, the licensee determines if replacing the relay would adversely affect the design function of the reactor pool level alarm. If the licensee concludes that the change would not affect the UFSAR-described design function of the circuit, then this determination would form the basis for screening out the change, and no 10 CFR 50.59 evaluation would be required.

Example 2

A licensee proposes a change to the operator on reactor pool cooling system isolation valves. The UFSAR describes that these isolation valves are open during normal operation. These are solenoid operated, safety-related valves that are required to remain open so that flow to the reactor pool will occur during an accident to provide reactor pool cooling credited in the safety analyses. If the proposed change was to configure these normally open valves to be normally closed valves that automatically open on high reactor pool temperature, 10 CFR 50.59 evaluation would be required because the change would adversely affect the reliability of the cooling function as credited in the safety analyses.

Example 3

A licensee proposes to replace a globe valve with a ball valve in a vent/drain application to reduce the propensity of this valve to leak. This vent/drain valve has two functions but only one of these functions is a design function. Screening considers whether the change adversely affects the function that is a design function. One vent/drain valve function, which is not a design function, is to provide a flow path when open to drain and refill when the system is out of service to support maintenance. The second vent/drain valve function, which is the UFSAR-described design function, is to maintain the integrity of the system boundary when closed. The vent/drain function to drain and refill the system does not relate to design functions credited in the safety analyses, and the licensee has determined that a ball valve is adequate to support the vent/drain function and is superior to the globe valve in terms of its isolation function.

Thus, the proposed change affects the design of the existing vent/drain valve—but not the design function (maintain the system boundary integrity) that supports system performance credited in the safety analyses—and evaluation/reporting under 10 CFR 50.59 is not required. The screening determination should be documented, and the UFSAR should be updated ~~per 10 CFR 50.71(e) to reflect the change~~.

Commented [CN18]: To backout the NPUF rule.

Example 4

The bolts for retaining a rupture disk are being replaced with bolts of a different material and fewer threads, but equivalent load capacity and strength, such that the rupture disk will still relieve at the same pressure as before the change. Because the replacement bolts are equivalent to the original bolts, the design function of the rupture disk (to relieve at a specified pressure) is unaffected, and this activity may be screened out as an equivalent change.

4.2.1.2 Screening of Changes to Procedures as Described in the UFSAR

Changes are “screened in” (i.e., require a 10 CFR 50.59 evaluation) if they adversely affect how SSC design functions are performed or controlled (including changes to UFSAR-described procedures, assumed operator actions and response times). Proposed changes that are determined to have positive or no effect on how SSC design functions are performed or controlled may be screened out.

For purposes of 10 CFR 50.59 screening, changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in. Such changes include replacement of automatic action by manual action (or vice versa), changes to the human-system interface (HSI) that adversely affect the "method of performing or controlling" the design function, changing a valve from “locked closed” to “administratively closed” and similar changes.

It is important to note that not all changes to the HSI fundamentally alter the means of performing or controlling design functions. Some HSI changes that accompany digital upgrades leave the method of performing functions essentially unchanged. Technical evaluations should determine whether changes to the HSI create adverse effects on design functions (including adverse effects on the licensing basis and safety analyses). Characteristics of HSI changes that could lead to potential adverse effects may include, but are not limited to:

- Changes to parameters monitored, decisions made, and actions taken in the control of facility equipment and systems during transients,
- Changes that could affect the overall response time of the human/machine system (e.g., changes that increase operator burden),
- Changes from manual to automatic initiation (or vice versa) of design functions,
- Fundamental changes in data presentation (such as replacing an edgewise analog meter with a numeric display or a multipurpose CRT where access to the data requires operator interactions to display), or
- Changes that create new potential failure modes in the interaction of operators with the system (e.g., new interrelationships or interdependencies of operator actions and facility response or new ways the operator assimilates facility status information).

If the HSI changes do not exhibit these characteristics, then it may be reasonable to conclude that the "method of performing or controlling" the design function is not adversely affected. Note, however, that these characteristics focus on potential adverse effects due to changes in the physical operator interface, not procedure changes. Changes in procedures that may be required in order to implement HSI changes also need to be screened.

The following examples illustrate the 10 CFR 50.59 screening process as applied to proposed changes affecting how SSC design functions are performed or controlled:

Example 1

Operating procedures include operator actions and response times associated with response to design basis events, which are described in the UFSAR, but may also address operator actions for scenarios that are outside the design basis and not described in the UFSAR. A change would screen out at this step if the change was to those procedures or parts of procedures dealing with operator actions during scenarios that are outside the design basis and not described in the UFSAR.

Example 2

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

Example 3

The UFSAR states that a particular flow path is isolated by a locked closed valve when not in use. A procedure change would remove the lock from this valve such that it becomes a normally closed valve. In this case, the design function is to remain closed, and the method of performing the design function has fundamentally changed from locked closed to administratively closed. Thus, this change would screen in and require a 10 CFR 50.59 evaluation to be performed.

Example 4

Operations proposes to revise its procedures to change from 8-hour shifts to 12-hour shifts. This change results in mid-shift rounds being conducted every 6 hours as opposed to every 4 hours. The UFSAR describes cooling system line breaks that reduce reactor pool level including mitigation criteria. Operator action to detect and terminate the line break is described in the UFSAR, which specifically states that 4 hours is assumed for the pipe break to go undetected before it would be identified during operator mid-shift rounds. The change from 4 to 6 hour rounds is a change to a procedure as described in the UFSAR that adversely affects the timing of operator actions credited in the safety analyses for limiting the effects of cooling system line breaks. Therefore, this change screens in, and a 10 CFR 50.59 evaluation is required.

Example 4

Replacement of a strip chart recorder with a digital, paperless recorder might screen out so long as the data presentation is similar, the recorder location is unchanged, the data displayed is at least as legible as the strip chart recorder was, and the operator uses the recorder in the same way to perform the design function. Therefore, there is no fundamental change in the method of performing or controlling the design function.

4.2.1.3 Screening Changes to UFSAR Methods of Evaluation

As discussed in Section 3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC design functions will be accomplished are considered part of the "facility as described in the UFSAR." Thus, use of new or revised methods of evaluation (as defined in Section 3.10) is considered to be a change that is controlled by 10 CFR 50.59 and needs to be considered as part of this screening step. Adverse changes to elements of a method of evaluation included in the UFSAR, or use of an alternative method, must be evaluated under 10 CFR 50.59(c)(2)(viii) to determine if prior NRC approval is required (see Section 4.3.8). Changes to methods of evaluation (only) do not require evaluation against the first seven criteria.

Changes to methods of evaluation not included in the UFSAR or to methodologies included in the UFSAR that are not used in the safety analyses or to establish design bases may be screened out.

Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not subject to control under 10 CFR 50.59 unless the UFSAR states they were used for specific analyses within the scope of 10 CFR 50.59(c)(2)(viii).

Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation under 10 CFR 50.59 if the changes are outside the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or NRC safety evaluation report (SER). If the changes are within constraints and limitations associated with use of the method, the change is not considered adverse and may be screened out.

Proposed use of an alternative method is considered an adverse change that must be evaluated under 10 CFR 50.59(c)(2)(viii).

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

Example 1

The UFSAR identifies the name of the computer code used for performing reactor fuel performance analyses, with no further discussion of the methods employed within the code for performing those analyses. Terms, conditions, and limitations relating to the application of the methodology were documented in the vendor topical report (e.g., submitted by the methodology owner), and the NRC SER. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated vendor topical report and SER. A change that goes beyond restrictions on the use of the method would be considered adverse and evaluated under 10 CFR 50.59(c)(2)(viii) to determine if prior NRC approval is required.

Example 2

The UFSAR describes the methods used for reactor fuel heat transfer calculations contained within the CONTEMPT computer code. Although this computer code is also used for developing long-term temperature profiles following a loss-of-coolant accident by modeling the reactor pool cooling water system, neither this application of the computer code nor the analysis method is discussed in the UFSAR. A revision to CONTEMPT computer code to incorporate more dynamic modeling of the reactor pool cooling water system to transfer heat would screen out because this application of the CONTEMPT computer code is not described in the UFSAR as being used in the safety analyses or to establish design bases. Changes to CONTEMPT computer code that affect the reactor fuel heat transfer may not screen out (because the UFSAR describes this application in the safety analyses) and may require a 10 CFR 50.59 evaluation.

Example 3

The reactor pool heatup rate calculations were originally performed at a power level of 105% of the nominal power in order to allow margin for future reactor fuel additions. The licensee later decided that it would not pursue the fuel additions and wished to use the margin to address other equipment qualification issues. The reactor pool heatup rate calculations were reanalyzed, using the same methodology, at 100% power. This change would screen out as a methodology change because the proposed activity involved a change to an input parameter (% power), which as described in the Section 3.8 definition of "input parameter," is not a methodology change. This change should be screened per Section 4.2.1.1 to determine if it constitutes a change to the facility as described in the UFSAR that requires evaluation under 10 CFR 50.59(c)(2)(i-vii).

Example 4

The reactor pool heatup rate calculations were originally performed at a power level of 105% of the nominal power. Some of the assumptions in the analysis were identified as nonconservative, but the NRC concluded in the associated NRC SER that the overall analysis was conservative because of the use of the higher initial power. The licensee later decided that it would not pursue the reactor fuel additions and wished to use the margin to address other equipment qualification issues. The reactor pool heatup rate calculations were reanalyzed, using the same methodology, at 100% power. As described in the Section 3.8 definition of "input parameter," if certain elements of a methodology or model were approved by the NRC on the basis of the conservatism of a selected input value, then that input value is considered an element of the methodology. This change would not screen out as a methodology change because the proposed activity involved a change to an input parameter that was integral to the NRC approval of the methodology that requires evaluation under 10 CFR 50.59(c)(2)(viii). Changes to methods of evaluation (only) do not require evaluation against the first seven criteria.

Example 5

Due to reactor fuel changes, the calculated core physics parameters changed. The UFSAR-described method of evaluation and associated NRC SER that describe how the core physics parameters are to be calculated explicitly allow use of either 2-D or 3-D modeling for the analysis. A change to recalculate the core physics parameters using 3-D methods instead of 2-D methods or vice versa would screen out because the change is within the terms and conditions of the NRC SER.

4.2.2 Is the Activity a Test or Experiment Not Described in the UFSAR?

Research and testing facilities are designed to support experiments. The details of the experiment are not typically in the TS or UFSAR, but the limits on the experiments are included in the TSs. Deviation from these TS limits (e.g., reactivity worth) requires a license amendment.

As discussed in Section 3.14, tests or experiments not described in the UFSAR also include activities where an SSC is utilized or controlled in a manner that is outside the reference bounds of the design for that SSC or inconsistent with analyses or description in the UFSAR.

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

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

- Performance of thermal calibration with different equipment or methodology.
- Operation with rearranged fuel elements (new loading pattern) to accommodate an in-core experiment.

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

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

4.2.3 Screening Documentation

The 10 CFR 50.59 recordkeeping requirements apply to 10 CFR 50.59 evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with facility procedures of screenings that conclude a proposed activity may be screened out (i.e., that a 10 CFR 50.59 evaluation was not required). The basis for the conclusion should be documented to a degree commensurate with the safety significance of the change. For changes, the documentation should include the basis for determining that there would be no adverse effect on design functions, etc. Typically, the screening documentation is retained along with the engineering and technical documentation supporting the change. This documentation does not constitute the record of changes required by 10 CFR 50.59, and thus is not subject to 10 CFR 50.59 documentation and reporting requirements. Screening records need not be retained for activities for which a 10 CFR 50.59 evaluation was performed or for activities that were never implemented.

4.3 EVALUATION PROCESS

Once it has been determined that a given activity requires a 10 CFR 50.59 evaluation, the written evaluation must address the applicable criteria of 10 CFR 50.59(c)(2). These eight criteria are used to evaluate the effects of proposed activities on accidents and malfunctions previously evaluated in the UFSAR and their potential to cause accidents or malfunctions whose effects are not bounded by previous analyses.

Criteria (c)(2)(i—vii) are applicable to activities other than changes in methods of evaluation. Criterion (c)(2)(viii) is applicable to changes in methods of evaluation. Each activity must be evaluated against each applicable criterion. If any of the criteria are met, the licensee must apply for and obtain a license amendment per 10 CFR 50.90 before implementing the activity. The evaluation against each criterion should be appropriately documented as discussed in Section 4.5. Subsections 4.3.1 through 4.3.8

provide guidance and examples for evaluating proposed activities against the eight criteria.

Each element (e.g., component replacement, procedure changes required to operate the new component, test method to validate the component will fulfill its intended function, etc.) of a proposed activity must undergo a 10 CFR 50.59 evaluation, except in instances where linking elements of an activity is appropriate, in which case the linked elements can be evaluated together. A test for linking elements of proposed changes is interdependence.

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

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

The effects of a proposed activity being evaluated under 10 CFR 50.59 should be assessed against each of the evaluation criteria separately. For example, an increase in frequency/likelihood of occurrence cannot be compensated for by additional mitigation of consequences. Evaluations should consider the effects of the proposed activity on operator actions.

Specific guidance for applying 10 CFR 50.59 to temporary changes proposed as compensatory actions for degraded or nonconforming conditions is provided in Section 4.4.

4.3.1 Does the Activity Result in More Than a Minimal Increase in the Frequency of Occurrence of an Accident?

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

Most facilities are designed to cope with anticipated transients and potential accidents (both of which are addressed by the term “accident” under 10 CFR 50.59), including those discussed in Chapter 13, "Accident Analyses," of the UFSAR. For ~~RTRs~~NPUFs, accidents are normally described in Chapter 13 of the UFSAR and do not typically have an explicit assessment of their frequency. For changes to the facility, the frequency of occurrence of an accident is directly related to the likelihood of failure of equipment that initiates the accident (e.g., an increase in the likelihood of a failure of a beam tube seal has a corresponding increase in the frequency of a loss of coolant accident). Thus, an increase in the likelihood of failure of the modified equipment causes an increase in the frequency of the accident. Minimal increases in frequency resulting from subsequent licensee activities do not significantly change the licensing basis of the facility and do not impact the conclusions reached about acceptability of the facility design.

Thus, the determination of a frequency increase would be based upon a qualitative assessment using engineering evaluations consistent with the UFSAR analysis assumptions. However, a facility-specific accident frequency calculation or probabilistic risk assessment (PRA) may be used to evaluate a proposed activity in a quantitative sense. It should be emphasized that PRAs are just one of the tools for evaluating the effect of proposed activities, and their use is not required to perform 10 CFR 50.59 evaluations.

Reasonable engineering practices, engineering judgment and PRA techniques, as appropriate, should be used in determining whether the frequency of occurrence of an accident would more than minimally increase as a result of implementing a proposed activity. Knowledge of accident frequency, where applicable, should be used in determining what constitutes more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR. The effect of a proposed activity on the frequency of an accident must be discernable and attributable to the proposed activity in order to exceed the more than minimal increase standard.

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in regulatory guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE standards). Further, departures from the design, fabrication, construction, testing and performance standards as outlined in the principle design criteria for the facility (see 10 CFR 50.34(a)(3)(i) and NUREG-1537 Part 1 Chapter 3) are not compatible with a “no more than minimal increase” standard.

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

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

Example 1

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

Example 2

The proposed activity meets applicable NRC requirements as well as the design, material and construction standards applicable to the SSC being modified. If the proposed activity would not meet applicable requirements and standards, the change is

considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.

Example 3

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

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

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

4.3.2 Does the Activity Result in More Than a Minimal Increase in the Likelihood of Occurrence of a Malfunction of an SSC Important to Safety?

The term "malfunction of an SSC important to safety" refers to the failure of structures, systems, and components (SSCs) to perform their intended design functions—including both nonsafety-related and safety-related SSCs. The cause and mode of a malfunction should be considered in determining whether there is a change in the likelihood of a malfunction. The consequences of malfunctions should be considered per Section 4.3.4 and the effect or result of a malfunction should be considered in determining whether a malfunction with a different result is involved per Section 4.3.6.

Commented [CN19]: This probably needs work. It neglects that malfunction consequences are addressed in 4.3.4.

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 first step is to determine what SSCs are affected by the proposed activity. Next, the effects of the proposed activity on the affected SSCs should be determined. This evaluation should include both direct and indirect effects.

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

After determining the effect of the proposed activity on the important to safety SSCs, a determination is made of whether the likelihood of a malfunction of the important to safety SSCs has increased more than minimally. Qualitative engineering judgment and/or an industry precedent is typically used to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense,

if available and practical. The effect of a proposed activity on the likelihood of malfunction must be discernable and attributable to the proposed activity in order to exceed the more than minimal increase standard. A proposed activity is considered to have a negligible effect on the likelihood of a malfunction when a change in likelihood is so small or the uncertainties in determining whether a change in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed (i.e., there is no clear trend toward increasing the likelihood). A proposed activity that has a negligible effect satisfies the minimal increase standard.

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

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

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in regulatory guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE standards). Further, departures from the design, fabrication, construction, testing and performance standards as outlined in the principle design criteria for the facility (see 10 CFR 50.34(a)(3)(i) and NUREG-1537 Part 1 Chapter 3) are not compatible with a “no more than minimal increase” standard.

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

Example 1

The change involves installing additional equipment or devices (e.g., cabling, manual valves, protective features) provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met. For example, adding protective devices to breakers or installing an additional drain line (with appropriate isolation capability) would not cause more than a minimal increase in the likelihood of malfunction.

Example 2

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

the existing analysis.

Example 3

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

Example 4

The change involves a new or modified operator action that supports a design function credited in safety analyses provided:

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

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

Example 5

The change would cause design stresses to exceed their code allowables or other applicable stress or deformation limit (if any), including vendor-specified stress limits for pump casings that ensure pump functionality.

Example 6

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

Example 7

The change would (permanently) substitute manual action for automatic action for performing UFSAR-described design functions. ~~(Guidance for temporary substitution of manual action for automatic action to compensate for a degraded/nonconforming condition is provided in NRC Generic Letter 91-18, Revision 1.)~~

Commented [CN20]: Not applicable to NPUFs

Example 8

The change in likelihood of occurrence of a malfunction is calculated in support of the evaluation and increases by more than a factor of two. Note: The factor of two should be applied at the component level. Certain changes that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval, e.g., exceed the minimal increase standard for accident/transient frequency under criterion 10 CFR 50.59(c)(2)(i). For example, a change that increases the likelihood of malfunction of a fuel movement tool by a factor of two may cause more than a 10% increase in the frequency of a fuel handling accident.

4.3.3 Does the Activity Result in More Than a Minimal Increase in the Consequences of an Accident?

The UFSAR, based on logic similar to ANSI standards, provides an acceptance criterion and frequency relationship for "conditions for design." When determining which activities represent "more than a minimal increase in consequences" pursuant to 10 CFR 50.59, it must be recognized that “consequences” means dose. Therefore, an increase in consequences must involve an increase in radiological doses to the public or to control room operators. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological dose to the public or to control room operators are addressed under Section 4.3.7, concerning integrity of fission product barriers, or the other criteria of 10 CFR 50.59(c)(2).

NRC regulates compliance with the provisions of 10 CFR Part 50 and 10 CFR Part 100 (applicable to testing facilities) to assure adequate protection of the public health and safety. Activities affecting on-site dose consequences that may require prior NRC approval are those that impede required actions ~~inside or outside the control room~~ to mitigate the consequences of ~~reactor~~ facility accidents. The guidance in the remainder of this section applies to evaluation of effects of changes on-site ~~main control room~~ and off-site doses.

Commented [CN21]: Suggested change since not all NPUFs have control rooms.

Commented [CN22]: Suggested change since not all NPUFs have control rooms.

The consequences covered include dose resulting from any accident evaluated in the UFSAR. The accidents include those typically covered in UFSAR Chapters 2 and 13 and other events for which the facility is designed to cope and are described in the UFSAR (e.g., earthquakes, hurricanes, tornadoes, loss of normal electrical power, and flooding). The consequences referred to in 10 CFR 50.59 do not apply to occupational exposures resulting from routine operations, maintenance, testing, etc. Occupational doses are controlled and maintained As Low As Reasonably Achievable (ALARA) through formal licensee programs.

10 CFR Part 20 establishes requirements for protection against radiation during normal operations, including dose criteria relative to radioactive waste handling and effluents. 10 CFR 50.59 accident dose consequence criteria and evaluation guidance are not applicable to proposed activities governed by 10 CFR Part 20 requirements.

The dose consequences referred to in 10 CFR 50.59 are those calculated by licensees—not the results of independent, confirmatory dose analyses by the NRC that may be documented in SERs.

The evaluation should determine the dose that would likely result from accidents associated with the proposed activity. If a proposed activity would result in more than a

minimal increase in dose from the existing calculated dose for any accident, then the activity would require prior NRC approval. Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e., there is no clear trend toward increasing the consequences), the change need not be considered an increase in consequences.

10 CFR Part 100 establishes requirements for exclusion area and low population zones around the ~~reactor~~ testing facilities so that an individual located at any point on its boundary immediately following onset of the postulated fission product release would not receive a total radiation dose to the whole body in excess of 25 rem or a total radiation dose of 300 rem to the thyroid for iodine exposure. 10 CFR Part 100 is only applicable to testing facilities. NPUFs that are not testing facilities do not have equivalent criteria for exclusion area and low population zones.

For a given accident, calculated or bounding dose values for that accident would be identified in the UFSAR. Dose guideline values for testing facilities are based on 10 CFR Part 100. For NPUFs that are not testing facilities, the results of the accident analysis have generally been compared with 10 CFR Part 20. ~~For testing facilities, these dose values should be within the 10 CFR 100 limits. For NPUFs that are not testing facilities, these dose values should be within the 10 CFR 50.34 limit of 1 Roentgen equivalent man (rem) (0.01 sievert (Sv)) total effective dose equivalent (TEDE) to a member of the public.~~ An increase in consequences from a proposed activity is defined to be no more than minimal if the increase is less than or equal to 10 percent of the difference between the current calculated dose value in the UFSAR and the regulatory guideline value[7] ~~(10 CFR 100, for testing facilities or 1 rem TEDE for research reactors and other NPUFs)~~. The current calculated dose values are those documented in the most up-to-date analyses of record.

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

(1) Will the proposed activity change, prevent or degrade the effectiveness of actions described or assumed in an accident discussed in the UFSAR?

(2) Will the proposed activity alter assumptions previously made in evaluating the radiological consequences of an accident described in the UFSAR?

(3) Will the proposed activity play a direct role in mitigating the radiological consequences of an accident described in the UFSAR?

The next step is to determine if the proposed activity does, in fact, increase the radiological consequences of any of the accidents evaluated in the UFSAR. If it is

[7] Dose guideline values for testing facilities are based on 10 CFR Part 100. For NPUFs that are not testing facilities, the results of the accident analysis have generally been compared with 10 CFR Part 20.

determined that the proposed activity does have an effect on the radiological consequences of any accident analysis described in the UFSAR, then either:

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

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

The following examples illustrate the implementation of this criterion. In each example it is assumed that the calculated consequences do not include a change in the methodology for calculating the consequences. Changes in methodology would need to be separately considered under 10 CFR 50.59(c)(2)(viii) as discussed in Section 4.3.8.

Example 1

The calculated fuel handling accident (FHA) dose at a test reactor is 50 rem to the thyroid at the site boundary. As a result of a proposed change, the calculated FHA dose would increase to 70 rem. Ten percent of the difference between the calculated value and the regulatory limit is 25 rem [10% of (300 rem- 50 rem)]. Because the calculated increase is less than 25 rem and the total is less than the 10 percent of the difference between the current calculated dose value in the UFSAR and the regulatory guideline value of 300 rem to the thyroid from iodine exposure in 10 CFR Part 100, the increase is not more than minimal.

Example 2

The calculated dose consequence at a research reactor for an accident is 0.095 rem whole body at the site boundary. As a result of a proposed change, the calculated dose consequence would increase to 0.100 rem. The increase is not more than minimal because the new calculated dose does not exceed the 10 percent of the difference between the previous calculated value and the 1.0 rem limit (the applicable the regulatory guideline value in this example). The difference between 1 rem and 0.095 rem is 0.905. 10 percent of 0.905 is 0.0905. Since 0.005 rem is less than 0.0905, this change does not cause more than a minimal increase in consequences.

Example 3

The calculated dose consequence of an accident at a test reactor is 25 rem to the thyroid at the site boundary. Because of a proposed change, the calculated dose consequence would increase to 65 rem. The incremental increase in dose consequence (40 rem), however, exceeds 10 percent of the difference to the regulatory limit or 27.5 rem [10% of (300 rem - 25 rem)]. Therefore, the change results in more than a minimal increase in consequences and thus requires prior NRC approval.

Example 4

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The calculated dose to a member of the public following a loss of coolant accident at a research reactor is 0.070 rem whole body. A change is proposed to the ventilation system such that the calculated dose would increase to 0.205 rem. Although the new calculated dose is less than 1.0 rem (the applicable the regulatory guideline value in this example), the incremental increase in dose (0.135 rem) exceeds the value of 10 percent of the difference between the previously calculated value and the regulatory value or 0.0.093 rem [10% of (1 rem - 0.070 rem)]. This change would require prior NRC review because the increase in consequences exceeds the minimal standard.

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Example 5

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The existing safety analysis for a failure of encapsulation of a fueled experiment at a test reactor predicts an off-site dose to the whole body of 1.225 rem. A proposed change would result in an increase in the calculated dose from 1.225 rem to 1.300 rem. In this case, the proposed change would not cause more than a minimal increase in consequences because the new calculated value is less than 10 percent of the difference between the previously calculated value and the 10 CFR Part 100 regulatory value (i.e., 25 rem).

4.3.4 Does the Activity Result in More Than a Minimal Increase in the Consequences of a Malfunction?

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions evaluated in the UFSAR have their radiological consequences affected as a result of the proposed activity. The next step is to determine if the proposed activity does, in fact, increase the radiological consequences and, if so, are they more than minimally increased. The guidance for determining whether a proposed activity results in more than a minimal increase in the consequences of a malfunction is the same as that for accidents. Refer to Section 4.3.3.

4.3.5 Does the Activity Create a Possibility for an Accident of a Different Type?

The UFSAR evaluates a broad spectrum of anticipated transients and potential accidents that assume a single initiating malfunction caused by a credible equipment malfunction, operator error, or a natural phenomenon or one caused by humans. During the initial design of the facility, enough various initiating malfunctions are considered simply to identify any accident scenarios with radiological consequences or that could impact a safety limit from the technical specifications. Accidents are categorized by type based on their effects on the facility so that only the limiting cases in each group must be quantitatively analyzed (e.g., the event in that group with the highest radiological dose consequences). For instance, accidents at NPUFs may be categorized by the following types according to characteristics of the particular facility:

- maximum hypothetical accident (MHA) [8]
- insertion of excess reactivity (ramp, step, startup, etc.)
- loss of coolant

[8] See discussion in Section 3.2, Accident Previously Evaluated in the UFSAR which includes a discussion of maximum hypothetical accident.

- loss of coolant flow
- mishandling or malfunction of fuel
- experiment malfunction
- loss of normal electrical power
- external events such as floods and earthquakes
- mishandling or malfunction of equipment

Categorizing accidents by type provides a basis for comparison between events, which makes it possible to identify and evaluate the limiting cases (i.e., the cases that can challenge the analysis acceptance criteria) and eliminate non-limiting cases from further consideration. Accidents that are not limiting cases are not discussed in the UFSAR. The limiting case of each type should be analyzed in Chapter 13 of the UFSAR. Importantly, this criterion deals with creating the possibility for accidents of a different type which are new accidents created by the activity that are distinct from any previously evaluated in the UFSAR but are of similar frequency (except for MHA) and significance to those accidents already included in the licensing basis for the facility. Thus, accidents that would require multiple independent failures or other circumstances in order to "be created" would not meet this criterion.

Certain accidents are not discussed in the UFSAR because their effects are bounded by other related events that are analyzed. For example, a postulated 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 proposed design change would introduce a small high energy line break into this area, postulated breaks in the smaller line need not be considered an accident of a different type.

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

In evaluating whether the proposed change or activity creates the possibility of an accident of a different type, the first step is to determine the types of accidents that have been evaluated in the UFSAR. An accident of a different type is any new accident, distinct from any previously evaluated in the UFSAR but of similar frequency (except for MHA) and significance. A different accident analysis, not simply a revision of an existing

analysis, would be needed for this different type of accident.

4.3.6 Does the Activity Create a Possibility for a Malfunction of an SSC Important to Safety with a Different Result Than Any Previously Evaluated in the UFSAR[9]?

Malfunctions of SSCs are generally postulated as potential single failures to evaluate facility performance with the focus being on the result of the malfunction rather than the cause or type of malfunction. Importantly, a malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described in the UFSAR is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or effect is the same as, or is bounded by, that previously evaluated in the UFSAR. The following examples illustrate this point:

- If a valve that is designed to fail open on the loss of electrical power is replaced with a new design, there may be a new failure mechanism introduced that would cause the valve to fail in the closed position. But if this effect (the loss of flow through the valve)) was previously evaluated and bounded, then a malfunction with a different result has not been created.

- If a secondary cooling control system is being upgraded from an analog to a digital system, new digital components (e.g., microprocessors) may be added that could fail in ways other than the analog components in the original design. The failure mode and failure result previously explicitly evaluated in the UFSAR was that the analog controller would fail to its minimum demand condition which sends a signal to temperature control valve to fully close. The UFSAR-described failure result was an increase primary coolant temperature to a specified value that was within the acceptable range. The new digital controller introduced a new failure mode where the digital controller would fail to its maximum demand condition which sends a signal to temperature control valve to fully open and the failure result is a decrease primary coolant temperature to a calculated value. Provided the end result of the component or subsystem failure is the same as, or is bounded by, the results of malfunctions that are affected by the activity (i.e., malfunctions of secondary cooling system) currently explicitly described in the UFSAR (i.e., the primary coolant water temperature remains within the temperature range previously evaluated in the UFSAR.), then this upgrade would not create a "malfunction with a different result."

An example of a change that would create the possibility for a malfunction with a different result is a substantial modification or upgrade to control station alarms, controls,

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[9] NEI 96-07, Revision 1, uses the following terms that are not explicitly defined but are necessary to understanding the guidance in NEI 96-07, Revision 1.
Failure mechanism is the physical process that led to the failure (e.g., broken valve stem, overheated microprocessor, latent software error).
Failure cause is the reason the failure mechanism occurred (e.g., stress corrosion cracking, poor software design process).
Failure mode is the undesirable state or condition of a system or component (e.g., fail to open, fail to close, failure as-is).
Failure result or **failure effect** is the concern.

or displays that are associated with SSCs important to safety that creates a new or common cause failure that is not bounded by previous analyses or evaluations.

Certain malfunctions are not explicitly described in the UFSAR because their effects are bounded by other malfunctions that are described. For example, failure of a pneumatic control line to supply control air to a primary confinement ventilation intake may not be explicitly described because a failure of the intake ventilation dampers to operate was described.

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

In evaluating a proposed activity against this criterion, the types and results of failure modes of SSCs that have previously been evaluated in the UFSAR and that are affected by the proposed activity should be identified. This evaluation should be performed consistent with any failure modes and effects analysis (FMEA) described in the UFSAR, recognizing that certain proposed activities may require a new FMEA to be performed. This criterion considers whether the activity creates a malfunction with a different result as compared to UFSAR-described malfunctions and results previously evaluated in the UFSAR in its entirety, which includes, but is not limited to the malfunctions and results described in the accident analyses or safety analyses. For instance, the UFSAR accident analyses provide previously evaluated malfunction results of a single initiating malfunction (e.g., caused by a credible equipment malfunction). If failures were previously postulated on a train or channel level because the trains or channels were independent, for example independent analog measuring channels, a proposed activity that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether different results of the new malfunction are introduced.

Once the malfunctions previously evaluated in the UFSAR and the results of these malfunctions have been determined, then the types and results of failure modes that the proposed activity could create are identified. Comparing the two lists can provide the answer to the criterion question. An example that might create a malfunction with a different result could be the addition of a normally open containment isolation valve that is designed to automatically close on the detection of radiation in containment. The different result of a malfunction could be potential release of radioactive gases. Another example that might create a malfunction with a different result could be an experiment that changes the configuration of the primary coolant flow within the core. The different result of a malfunction could decrease the flow that is stated in the UFSAR.

4.3.7 Does the Activity Result in a Design Basis Limit for a Fission Product Barrier Being Exceeded or Altered?

10 CFR 50.59 evaluation under criterion (c)(2)(vii) focuses on the fission product barriers and on the critical design information that supports their continued integrity. Examples

of fission product barriers at NPUFs may include the fuel matrix, fuel cladding, experiment encapsulations, reaction vessels (facilities with fission reactions in solution), reactor coolant system boundary, and containment or confinement. Guidance for applying this criterion is structured around a two-step approach:

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

Identification of affected design basis limits for a fission product barrier

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

- The parameter is fundamental to the barrier's integrity. Design basis limits for fission product barriers establish the reference bounds for design of the barriers, as defined in 10 CFR 50.2. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, design bases limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.

  For purposes of this evaluation, design bases parameters that are used to directly determine fission product barrier integrity should be distinguished from subordinate parameters that can indirectly affect fission product barrier performance. Indirect effects of changes to subordinate parameters are evaluated in terms of their effect on the more fundamental design bases parameters/limits that ensure fission product barrier integrity. For example, primary coolant design flow is a subordinate parameter for purposes of this evaluation, not a design bases parameter/limit. The acceptability of a reduction in primary coolant design flow would be determined based on its effect on design bases limits for the fuel cladding.

- The limit is expressed numerically. Design basis limits are numerical values used in the overall design process, not descriptions of functional requirements. Design basis limits are typically the numerical event acceptance criteria used in the accident analysis methodology. The facility's design and operation associated with these parameters as described in the UFSAR will be at or below (more conservative than) the design basis limit.

- The limit is identified in the UFSAR. As required by 10 CFR 50.34(b), design basis limits were presented in the original UFSAR and continue to reside in the UFSAR. They may also be located in a vendor topical report that is incorporated by reference in the UFSAR. An example of this would be fuel vendor topical reports which define the limits for pressure and temperature for a specific fuel design.

Consistent with the discussion of 10 CFR 50.59 applicability in Section 4.1, any design basis limit for a fission product barrier that is controlled by another, more specific regulation or technical specification would not require evaluation under criterion (c)(2)(vii). The effect of the proposed activity on those parameters would be evaluated in accordance with the more specific regulation. Effects (either direct or indirect—see discussion below) on design basis parameters covered by another regulation or technical specification need not be considered as part of evaluations under this criterion.

Examples of typical fission product barrier design basis limits are identified in the following table (not all of these examples apply to all NPUFs):

Barrier	Design Bases Parameter	Example Design Basis Limits
Fuel Cladding	DNBR	Value corresponding to a DNBR criterion of 2.0 for a given DNB correlation
	Fuel temperature	Centerline fuel melting temperature
	Linear heat rate	Peak linear heat rate (typ. in kW/ft) established to ensure clad integrity
	Fuel enthalpy	Cal/gm associated with dispersion
	Clad strain	Internal pressure associated with cladding failure
	Fuel burnup	Limit (fissions/cc or MWd/ton) established to ensure clad integrity
	Clad temperature	Temperature limit established to ensure fuel clad integrity
	Clad oxidation	Clad oxidation limit established to ensure fuel clad integrity
Primary Coolant System Boundary	Pressure	Designated limit in safety analysis for specific accident
	Stresses	Stress limit established to ensure primary coolant system boundary integrity
Containment or Confinement	Pressure	Containment or confinement design pressure

The list above may vary slightly for a given facility and/or fuel vendor and may include other parameters for specific accidents. For example,

- NPUFs that utilize plate-type fuel may use primary coolant inflow and outflow temperatures as a limiting parameter to ensure fuel cladding integrity for some accident sequences.

If a given facility has these or other parameters incorporated into the UFSAR as a design basis limit for a fission product barrier, then changes affecting it should be evaluated under this criterion.

Two of the ways that a licensee can evaluate proposed activities against this criterion are as follows. The licensee may identify all design bases parameters for fission product barriers and include them explicitly in the procedure for performing 10 CFR 50.59 evaluations. Alternatively, the effects of a proposed activity could be evaluated first to determine if the change affects design bases parameters for fission product barriers. The results of these two approaches are equivalent provided the guidance for “exceeded or altered” described below is followed. In all cases, the direct and indirect effects of proposed activities must be included in the evaluation.

Exceeded or altered

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

The effect of the proposed activity includes both direct and indirect effects. Direct effects are usually self-evident. As an example, extending the maximum fuel temperature limits until the fuel element internal gas pressure exceeds the design basis limit is a direct effect that would require a license amendment. As discussed earlier, indirect effects provide for another parameter or effect to cascade from the proposed activity to the design basis limit. For example, reducing the design flow of the primary coolant pumps could reduce the heat transferred from the fuel to the primary coolant. That effect could increase the fuel temperature during a loss of coolant flow accident. The 10 CFR 50.59(c)(2)(vii) evaluation of this change would focus on whether the design basis limit associated with fuel cladding temperature for that accident sequence would be exceeded.

Altering a design basis limit for a fission product barrier is not a routine activity, but it can occur. An example of this would be changing the DNBR value from the value corresponding to the 2.0 criterion for calculations of DNBR at NPUFs, perhaps as a result of a new fuel design being implemented (e.g., new fuel element top piece affecting coolant channel flow). (A new correlation or a new value for the "2.0 DNBR criterion" with the same fuel type would be evaluated under criterion (c)(2)(viii) of the rule.) Another example is redesigning portions of the coolant system boundary to no longer comply with the code of construction. These are infrequent activities affecting key elements of the defense-in-depth philosophy. As such, no distinction has been made between a conservative and nonconservative change in these limits. In contrast with these examples, altering primary coolant design flow, or other subordinate parameter/limit, is not subject to the "may not be altered" criterion because primary coolant design flow is not a design bases limit for fission product barrier integrity.

Evaluations performed under this criterion may incorporate a number of refinements to simplify the review. For example, if an engineering evaluation demonstrates that no parameters are affected that have design basis limits for fission product barriers associated with them, no further 10 CFR 50.59(c)(2)(vii) evaluation is required. Similarly, most parameters that require evaluation under this criterion have calculations or analyses supporting the facility's design. If an engineering evaluation demonstrates that the analysis presented in the UFSAR remains bounding, then no further 10 CFR 50.59(c)(2)(vii) evaluation is required. When using these techniques, both indirect and direct effects must be considered to ensure that important interactions are not overlooked.

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

Example 1

It is proposed to delay the automatic start of one of two primary coolant pumps to eliminate spurious automatic starts caused by other systems starting up at the same time. The proposed change is of sufficient magnitude such that it "screens in" as affecting a UFSAR-described design function.

Identification of design basis limits

The direct effects of a reduction in the primary flow during startup would be reviewed to identify potentially affected design basis parameters. In addition, the indirect effect on the heat exchanger of a possible transient pressure imbalance would be considered. Likewise, consideration of indirect effects would likely be extended to the demineralization or secondary cooling systems as well. The review concludes that no design basis limits are either directly or indirectly affected.

The change in the frequency of a reactor trip as a result of normal primary coolant system malfunctions would be evaluated under other 10 CFR 50.59 criteria.

Exceeded or altered

Since no design basis limits were identified, this element of the evaluation is not applicable.

Example 2

Recently identified corrosion inside the primary containment has prompted a re-evaluation of the existing containment design pressure of 2 psig. This re-evaluation has concluded that a design pressure of 1.5 psig is the maximum supportable. As the final resolution to the degraded containment condition, the licensee proposes to reduce the containment design pressure as reflected in UFSAR safety analyses from 2 to 1.5 psig.

Identification of design basis limit

The affected parameter is post-accident peak containment pressure. This parameter directly affects the containment barrier. Its design basis limit from the UFSAR is the existing containment design pressure of 2 psig.

Exceeded or altered

The design basis limit itself has been "altered" and thus a license amendment is required. The issue of conservative vs. nonconservative is not germane to requiring a submittal. That is, prior NRC approval is required regardless of direction because this is a fundamental change in the facility's design.

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

Criterion 10 CFR 50.59(c)(2)(viii) uses terminology with specific definitions in Section 3 including:

- 3.4 Departure from the Method of Evaluation Described in the UFSAR
- 3.5 Design Bases
- 3.10 Method of Evaluation
- 3.12 Safety Evaluation

The word "method," when used in the context of criterion 10 CFR 50.59(c)(2)(viii), relates to definition in Section 3.10, for Method of Evaluation, which states "Methods of evaluation means the calculational framework used for evaluating behavior or response of the facility or an SSC," but not the commonly understood dictionary definition of "method" which is broader than just "calculational framework."

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

Because 10 CFR 50.59 provides a process for determining if prior NRC approval is required before making changes to the facility as described in the UFSAR, changes to the methodologies described in the UFSAR also fall under the provisions of the 10 CFR 50.59 process, specifically criterion (c)(2)(viii). In general, licensees can make changes to elements of a methodology without first obtaining a license amendment if the results are essentially the same as, or more conservative than, previous results. Similarly, licensees can also use different methods without first obtaining a license amendment if those methods have been previously approved by the NRC for the intended application.

If the proposed activity does not involve a change to a method of evaluation, then the 10 CFR 50.59 evaluation should reflect that this criterion is not applicable. If the activity involves only a change to a method of evaluation, then the 10 CFR 50.59 evaluation should reflect that criteria 10 CFR 50.59(c)(2)(i—vii) are not applicable.

The first step in applying this criterion is to identify the methods of evaluation that are affected by the change. This is accomplished during application of the screening criteria in Section 4.2.1.3.

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

- Changes to any element of analysis methodology that yield results that are nonconservative or not essentially the same as the results from the analyses of record

- Use of new or different methods of evaluation that are not approved by NRC for the intended application

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

- Departures from methods of evaluation that are not described, outlined, summarized or incorporated by reference in the UFSAR (such changes may have been screened out as discussed in Section 4.2.1.3).

- Use of a new NRC-approved methodology (e.g., new or upgraded computer code) to reduce uncertainty, provide more precise results or other reason, provided such use is (a) based on sound engineering practice, (b) appropriate for the intended application and (c) within the limitations of the applicable SER. The basis for this determination should be documented in the licensee evaluation.

- Use of a methodology revision that is documented either (1) as a change to any of the elements of the methodology described in the UFSAR (i.e., paragraph 50.59(a)(2)(i) of the departure definition), or (2) as a change from the methodology described in the UFSAR to another method (i.e., paragraph of the 10 CFR 50.59(a)(2)(ii) departure definition). If a methodology revision is documented as a change from the methodology described in the UFSAR to another method using paragraph 10 CFR 50.59(a)(2)(ii) of the departure definition, then paragraph 10 CFR 50.59(a)(2)(i) of the departure definition (i.e., "the results of the analysis are conservative or essentially the same") is not applicable.

Subsection 4.3.8.1 provides guidance for making changes to one or more elements of an existing method of evaluation used to establish the design bases or in the safety analyses. Subsection 4.3.8.2 provides guidance for adopting an entirely new method of evaluation to replace an existing one.

Examples illustrating the implementation of this criterion are provided in Section 4.3.8.3.

4.3.8.1 Guidance for Changing One or More Elements of a Method of Evaluation

The definition of "departure …" provides licensees with the flexibility to make changes under 10 CFR 50.59 to methods of evaluation whose results are "conservative" or that are not important with respect to the demonstrations of performance that the analyses provide. Changes to elements of analysis methods that yield conservative results, or results that are essentially the same, would not be departures from approved methods.

Conservative vs. Nonconservative Results

Gaining margin by changing one or more elements of a method of evaluation is considered to be a nonconservative change and thus a departure from a method of evaluation for purposes of 10 CFR 50.59. Such departures require prior NRC approval of the revised method. Analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change from 1 psig to 1.5 psig in the result of a containment peak pressure analysis (with design basis limit of 2 psig) using a revised method of evaluation would be

considered a conservative change when applying this criterion. In other words, the revised method is more conservative if it predicts more severe conditions given the same set of inputs. This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making potential physical or procedure changes without a license amendment.

In contrast, if the use of a modified method of evaluation resulted in a change in calculated containment peak pressure from 1 psig to 0.8 psig, this would be a nonconservative change. That is because the change would result in more margin being available (to the design basis limit of 2 psig) for the licensee to make more significant changes to the physical facility or procedures.

"Essentially the Same"

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

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

4.3.8.2 Guidance for Changing from One Method of Evaluation to Another

The definition of "departure…" provides licensees with the flexibility to make changes under 10 CFR 50.59 from one method of evaluation to another provided that the new method is approved by the NRC for the intended application. A new method is approved by the NRC for intended application if it is approved for the type of analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied.

NRC approval has typically followed one of two paths. Most reactor or fuel vendors have prepared and obtained NRC approval of topical reports that describe methodologies for the performance of a given type or class of analysis. Through a SER, the NRC approved the use of the methodologies for a given class of NPUFs (e.g., NPUFs with certain specified primary coolant configuration, NPUFs that use a specified vendor's fuel). In some cases, the NRC has accorded "generic" approval of analysis

methodologies. Terms, conditions, and limitations relating to the application of the methodologies are usually documented in the topical reports, the SER, and correspondence between the NRC and the methodology owner that is referenced in the SER or associated transmittal letter.

The second path is the approval of a specific analysis rather than a more generic methodology. In these cases, the NRC's approval has typically been part of a facility's licensing basis and limited to a given facility design and a given application. Again, a thorough understanding of the terms, conditions, and limitations relating to the application of the methodology is essential. This information is usually documented in the original license application or license amendment request, the SER, and any correspondence between the NRC and the analysis owner that is referenced in the SER or associated transmittal letter. An example of this is the use of newer neutronics codes as applied to a specific facility.

It is incumbent upon the users of a new methodology—even one generically approved by the NRC—to ensure they have a thorough understanding of the methodology in question, the terms of its existing application and conditions/limitations on its use. A range of considerations is identified below that may be applicable to determining whether new methods are technically appropriate for the intended application. The licensee should address these and similar considerations, as applicable, and document in the 10 CFR 50.59 evaluation the basis for determining that a method is appropriate and approved for the intended application. To obtain an adequate understanding of the method and basis for determining it is approved for use in the intended application, licensees should consult various sources, as appropriate. These include SERs, topical reports, licensee correspondence with the NRC and licensee personnel familiar with the existing application of the method. If adequate information cannot be found on which to base the intended application of the methodology, the method should not be considered "approved by the NRC for the intended application."

When considering the application of a methodology, it is necessary to adopt the methodology *en toto* and apply it consistent with applicable terms, conditions, and limitations. Mixing attributes of new and existing methodologies is considered a revision to a methodology and must be evaluated as such per the guidance in Section 4.3.8.1.

Considerations for Determining if New Methods May be Considered "Approved by the NRC for the Intended Application"

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

- Is the application of the methodology consistent with the facility's licensing basis (e.g., NUREG-1537 or other facility-specific commitments)?
- Is the methodology consistent with relevant industry standards?
- If application of the new methodology requires exemptions from regulations or facility-specific commitments, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with a facility's licensing basis, then prior NRC approval may be required. The applicable change process must be

followed to make the facility's licensing basis consistent with the requirements of the new methodology.

- If a computer code is involved, has the code been installed in accordance with applicable software quality assurance requirements?
- Has the facility-specific model been adequately qualified through benchmark comparisons against test data, facility data or approved engineering analyses?
- Is the application consistent with the capabilities and limitations of the computer code?
- Has industry experience with the computer code been appropriately considered?

The computer code installation and facility-specific model qualification are not directly transferable from one organization to another. The installation and qualification should be in accordance with the licensee's quality assurance program.

If the facility is designed and operated in a similar, but not identical, manner, the following types of considerations should be addressed to assess the applicability of the methodology:

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

Differences in the facility configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage facilities may not include an analytical analysis of certain accidents that was performed in later vintage facilities. Some facilities may be required to postulate a loss of off-site power or a maximum break size for certain events; others may have obtained exemptions to these requirements from the NRC. Some facilities may have emergency core cooling systems; other facilities do not. Facility specific failure modes and effects analyses may reveal new potential single failure scenarios that cannot be adequately assessed with the original methodology. The existence of these differences does not preclude application of a new methodology to a facility; however, differences must be identified, understood and the basis documented for concluding that the differences are not relevant to determining that the new application is technically appropriate.

4.3.8.3 Examples

The following examples illustrate the implementation of this criterion:

Example 1

The UFSAR states that a damping value of 0.5 percent is used in the seismic analysis of the reactor pool. The licensee wishes to change this value to 2 percent to reanalyze the seismic loads for the reactor pool. Using a higher damping value to represent the response of the reactor pool to the acceleration from the postulated earthquake in the analysis would result in lower calculated stresses because the increased damping

reduces the loads. Since this analysis was used in establishing the seismic design bases for the reactor pool, and since this is a change to an element of the method that is not conservative and is not essentially the same, this change would require prior NRC approval under this criterion.

On the other hand, had NRC 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 2 percent damping under these circumstances would not be a departure because this method of evaluation is considered "approved by the NRC for the intended application."

Example 2

A facility has a design basis containment pressure limit of 2 psig. The current worst-case design basis accident calculation results in a peak pressure of 1.5 psig within two minutes. The licensee revises the method of evaluation, and the recalculated result is 1.0 psig. This change would require prior NRC approval because the result of the recalculation is not conservative. If the licensee used a different method that was approved by the NRC and met all the terms and conditions of the method, a recalculated result of 1.0 psig would not require prior NRC approval.

Example 3

A licensee revises the radiological consequences analysis of the MHA described in the UFSAR to include the analysis of the amount of iodine released from the failed fuel that is absorbed into the primary water. This revised method is used to reduce the level of iodine in the containment/confinement building to demonstrate that the radiological consequences will be less than previously calculated. This change would require prior NRC approval as it would not produce results that are essentially the same.

Example 4

Licensee X has received NRC approval for the use of a method of evaluation for performing transient pulse calculations for evaluating reactivity insertion accidents. The terms and conditions for the use of the method are detailed in the NRC SER. The SER also describes limitations associated with the method. Licensee Y wants to apply the method at its facility. After reviewing the method, approved application, SER and related documentation, to verify that applicable terms, conditions and limitations are met and to ensure the method is applicable to their type of facility, Licensee Y conducts a 10 CFR 50.59 evaluation. Licensee Y concludes that the change is not a departure from a method of evaluation because it has determined the method is appropriate for the intended application, the terms and conditions for its use as specified in the SER have been satisfied, and the method has been approved by the NRC.

Example 5

The NRC has approved the use of computer code and the associated analysis of an MHA to evaluate component stresses. A licensee uses the same computer code and analysis methodology to replace its evaluation of the containment pressure response.

This change would require prior NRC approval unless the methodology had been previously approved for evaluating containment pressure response.

4.4 APPLYING 10 CFR 50.59 TO COMPENSATORY ACTIONS TO ADDRESS NONCONFORMING OR DEGRADED CONDITIONS

Three general courses of action are available to licensees to address nonconforming and degraded conditions. Whether or not 10 CFR 50.59 must be applied, and the focus of a 10 CFR 50.59 evaluation if one is required, depends on the corrective action plan chosen by the licensee, as discussed below:

- If the licensee intends to restore the SSC back to its as-designed condition then this corrective action should be performed in a timely manner commensurate with safety. This activity is not subject to 10 CFR 50.59.

- If an interim compensatory action is taken to address the condition and involves a temporary procedure or facility change, 10 CFR 50.59 should be applied to the temporary change. The intent is to determine whether the temporary change/compensatory action itself (not the degraded condition) impacts other aspects of the facility or procedures described in the UFSAR. In considering whether a temporary change impacts other aspects of the facility, a licensee should pay particular attention to ancillary aspects of the temporary change that result from actions taken to directly compensate for the degraded condition.

- If the licensee corrective action is either to accept the condition “as-is” resulting in something different than its as-designed condition, or to change the facility or procedures, 10 CFR 50.59 should be applied to the corrective action, unless another regulation applies, e.g., 10 CFR 50.54(q) In these cases, the final corrective action becomes the proposed change that would be subject to 10 CFR 50.59.

In resolving degraded or nonconforming conditions, the need to obtain NRC approval for a proposed activity does not affect the licensee's authority to operate the facility. The licensee may make mode changes, restart from outages, etc., provided that necessary SSCs are operable and the degraded condition is not in conflict with the technical specifications or the license.

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

A mechanical switch for one beam port shield shutter failed while at power. The switch provides an alarm function, but not an automatic protective action function. The switch and associated alarm are described in the UFSAR, as protective features to alert the control room operator to a potential high radiation area created by opening a beam port shutter while at power, but no technical specification applies. Loss of the transmitter does not result in the loss of operability for any technical specification equipment. The switch fails in a direction resulting in a continuous alarm in the control room. The alarm circuitry provides a common alarm for three other beam port shutter position indication circuits, so any single switch failure causes a hanging alarm and a masking of proper

operation of the remaining functional switches. Precautionary measures are taken to mechanically lock down the shutter position. An interim compensatory action is proposed to lift the leads (temporary change) from the failed switch to restore the alarm function for the remaining functioning position switches.

Lifting the leads is a compensatory action (temporary change) that is subject to 10 CFR 50.59. The 10 CFR 50.59 screening would be applied to the temporary change itself (lifted leads), not the degraded condition (failed switch), to determine its impact on other aspects of the facility described in the UFSAR. If screening determines that no other UFSAR-described SSCs would be affected by this compensatory action, the temporary change would screen out, i.e., not require a 10 CFR 50.59 evaluation.

4.5 DISPOSITION OF 10 CFR 50.59 EVALUATIONS

There are two possible conclusions to a 10 CFR 50.59 evaluation:

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

Where an activity requires prior NRC approval, the activity must be approved by the NRC via license amendment in accordance with 10 CFR 50.90 prior to implementation. An activity is considered “implemented” when it provides its intended function, that is, when it is placed in service and declared operable. Thus, a licensee may design, plan, install and test a modification prior to receiving the license amendment to the extent that these preliminary activities do not themselves require prior NRC approval under 10 CFR 50.59.

For example, a modification to a facility involved the replacement of the nuclear instrumentation (NI) system and its associated protection logic. The existing NI system uses a combination of fission, compensated ion, and uncompensated ion chambers that provide signals to the reactor protection system using a 1-out-of-3 logic. The new NI system uses exclusively fission chambers that provide signals to the reactor protection system using a 2-out-of-3 logic. The installation of the new system is largely a new, separate structure. Ultimately, the modification would require NRC approval because of impacts on the technical specifications requiring a 1-out-of-3 logic on protection system inputs from the NI system. There was insufficient time to seek and gain NRC approval prior to construction and initial testing. The licensee prepared a 10 CFR 50.59 screening to support construction of the separate structure through preliminary testing. The limited interfaces with the existing facility were assessed and determined to not change the facility or procedures as described in the UFSAR. Upon receipt of the license amendment, the final tie-in to the protection system, testing and operation were fully authorized. 10 CFR 50.59 should be applied to any aspects of the activity not addressed in the license amendment request and/or associated SER.

In another example, a modification to a facility involved the replacement of part of the primary cooling system with one including different primary components (e.g., piston pump being replaced with an impeller pump) as well as associated changes in piping. The installation of the replacement system was largely in a new, separate structure. Ultimately the modification would require NRC approval because of impacts on the technical specifications as well as due to differences in reliability of the replacement

pump in some situations. There was insufficient time to seek and gain NRC approval prior to construction. The licensee prepared a 10 CFR 50.59 screening to support construction of the separate structure through preliminary testing. The limited interfaces with the existing facility were assessed and determined to not change the facility or procedures as described in the UFSAR. Upon receipt of the license amendment the final tie-in, testing and operation were fully authorized. 10 CFR 50.59 should be applied to any aspects of the activity not addressed in the license amendment request and/or associated SER.

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

(1) Cancel the planned activity.

(2) Redesign the proposed activity so that the it may proceed without prior NRC approval.

(3) Apply for and obtain a license amendment under 10 CFR 50.90 prior to implementing the activity. Technical and licensing evaluations performed for such activities may be used as part of the basis for license amendment requests.

It is important to remember that determining that a proposed activity requires prior NRC approval does not determine whether it is safe. In fact, a proposed activity that requires prior NRC approval may significantly enhance overall facility safety at the expense of a small adverse impact in a specific area. It is the responsibility of the facility to assure that proposed activities are safe, and it is the role of the NRC to confirm the safety of those activities that are determined to require prior NRC review.

5.0 DOCUMENTATION AND REPORTING

10 CFR 50.59(d) requires the following documentation and recordkeeping:

The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made pursuant to 10 CFR 50.59(c). These records must include a written evaluation that provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to 10 CFR 50.59(c)(2).

(1) The licensee shall submit, as specified in 10 CFR 50.4, a report containing a brief description of any changes, tests and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. [For most NPUF licensees, technical specifications require this information be submitted annually.]
(2) The records of changes in the facility must be maintained until the termination of a license issued under 10 CFR ~~Part~~ 50.59(d)(3). Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years. [The technical specifications contain record retention requirements that must also be met.]

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

Documenting 10 CFR 50.59 Evaluations

In performing a 10 CFR 50.59 evaluation of a proposed activity, the evaluator must address the eight criteria in 10 CFR 50.59(c)(2) to determine if prior NRC approval is required. Although the conclusion in each criterion may be simply "yes," "no" or "not applicable," there must be an accompanying explanation providing adequate basis for the conclusion. Consistent with the intent of 10 CFR 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.

The importance of the documentation is emphasized by the fact that experience and engineering knowledge (other than models and experimental data) are often relied upon in determining whether evaluation criteria are met. Thus, the basis for the engineering judgment and the logic used in the determination should be documented to the extent practicable and to a degree commensurate with the safety significance and complexity of the activity. This type of documentation is of particular importance in areas where no established consensus methods are available, such as for software reliability, or the use of commercial-grade hardware and software where full documentation of the design process is not available.

Since an important goal of the 10 CFR 50.59 evaluation is completeness, the items considered by the evaluator must be clearly stated.

Each 10 CFR 50.59 evaluation is unique. Although each applicable criterion must be addressed, the questions and considerations listed throughout this guidance document to assist evaluating the criteria are not requirements for all evaluations. Some evaluations may require that none of these questions be addressed while others will require additional considerations beyond those identified in this guidance.

When preparing 10 CFR 50.59 evaluations, licensees may combine responses to individual criteria or reference other portions of the evaluation.

As discussed in Section 4.2.3, licensees may elect to use screening criteria to limit the number of activities for which written 10 CFR 50.59 evaluations are performed. A documentation basis should be maintained for determinations that the changes meet the screening criteria, i.e., screen out. This documentation does not constitute the record of

changes required by 10 CFR 50.59, and thus is not subject to the recordkeeping requirements of the rule.

Reporting to NRC

A summary of 10 CFR 50.59 evaluations for activities implemented under 10 CFR 50.59 must be provided to NRC. Activities that were screened out, canceled or implemented via license amendment need not be included in this report.