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Subject: NRC Comments on NEI 22-05, Rev. A
Attachments: NRC comments on NEI 22-05 Revision A 4-17-23.docx

Brandon, Mike, and Ben,

Attached are the NRC's comments on NEI 22-05, Revision A. We look forward to discussing these on May 9th.

Mike

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TECHNICAL REPORT

NEI 22-05, Rev A

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Technology Inclusive Risk Informed Change Evaluation (TIRICE)

Guidance for the Evaluation of Changes to Facilities
Utilizing NEI 18-04 and NEI 21-07

Prepared by the Nuclear Energy Institute
March 2023

Revision Table

Revision	Description of Changes	Date Modified	Responsible Person

Acknowledgements

This document was developed by the Nuclear Energy Institute based on content provided by the Technology Inclusive Risk Informed Change Evaluation (TIRICE) team. NEI acknowledges and appreciates the contributions of NEI Advanced Reactor Regulatory Task Force members in reviewing and commenting on the document.

NEI Project Lead: Ben Holtzman

Notice

Foreword

Nuclear Regulatory Commission (NRC) regulation 10 CFR 50.59 establishes criteria for determining if prior NRC approval is required before implementing changes to a reactor licensed under 10 CFR Part 50 or 10 CFR Part 52. Nuclear Energy Institute (NEI) document NEI 96-07 “Guidelines for 10 CFR 50.59 Implementation” provides guidance for applying the 10 CFR 50.59 criteria to currently operating light water reactors (LWRs). This guidance was developed based on the existing change control guidance in NEI 96-07, with appropriate additions and adjustments as provided herein. This guidance provides an alternative change evaluation process for determining if NRC approval is required before implementing certain facility changes to reactors that were licensed using the methodologies in NEI 18-04 “Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development” and NEI 21-07 “Technology Inclusive Guidance for Non-Light Water Reactors - Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology.” Used in conjunction with an enabling license condition and a full, or partial, exemption to 10 CFR 50.59, this guidance allows reactor licensees that have utilized this approach to implement appropriate change control programs for the operation of their reactors.

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List of Abbreviations

AFW	Auxiliary feedwater
AHRS	Auxiliary Heat Removal System
AOO	Anticipated Operational Occurrence
ANS	American Nuclear Society
ANSI	American National Standards Institute
ARCS	Auxiliary Reactivity Control System
ASME	American Society of Mechanical Engineers
BDBE	Beyond Design Basis Event
CDC	Complementary Design Criteria
CFR	Code of Federal Regulations
COL	Combined construction and operating license
CP	Construction Permit
DBA	Design Basis Accident
DBE	Design Basis Event
DBHL	Design Basis Hazard Level
DID	Defense-in-Depth
ECCS	Emergency Core Cooling System
EDG	Emergency Diesel Generator
F-C	Frequency-Consequence
FSAR	Final Safety Analysis Report
IDP	Integrated Decision-Making Process
IDPP	Integrated Decision-Making Process Panel
LBE	Licensing Basis Event
LMP	Licensing Modernization Project
LOCA	Loss of Coolant Accident
LWR	Light water reactor
MFW	Main feedwater
NEI	Nuclear Energy Institute
non-LWR	Non-light water reactor
NRC	Nuclear Regulatory Commission
NSRST	Non-Safety-Related with Special Treatment
NST	Non-Safety-Related with No Special Treatment
NUMARC	Nuclear Management and Resources Council
NUREG	Nuclear Regulatory Commission technical report designation
OL	Operating license
PDC	Principle Design Criteria
PRA	Probabilistic Risk Assessment
QHO	Quantitative Health Objective
RCCS	Reactor Cavity Cooling System
RCP	Reactor Coolant Pump
RCS	Reactor Coolant System
RG	Regulatory Guide
RIPB	Risk-informed and performance-based
RSF	Required Safety Function
SAR	Safety Analysis Report
SER	Safety Evaluation Report
SG	Steam Generator
SR	Safety-Related
SGTR	Steam Generator Tube Rupture
SSCs	Structures, Systems, and Components
TEDE	Total effective dose equivalent
TICAP	Technology Inclusive Content of Application Project
TIRICE	Technology Inclusive Risk Informed Change Evaluation
UFSAR	Updated Final Safety Analysis Report

1 INTRODUCTION

1.1 Background

Commented [A1]: In previous public discussions on TIRICE, the NRC staff expressed the need for a separate guidance document that details the PRA change control process. In the forthcoming May 9th public meeting, the NRC staff would like to understand the status of a document of this subject.

10 CFR 50.59 establishes a process and criteria for determining the regulatory threshold for when the Nuclear Regulatory Commission (NRC) must review and approve a proposed change to the facility before its implementation. 10 CFR 50.59 is not a determination of safety nor of overall acceptability. It defines the boundary between those proposed changes to the facility that can be implemented by the licensee without prior NRC approval and those that must receive NRC review and approval before implementation. Nuclear Energy Institute (NEI) document NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation,"[1] provides guidance for applying the 10 CFR 50.59 criteria to currently operating light water reactors (LWRs). NRC endorsed the use of NEI 96-07 in Regulatory Guide (RG) 1.187 "Guidance for Implementation of 10 CFR 50.59."[2] This guidance was developed based on the existing change control guidance in NEI 96-07, with appropriate additions and adjustments as provided herein as needed to address the risk-informed and performance-based (RIPB) licensing approach utilized in NEI 18-04 Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development"[3] and documented per NEI 21-07, "Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology."[4] A glossary of terms used in this guidance that are common to NEI 18-04 and NEI 21-07 is provided in Appendix A.

The guidance and associated criteria in this document are intended to take the place of 10 CFR 50.59 for certain nuclear power reactors which follow the methodology endorsed in RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors."[5] The guidance and criteria would be invoked by a license condition in combination with an exemption, in whole or in part, to 10 CFR 50.59. This regulatory change guidance is predicated on the same logic as 10 CFR 50.59. Further, this guidance contains a provision analogous to 10 CFR 50.59(c)(4), commonly known as "Applicability Determinations." The aggregate effects on Updated Final Safety Analysis Report (UFSAR) content of this regulatory change process and any other applicable regulation are managed by 10 CFR 50.71(e), as explained in more detail in Section 1.3.

1.1.1 NEI 18-04 "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development"

NEI 18-04 Revision 1 presents a technology-inclusive, RIPB process for selection of Licensing Basis Events (LBEs); safety classification of Structures, Systems, and Components (SSCs) and associated risk-informed special treatments; and determination of Defense-in-Depth (DID) adequacy. The methodology can be applied to various advanced reactor designs, such as, molten salt reactors, high-temperature gas cooled reactors, and a variety of fast reactors at all thermal power capacities. NRC endorsed the methodology in RG 1.233.

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[1] NRC ADAMS Accession Number ML003771157, November 2000
[2] NRC ADAMS Accession Number ML003759710, November 2000
[3] NRC ADAMS Accession Number ML19241A336, August 2019
[4] NRC ADAMS Accession Number ML21343A198, December 2021
[5] NRC ADAMS Accession Number ML20091L698, June 2020

Significant attributes of the methodology that relate to the application of change control are summarized below.

- The NEI 18-04 process includes the selection of a set of Licensing Basis Events (LBEs) that form the basis for defining the safety case. LBEs consist of Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Beyond Design Basis Events (BDBEs), and Design Basis Accidents (DBAs). AOOs, DBEs, and BDBEs are composed of event sequence families identified and evaluated in the PRA.

Commented [A2]: "methodology" and "process" keep being used for 18-04. One word should be chosen for consistency

- The technical adequacy of the PRA is addressed by meeting the technical requirements in the ASME/ANS PRA Standard for Advanced Non-LWRs (ASME/ANS-RA-S-1.4-2021) and PRA Peer Reviews performed against the guidance in NEI 20-09.

- The probabilistic risk assessment (PRA) plays a central role in the identification and categorization of LBEs, identification of the SSC functions responsible for preventing and mitigating LBEs, quantification of their frequencies and consequences, and evaluation of their risk significance.

- Risk significance of individual LBEs is established via a Frequency-Consequence (F-C) Target and the entire set of LBEs using a set of Cumulative Risk Metrics to ensure that the NRC Safety Goal Quantitative Health Objectives (QHOs) are met and that frequent events are maintained within 10 CFR 20 release limits.

- DBAs are defined using a set of deterministic rules that include the identification of Required Safety Functions (RSFs) responsible for keeping the consequences of DBEs within the F-C Target. Safety Related SSCs are selected among those available for all the DBEs to perform each RSF. DBAs are derived from DBEs but rely upon only Safety-Related (SR) SSCs for performance of the RSFs. The DBA consequences are evaluated conservatively, using the same dose criteria applied to light water reactor (LWR) DBAs.

- A set of Required Functional Design Criteria (RFDC) are developed for each RSF that are used to define the Safety Related SSC Design Criteria (SRDC).

- The Licensing Modernization Project (LMP) process includes an evaluation of defense-in-depth (DID) adequacy that is performed via an Integrated Decision Process (IDP) that incorporates deterministic criteria in each risk-informed performance based (RIPB) decision that is made in the development of the safety case.

- The non-safety related SSCs are grouped into two categories. The first category is classified as Non-Safety Related with Special Treatment (NSRST) SSCs when they meet risk significance criteria tied to the risk significance of LBEs or found to provide functions judged by the IDP to be necessary for adequate DID. The remaining non-safety related SSCs are classified as Non-Safety Related with No Special Treatment (NST). Both SR and NSRST SSCs are classified as Safety Significant.

- A key product of the IDP is the selection of reliability and capability targets for all safety significant SSCs that are linked to their functions in the prevention and mitigation of LBEs. These targets inform the IDP selection of programs for monitoring performance of the SSCs against these targets and for other special treatments that may be needed to ensure adequate DID.

NEI 18-04 addresses how to establish an LMP-based affirmative safety case[6]. That safety case becomes part of the licensing basis when NRC issues a 10 CFR Part 50 or Part 52 operating license for the reactor (or certifies the design under Part 52). Nothing described in this guidance affects the substance of that initial LMP-based affirmative safety case. This guidance applies only to activities that take place subsequent to initial licensing, which may involve changes that impact the licensing basis.

Commented [A3]: The term "affirmative safety case" is still used here and in other locations within this draft document, even though DG-1404 states that it should be replaced with "safety analysis" or "licensing basis".

1.1.2 NEI 21-07 "Technology Inclusive Guidance for Non-Light Water Reactors - Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology"

NEI 21-07 Revision 1[7] provides guidance for developing portions of the Safety Analysis Report (SAR) that cover topics relevant to assurance of offsite public safety for reactor applicants that utilize NEI 18-04. The guidance describes eight chapters of a SAR related directly to the implementation of the NEI 18-04 methodology. The chapters do not follow the standard LWR SAR outline as provided in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition." The intent of the guidance is to help ensure completeness of information submitted to NRC while avoiding unnecessary burden on the applicant and rightsizing the content of the application commensurate with the complexity of the design being reviewed.

Significant attributes of the guidance in NEI 21-07 that relate to the application of change control are summarized below.

- The document describes the LMP-based affirmative safety case, which is developed through the application of the NEI 18-04 methodology as endorsed by RG 1.233.
- Applicants are expected to describe the PRA at a summary level and provide key results related to the LMP-based affirmative safety case.
- DBA analyses are documented in the SAR consistent with LWR DBAs.
- AOOs, DBEs, and BDBEs are also documented in the SAR but with less detail than the DBAs.
- The document includes a method for using key elements of the LMP methodology to formulate the Principal Design Criteria (PDC) for the licensing application. The PDCs include the RFDC that are developed for the SR SSCs, a set of Complementary Design Criteria for the NSRST SSC and quality assurance criteria.
- Plant design and plant program information related to the safety case are included in the SAR.

NRC is developing a regulatory guide that will address the acceptability of using NEI 21-07 to develop portions of a SAR for an applicant that has utilized NEI 18-04. NRC also plans to issue guidance for

[6] The term "LMP-based affirmative safety case is defined in Section 1.3 of NEI 21-07. The LMP-based safety case is developed by using the methodology in NEI 18-04 as endorsed in RG 1.233 and documented using the content of a licensing application presented in NEI 21-07.
[7] ADAMS Accession Number ML22060A190, February 2022.

developing the remaining portions of the SAR (i.e., those portions not covered by NEI 21-07) and for other elements of a license application as part of its Advanced Reactor Content of Application Project.[8]

1.2 Application of this Guidance

Sections 3, 4, and 5 provide change control guidance for licensees following NEI 18-04 and NEI 21-07. This guidance must be authorized for use by an enabling license condition and an exemption, in whole or part, to 10 CFR 50.59. This guidance allows licensees to implement appropriate change control programs for the operation of their reactors. This guidance was developed based on the existing change control guidance in NEI 96-07, with appropriate additions and adjustments as provided herein.

It should be noted that some of the examples included in this guidance are LWR-based but remain useful for illustrating a point. In order to put any of the examples into context for a specific design, it is necessary to explain how the change impacts the safety case for that specific design. For example, in some reactors, the Emergency Diesel Generators (EDGs) might be categorized as NST, so changes in diesel generator-start time may have no impact on the LMP safety case.

1.3 Purpose and Scope

The purpose of this guidance is to provide a process to evaluate changes, tests, and experiments, hereafter referred to collectively as activities, for 1.) determining if this process is applicable for evaluating the activity; 2.) determining if an evaluation is required for the activity; and 3.) evaluating the activity to determine whether it crosses the regulatory threshold for requiring prior Nuclear Regulatory Commission (NRC) review and approval.

For currently licensed light water reactors, activities involving changes to plant design and operation and the conduct of new tests and experiments have the potential to affect the frequencies and consequences of accidents, create new accidents, and impact the integrity of fission product barriers. Therefore, these activities are subject to 10 CFR 50.59.

This guidance and associated criteria are intended to take the place of 10 CFR 50.59 and be invoked by a license condition in combination with an exemption, in whole or in part, to 10 CFR 50.59. A discussion of the basis for the evaluation criteria in this guidance is provided in Appendix B of this guidance. Proposed changes, tests, and experiments that satisfy one or more of the criteria specified in this guidance must be reviewed and approved by NRC before implementation. Thus, the criteria identified in this guidance provide a threshold for regulatory review—not the final determination of safety—for proposed activities. Specifically, the process and criteria identified in this guidance establish the conditions under which licensees may make changes to the facility or procedures and conduct tests or experiments without prior NRC approval.

The guidance is applicable only to licensees that implemented NEI 18-04, consistent with RG 1.233, and NEI 21-07. The NEI 18-04 methodology is also referred to as the LMP methodology, and the NEI 21-07 guidance is referred to as the Technology Inclusive Content of Application Project (TICAP). This guidance assumes that these two guidance documents have been used in obtaining a license from the NRC.

Commented [A4]: What about the guidance in DG-1404? A reference to DG-1404 may be made when DG-1404 is published.

[8] Slides from the February 25, 2021, NRC Advanced Reactor Stakeholder Meeting provide information on the ARCAP project and its relationship with the TICAP project. See ML21055A541 pp. 91-105.

The NEI 18-04 methodology relies on information from a PRA, and the NEI 21-07 guidance anticipates that the PRA will conform to American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced non-Light Water Reactor Nuclear Power Plants" (referred to herein as the non-LWR PRA standard). This guidance applies to licensees that follow NEI 18-04, NEI 21-07, and the non-LWR PRA standard. Licensees that deviate from elements of NEI 18-04, NEI 21-07, or the non-LWR PRA standard must justify the application of this guidance to change control. For example, an applicant would need to address differences in its approach for its PRA if it elects not to follow the non-LWR PRA standard.

Commented [A5]: This should also include NEI 20-09. Also for discussion is the omission of RG 1.247

Commented [A6R5]: This paragraph should somewhere state that RG 1.247 endorses RA-S-1.4-2021 and NEI 20-09, Rev. 1.

NEI 21-07 provides guidance for developing reactor SARs for certain licensing pathways, including: 10 CFR Part 52 combined construction and operating license (COL) without reference to a design certification or an early site permit; 10 CFR Part 50 construction permit (CP) followed by an operating license (OL); and 10 CFR Part 52 design certification. This NEI 22-05 guidance does not address change control for certified designs under 10 CFR Part 52. Its scope is limited to reactors that have received an operating license under 10 CFR Part 50 or the 10 CFR Part 52. The use of this guidance for other regulatory approvals would need justification to address any differences or unique considerations.

Commented [A7]: As mentioned in previous public discussions on TIRICE, this document should consider including a discussion on the 50.59-like change process included in the DC rules or what a 50.59-like change process would look like for an LMP-based DC.

The objectives of this guidance are to:

- Establish a clear understanding and process for how the criteria for making changes to the facility, as described in the final safety analysis report (as updated), without prior NRC approval may be met.
- Ensure that the changes that require NRC prior approval are properly identified.
- Minimize burden to the regulator and operators associated with the process of determining whether or not changes require a license amendment.

Change control under 10 CFR 50.59 is only one of many regulations that apply to nuclear power reactors. The regulation addresses the need for prior NRC approval for certain changes to a facility licensed under 10 CFR Part 50 or 10 CFR Part 52 and as supplemented pursuant to 10 CFR 54.21(d) for a license renewal. Other regulatory processes address areas such as operability, reportability, and corrective action are not addressed herein.

1.4 Relationship of this Guidance to Regulatory Requirements and Controls

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

1.4.1 Relationship of this Guidance to Other Processes that Control Licensing Basis Activities

This guidance focuses on the effects of proposed activities on the safety analyses contained in the UFSAR and is a cornerstone of each plant's licensing basis. In addition to control of changes affecting the safety analyses, there are several other complementary processes for controlling activities that affect other aspects of the licensing basis, as described below.

- Amendments to the operating license (including the technical specifications) are sought and obtained under 10 CFR 50.90.
- 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(a), (p), and (q), respectively), the more specific regulation applies.
- Changes that require an exemption from a regulation are processed in accordance with 10 CFR 50.12.
- Guidance for controlling changes to licensee commitments is provided by NEI 99-04, "Guideline for Managing NRC Commitment Changes."[9]
- Where a licensee possesses a license condition that specifically permits changes to the NRC-approved fire protection program (i.e., has received the standard fire protection license condition contained in NRC Generic Letter 86-10), subsequent changes to the fire protection program would be controlled under the license condition and not this guidance.
- Maintenance activities, including associated temporary changes, can be subject to the technical specifications (when applicable) and are assessed and managed in accordance with the Maintenance Rule, 10 CFR 50.65; screening and evaluation under this guidance are not required.

Commented [A8]: Does this only apply to the emergency plan, or also changes that may impact the analysis that results in the EPZ sizing, per the new EP rule 50.160?

NEI may want to consider adding a section in this document regarding EPZ sizing.

Commented [A9]: This is not the full scope of applicable applications, as described in the comment in Section 4.1.5 below.

Together with the process provided in this guidance, 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 this guidance in relation to other processes, including circumstances under which different processes (e.g., 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, licensees may also choose to commit to control changes to other licensing basis information using the process provided in this guidance. This may be in accordance with a requirement of the license or commitment to NRC. The technical specifications bases are an example of documentation that may be outside the UFSAR, but that could be controlled via application of the process provided in this guidance.

1.4.2 Relationship of this Guidance to 10 CFR Part 50, Appendix B

In NEI 21-07, quality assurance is included as a part of the Principal Design Criteria (PDC) consistent with 10 CFR 50.54(a)(1). Prior to the operating license, 10 CFR Part 50, Appendix B, assures that the facility design and construction meet applicable requirements, codes, and standards in accordance with the safety classification SSCs. Appendix B design control provisions ensure that all changes continue to meet applicable design and quality requirements. The design and licensing bases evolve in accordance with Appendix B requirements up to the time that an operating license is received, and this guidance is not

[9] NRC Regulatory Issue Summary 00-017, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," documents the NRC position that NEI 99-04 describes an acceptable way for licensees to control regulatory commitments. ADAMS Accession Number ML003741774).

applicable until after that time. Both Appendix B and this guidance, when invoked by a license condition in combination with an exemption to 10 CFR 50.59, apply following receipt of an OL or COL.

Appendix B also addresses corrective action. The application of this guidance to compensatory actions that address degraded and nonconforming conditions is described in Section 4.4.

1.4.3 Relationship of this Guidance to the UFSAR

This guidance delineates a 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 this guidance is provided by RG 1.181, which endorses NEI 98-03 Revision 1. ~~Reactors~~ Applicants utilizing NEI 18-04 and NEI 21-07 should substitute the 10 CFR 50.59 controls described in NEI 98-03, Revision 1 with the process described in this guidance.

1.4.4 Relationship of this Guidance to 10 CFR 50.2 Design Bases

This guidance controls changes to both 10 CFR 50.2 design bases and supporting design information contained in the UFSAR. In support of implementation, Section 4.3.9 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 Criterion (i) (see Section 4.3.9). Additional guidance for identifying 10 CFR 50.2 design bases is provided in NEI 97-04, Appendix B, "Guidance and Examples for Identifying 10 CFR 50.2 Design Bases."

The controls of the methodology used in establishing design bases or in the safety analyses are implemented with Section 4.3.9 of this guidance. As described in Section 2.0, the controls established in 10 CFR 50.59(c)(2)(vii)) of design basis limits for fission product barriers are implemented through other criteria, specifically Criteria (f) and (g) of Section 4.3.

1.5 Activity Evaluation Process Summary

After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the activity evaluation process is applied to determine if a license amendment is required prior to implementation. The activity evaluation process involves some or all of the following basic steps, as depicted in Figure 1:

- Applicability and Screening: Determine if a proposed activity evaluation is required.
- Evaluation: Apply the nine evaluation criteria of Section 4.3.1 through 4.3.9 (Criteria (a) - (i)) to determine if a license amendment must be obtained from NRC.
- Documentation and reporting: Document and report to NRC activities implemented under the activity evaluation process.

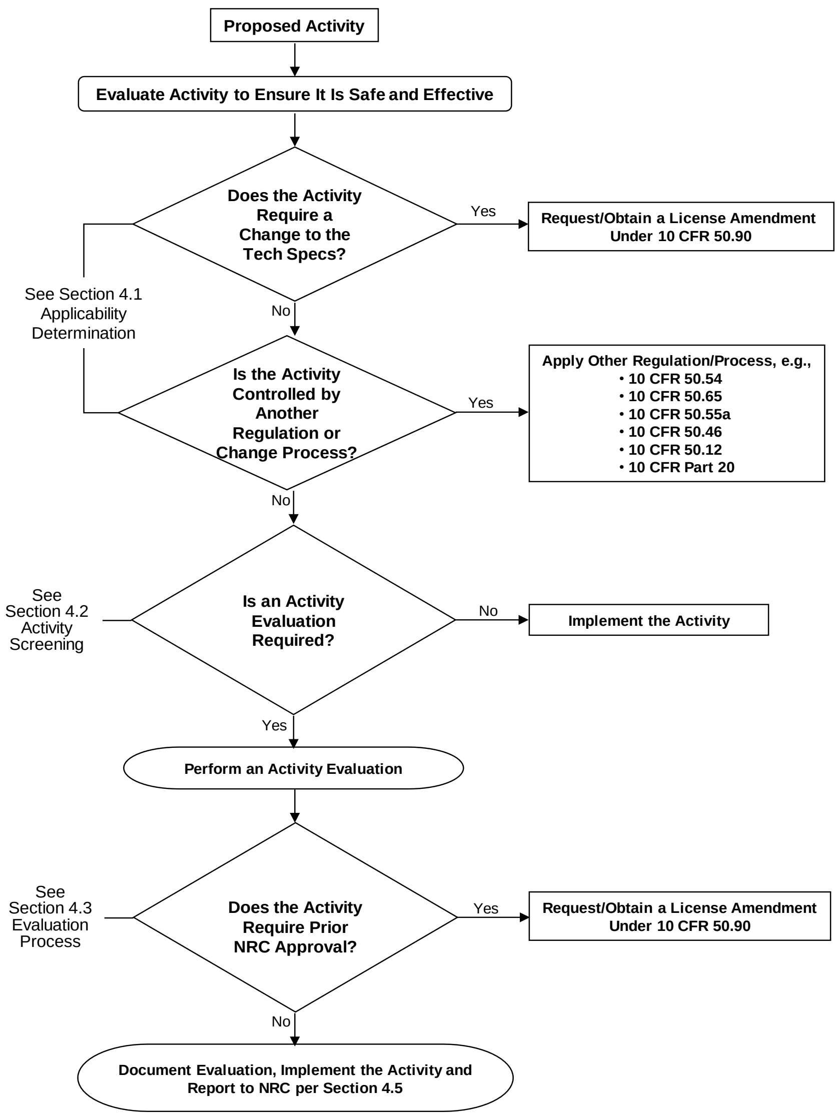

Figure 1. Activity Screening and Evaluation Process

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

1.6 Content of this Guidance

NRC has established requirements for nuclear plant SSCs to provide reasonable assurance of adequate protection of public health and safety. Many of these requirements, and descriptions of how they are met, are documented in the UFSAR. When followed, the process delineated in this guidance allows a licensee to determine if NRC approval is required before making 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 activity screenings and evaluations, an understanding of the design and licensing basis of the plant and of the specific requirements of the regulations are necessary. Individuals performing activity screenings and evaluations should also understand the concepts discussed in this guidance.

In Section 2, the approach for determining the adequacy of DID is discussed as background for applying the guidance.

Section 3 presents definitions and a discussion of key terms used in this guidance. This section includes guidance on the applicability requirements for the use of this guidance, the screening process for determining when an activity evaluation must be performed and the evaluation criteria for determining if prior NRC approval is required. Section 4 discusses the application of the criteria presented in Sections 4.3.1 through 4.3.9 to the process of changing the plant or procedures and the conduct of tests or experiments. Examples are provided to reinforce the guidance. Guidance is also provided on addressing degraded and nonconforming conditions and on dispositioning activity evaluations.

Section 5 provides guidance on documenting activity evaluations and reporting to NRC.

2 DEFENSE IN DEPTH PHILOSOPHY

DID,[10] the use of multiple layers of defense for protecting the public from potential harm from nuclear reactor operation, is an important part of the design, licensing, and operation of nuclear power plants. NEI 18-04 provides a systematic means for establishing DID adequacy and creating a baseline of information in the design records and the UFSAR as described in NEI 21-07 Revision 1. The baseline of information serves as the foundation of 10 CFR 50.59 change evaluations that are relevant to maintaining DID adequacy.

The DID adequacy evaluation summarized in the UFSAR is structured around three elements: Plant Capability DID, Programmatic Capability DID, and the integrated DID evaluation. The licensing baseline information for these elements is distributed across multiple chapters of a SAR based on the methodology endorsed in RG 1.233. Changes to DID adequacy relevant to the activity evaluation process are discussed in this guidance in Section 4.3.8. This guidance utilizes the layers of defense framework as described in NEI 18-04, including the explicit considerations of individual changes in LBE performance margins, changes in SSC safety significance, changes in uncertainties, and integrated risk topics that aggregate impacts across LBEs. Thresholds for NRC review of proposed changes in Section 4.3 are

[10] A more detailed definition of DID is provided in the NRC glossary provided in Appendix A to NEI 21-07.

adapted to the LMP terminology and the RIPB integrated decision-making methodology endorsed by RG 1.233 such that adequate DID remains assured when the attributes for DID adequacy described in NEI 18-04 Chapter 5 are confirmed for the change. These thresholds enable focused evaluations of DID to determine when a license amendment request is required.

3 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

Section	Definitions and Terms
3.1	Activity Evaluation
3.2	Design Function
3.3	Change
3.4	Design Bases (Design Basis)
3.5	Facility as Described in the FSAR (as updated)
3.6	Final Safety Analysis Report (as updated)
3.7	Input Parameters
3.8	Malfunction of an SSC Important to Safety
3.9	Methods of Evaluation
3.10	Departure from a Method of Evaluation Described in the FSAR (as updated)
3.11	Procedures as Described in the FSAR (as updated)
3.12	Safety Analyses
3.13	Activity Screening
3.14	Tests or Experiments Not Described in the FSAR (as updated)

3.1 Activity Evaluation

Definition

An activity evaluation is the documented evaluation against the nine criteria in Sections 4.3.1 through 4.3.9 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 activity evaluation process. The definitions of Screening and Activity Evaluation 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 nine criteria in Sections 4.3.1 through 4.3.9. The screening process is discussed in Section 4.2. Section 4.3 provides guidance for performing activity evaluations.

The phrase “change made under this guidance” (or equivalent) refers to changes subject to this guidance (see Section 4.1) that either screened out of the activity evaluation process or did not require prior NRC approval based on the results of an activity evaluation. Similarly, the phrases “this guidance applies [to an activity]” or “[an activity] is subject to an activity screening and evaluation” mean that screening and, if necessary, evaluation are required for the activity. The “evaluation process” includes:

- Screening
- Evaluation
- Documentation
- Reporting to NRC of activities subject to the application of this guidance

3.2 Design Function

Definition

Design functions are UFSAR-described design functions and other SSC functions described in the UFSAR that support or impact design 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, and equipment qualification. For reactors with an LMP-based affirmative safety case, “design functions” are the RSFs, risk-significant functions per NEI 21-07 SAR Section 5.5.1, and safety functions required for adequate DID per NEI 21-07 SAR Section 5.5.2. Design functions that are related to the LMP-based affirmative safety case include the safety significant functions performed by SSCs classified as SR and NSRST per NEI 21-07 SAR Sections 6 and 7, respectively.

Discussion

The phrase “support or impact design functions” refers both to those SSCs needed to support design functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design functions (for instance, control systems and physical arrangements).

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 to and removals from 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 non-reliance on a system to meet a requirement) to the facility or procedures.

The definitions of “change,” “facility” (see Sections 3.3 and 3.5), and “procedures” (see Section 3.11) make clear that this guidance applies to changes to underlying analytical bases for the facility design and operation as well as for changes to SSCs and procedures. Thus, this activity evaluation process 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:

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

"Evaluation that demonstrates that intended functions will be accomplished" means the method(s) used to perform the evaluation (as discussed in Section 3.9). Example: a thermodynamic calculation that demonstrates an auxiliary cooling system has sufficient heat removal capacity for responding to a DBA.

See Section 4.2 for a discussion of adverse effects and their role in the overall screening process.

Temporary changes to the facility or procedures, such as installation of terminal jumpers, 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 plant activities and are subject to this activity evaluation process as follows:

- An activity evaluation 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 are subject to an activity evaluation 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.

Risk impacts of temporary changes associated with maintenance activities (i.e., temporary alterations) should be assessed and managed in accordance with 10 CFR 50.65(a)(4) and associated guidance, as discussed in Section 4.1.2. Performing an activity evaluation for such activities is not required provided that temporary alterations are not in effect longer than 90 days at power, and affected SSCs are restored to their normal, as-designed condition at the conclusion of the maintenance activity.

3.4 Design Bases (Design Basis)

Definition

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 design basis 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 are provided in Appendix B of NEI 97-04, "Design Bases Program Guidelines," Revision 1, November 2000.

3.5 Facility as Described in the FSAR (As Updated)

Definition

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

- The SSCs that are described in the FSAR (as updated),
- The design and performance requirements for such SSCs described in the FSAR (as updated), and
- The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs, which demonstrate that their intended function(s) will be accomplished.

Discussion

The scope of information that is the focus of activity screenings and evaluations performed using this guidance, is the information presented in the original FSAR to satisfy the requirements of 10 CFR 50.34(b), as updated per the requirements of 10 CFR 50.71(e) and as supplemented pursuant to 10 CFR 54.21(d) for renewed licenses, as applicable. The definition of "facility as described in the FSAR (as updated)" follows from the requirement of 10 CFR 50.34(b) that the 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."

An activity screening of facility changes is discussed in Section 4.2.1.1.

3.6 Final Safety Analysis Report (As Updated)

Definition

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) or 10 CFR 50.71(f) or as supplemented pursuant to 10 CFR 54.21(d) for renewed licenses, as applicable. For Part 52 COLs, the content of the Final Safety Analysis Report should be in accordance with the requirements specified in 10 CFR 52.79, "Contents of applications; technical information in final safety analysis report."

Discussion

As used throughout this guidance, UFSAR is synonymous with "FSAR (as updated)." The scope of the UFSAR includes its text, tables, and diagrams, 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 this guidance and associated license condition.

Use of this guidance for activity screening and evaluation is not required for UFSAR information that is subject to other specific change control regulations. For example, licensee quality assurance programs, emergency plans and security plans are controlled by 10 CFR 50.54(a), (p) and (q), respectively.

The "FSAR (as updated)," for purposes of this guidance, also includes UFSAR update pages approved by the licensee for incorporation in the UFSAR since the last 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 approval for incorporation in the next required update should be considered as part of the UFSAR for purposes of activity screenings and evaluations, as appropriate. Appropriate configuration management mechanisms should be in place to identify and assess interactions between concurrent changes affecting the same SSCs or the same portion of the UFSAR.

Guidance on the required content of UFSAR updates is provided in RG 1.181 and NEI 98-03, Revision 1, "Guidelines for Updating FSARs," June 1999.

3.7 Input Parameters

Definition

Input parameters are those values derived directly from the physical characteristics of SSC or processes in the plant, including flow rates, temperatures, pressures, dimensions or measurements (e.g., volume, weight, and size), 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 3.9) are evaluated under Criterion (i) in Section 4.3.9, whereas changes to input parameters described in the FSAR are considered changes to the facility that would be evaluated under the other eight criteria in Sections 4.3.1 through 4.3.8, but not under Criterion (i).

If a methodology permits the licensee to establish the value of an input parameter on the basis of plant-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 4.3.9 provides guidance and examples to describe the specific elements of evaluation methodology that would require evaluation under Criterion (i) and to clearly distinguish these from specific types of input parameters that are controlled by the other eight criteria of Sections 4.3.1 through 4.3.8.

3.8 Malfunction of Safety-Significant SSCs

Definition

Malfunction of SR or NSRST SSCs means the failure of SSCs to perform their intended design functions as described in the UFSAR.

Discussion

For the purpose of evaluating changes to a reactor with a safety analysis based on the methodology endorsed in RG 1.233, safety-significant SSCs are defined to be the population of SSCs that are either SR or NSRST SSCs, as defined by NEI 18-04.

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

3.9 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 an activity evaluation include changes to elements of the larger, existing methods described in the UFSAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies. That is, the larger method of evaluation is subject to this process if it satisfies definition of a method of evaluation, which includes the requirement for UFSAR inclusion, however, the smaller pieces, or elements, of that method do not have a stand-alone requirement for UFSAR inclusion.

Examples

- Plant transient models
- Fuel performance models
- Radionuclide inventory models

- Mechanistic source term models
- Vendor-specific thermal design procedure
- Dose conversion factors and assumed source term(s) (e.g., International Commission on Radiological Protection factors)
- Data correlations (e.g., heat transfer correlations)
- Means of data reduction (e.g., ASME III and Appendix G methods for evaluating reactor vessel embrittlement specimens)
- Physical constants or coefficients (e.g., heat transfer coefficients)
- Mathematical models (e.g., decay heat models)
- Specific limitations of a computer program
- Specified factors to account for uncertainty in measurements or data
- Statistical analysis of results

Methods of evaluation described in the UFSAR subject to Section 4.3.9 Criterion (i) are:

- Methods of evaluation used in UFSAR safety analyses, to demonstrate that consequences of DBAs do not exceed 10 CFR 100 or 10 CFR 50.34, regulatory dose criteria. Such analyses are typically presented in UFSAR Chapters 2 and/or 3 per NEI 21-07.
- Methods of evaluation used in supporting UFSAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the plant is required to withstand, including natural phenomena, environmental conditions, dynamic effects, as reflected in the definition and evaluation of the DBHLs.

3.10 Departure from a Method of Evaluation Described in the FSAR (As Updated)

Definition

Departure from a method of evaluation described in the FSAR (as updated) means (i) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Discussion

The definition of “departure” provides licensees with flexibility to make changes in methods of evaluation that are “conservative” or essentially the same with respect to demonstrating that SSCs can perform their intended design functions. See also the definition and discussion of “Methods of

Evaluation" in Section 3.9. Guidance for evaluating changes in methods of evaluation under Criterion (i) is provided in Section 4.3.9.

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 this guidance. 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 containment peak pressure analysis from 45 psig to 48 psig (with a design basis limit of 50 psig) would be considered a conservative change for purposes of an activity evaluation under Criterion (i) provided in Section 4.3.9. 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 containment peak pressure from 45 psig to 40 psig, this would be nonconservative. This is because the change would result in more margin being available (to the design basis limit of 50 psig) for a licensee to make more significant future changes to the physical plant 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 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 NRC for the intended application. A new method is "approved by 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 4.3.9.

3.11 Procedures as Described in the FSAR (As Updated)

Definition

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

Discussion

The scope of information that is the focus of the application of the activity screening and evaluation process is the information presented in the original FSAR to satisfy the requirements of 10 CFR 50.34(b), as updated per the requirements of 10 CFR 50.71(e) and as supplemented pursuant to 10 CFR 54.21(d) for renewed licenses, as applicable.

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

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 the activity screening and evaluation process. Sections 4.1.2 and 4.1.4 identify examples of procedures that are not subject to an activity screening and evaluation.

Activity screening of procedure changes is discussed in Section 4.2.1.2.

3.12 Safety Analyses

Definition

Safety analyses are performed pursuant to NRC requirements to demonstrate that doses to the public following DBAs meet the acceptance criteria in 10 CFR 50.34 and to demonstrate that SSC design functions will be accomplished as credited in the safety analyses, including consideration of DBHLs. 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 DBA analyses typically presented in Chapter 3 of the UFSAR as defined in NEI 21-07.

Discussion

Safety analyses are those analyses or evaluations that demonstrate that acceptance criteria for the facility's capability to withstand or respond to design basis accidents are met. Safety analyses include DBA analyses and the deterministic analyses that are done to ensure the SR SSCs are able to perform their RSFs following a DBHL. Examples of the latter include:

- 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 turbine missiles, fires, floods, earthquakes

Note that although fire is an event that a plant is required to withstand and for which it has been analyzed accordingly in the UFSAR (by reference to the Fire Hazards Analysis for some licensees), changes to the fire protection program and associated analyses are (for most licensees) governed by licensee requirements other than this activity evaluation process, as discussed in Section 4.1.5.

3.13 Activity Screening

Definition

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

Discussion

Screening is that part of the process that determines whether an activity 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 screening process. Activities that do not meet these criteria are said to “screen out” from further review under an activity evaluation, i.e., they may be implemented without an activity 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 an activity evaluation.

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

3.14 Tests or Experiments Not Described in the FSAR (As Updated)

Definition

Tests or experiments not described in the final safety analysis report (as updated) means any activity where any 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

Activity screening and evaluation 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.

Maintenance-related testing is assessed and managed under 10 CFR 50.65(a)(4), as discussed in Section 4.1.2. Activity 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 activity screening and evaluation include (1) most core physics testing, (2) room heat-up testing to validate a design/analysis input, and (3) testing to help determine which of two redesign alternatives to pursue.

4 IMPLEMENTATION GUIDANCE

Licensees may perform applicability determination and adverse impact screening activities to determine if activity evaluations are required as described in Sections 4.1 and 4.2, or equivalent manner.

4.1 Applicability

This guidance applies to licensees that follow (i) NEI 18-04 as endorsed by RG 1.233, (ii) NEI 21-07, and (iii) the non-LWR PRA standard. Licensees that deviate from elements of NEI 18-04, NEI 21-07, or the non-LWR PRA standard must justify the application of this guidance. NEI 21-07 also provides guidance for developing reactor SARs for certain licensing pathways: 10 CFR Part 52 COL without reference to a design certification or an early site permit; 10 CFR Part 50 CP followed by an OL; and 10 CFR Part 52 design certification. This guidance does not address the design certification pathway, so its applicability is limited to the 10 CFR Part 52 COL (no design certification or early site permit) and the 10 CFR Part 50 CP/OL.

Commented [A10]: Endorsement by DG-1404 should be noted.

This guidance applies to each holder of a license authorizing operation of a commercial nuclear reactor, that has a license condition that invokes the use of this guidance and an approved exemption, in whole or in part, from 10 CFR 50.59. This guidance also covers the holder of a license authorizing operation of a nuclear power reactor that has submitted a certification of permanent cessation of operations required under 10 CFR 50.82(a)(1) or a reactor licensee whose license has been amended to allow possession but not operation of the facility.

4.1.1 Applicability to Licensee Activities

The use of this guidance is required and applicable to tests or experiments not described in the UFSAR 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:

- 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 activity screening and evaluation.

- To reduce duplication of effort, changes to the facility or procedures that are controlled by other more specific requirements and criteria established by regulation are specifically excluded from the scope of activities that are required to be evaluated using this guidance. For example, 10 CFR 50.54 specifies criteria and reporting requirements for changing quality assurance, physical security, and emergency plans.

In addition to 50.90 and 50.54(a), (p) and (q), the following include change control requirements that meet the intent of applicable regulations that establish more specific criteria for accomplishing such changes and must take precedence over the use of this guidance for control of specific changes:

- 10 CFR 50.65 (Maintenance Rule) (See additional discussion in Section 4.1.2.)
- 10 CFR Part 50, Appendix B, (Quality Assurance Criteria) (See additional discussion in Section 4.1.4.)
- Standard Fire Protection license condition (if applicable) (See additional discussion in Section 4.1.5.)
- 10 CFR 50.55a (Codes and Standards)
- 10 CFR 50.12 (Specific Exemptions)
- 10 CFR Part 20 (Standards for Radiation Protection)

Changes to PRA methods are outside the scope of this guidance and are controlled by the non-LWR PRA standard with one exception. In some cases, methods for evaluation of plant response to events and estimation of source terms may be common to the PRA and the DBA analysis. In this case, changes to the methods are covered under the DBA criterion. For instances where a change is made to a PRA method of evaluation that demonstrates that DBA limits are met, the change must be evaluated as a change to a method of evaluation in accordance with Section 4.3.9 Criterion (i).

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 activity screening and evaluation is not required. UFSAR changes should be identified to 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 this screening and evaluation process 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. The activity screening and evaluation should be applied to the balance of the modification, including impacts on required operator actions.

4.1.2 Maintenance Activities

Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities are not subject to this screening and evaluation process but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications.

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 installation of terminal jumpers, lifting leads, placing temporary lead shielding on pipes and equipment, removal of barriers, and use of temporary blocks, bypasses, scaffolding, and supports.

Licensees should ensure operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NUMARC 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."[11]

In addition to assessments required by 10 CFR 50.65(a)(4), this screening and evaluation process should also be applied in the following cases:

- A temporary alteration in support of the maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, this screening and evaluation process would be applied to the temporary alteration prior to implementation in the same manner as a permanent change.
- The plant 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, this screening and evaluation process would be applied to the permanent change to the plant.

Installation and post-modification testing of approved facility changes are indistinguishable, in terms of their risk impact on the plant, from maintenance activities that restore SSCs to their as-designed condition. As such, installation and testing of approved facility changes are maintenance activities that must be assessed and managed in accordance with 10 CFR 50.65(a)(4). This screening and evaluation process will address the effect, following implementation, of proposed facility changes to determine if prior NRC approval is required; the risk impact of actually implementing the change will be assessed and managed per 10 CFR 50.65(a)(4).

If a temporary alteration necessary to install a facility change is expected to be in effect longer than 90 days at power, the required screening and evaluation review of the temporary alteration may be performed as part of the screening and evaluation process review for the facility change.

This screening and evaluation process 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 applicable 10 CFR Part 50, Appendix B criteria and licensee procedures. Licensee processes should ensure that changes to plant configurations called for by procedures are consistent with the technical specifications. This screening and evaluation process 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.

Certain maintenance procedures, including those for technical specification required surveillance and inspection, may contain important information concerning SSC design, performance, operation, or

[11] Regulatory Guide 1.182, issued June 1, 2000, endorses the industry guidance on 10 CFR 50.65(a)(4) provided in Section 11 of NUMARC 93-01, Revision 3, August 2000.

control. Examples include acceptance criteria for valve stroke times or other SSC function, torque values, and types of materials (gaskets, elastomers, lubricants, etc.). Licensee design and/or configuration control processes should ensure that this screening and evaluation process 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).

4.1.3 UFSAR Modifications

Modifications to the UFSAR that are not the result of activities performed under this screening and evaluation process are not subject to control under this guidance. Such modifications include reformatting and simplification of UFSAR information and removal of obsolete or redundant information and excessive detail.

Similarly, this screening and evaluation process 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 controlled under 10 CFR Part 50, Appendix B, programs and are not subject to control under this screening and evaluation process. These include, but are not limited to, procedures in the following areas:

- Operations and work process procedures such as control of equipment status (tag outs)
- Shift staffing and personnel qualifications
- Changes to position titles
- Administrative controls for creating or modifying procedures
- Training programs
- On-site/off-site safety review committees

- Plant modification process
- Calculation process

Example 1

The UFSAR states that the shift supervisor will authorize all radioactive liquid releases. This is an administrative requirement on the conduct of facility operations. Thus, assigning this function to another individual would not be subject to this screening and evaluation process but would be done in accordance with 10 CFR Part 50, Appendix B criteria and licensee procedures. The licensee would be required to reflect the change in the next required update of the UFSAR per 10 CFR 50.71(e).

4.1.5 Changes to Approved Fire Protection Programs

Most nuclear power plant licenses contain a section on fire protection. Originally, these fire protection license conditions varied widely in scope and content. These variations created problems for licensees and for NRC inspectors in identifying the operative and enforceable fire protection requirements at each facility.

To resolve these problems, NRC promulgated guidance in Generic Letter 86-10, "Implementation of Fire Protection Requirements," for licensees to:

- Incorporate the fire protection program and major commitments into the FSAR for the facility, and
- Amend the operating license to substitute a standard fire protection license condition for the previous license condition(s) regarding fire protection.

Under the standard fire protection license condition, licensees may:

1. Make changes to their approved fire protection programs without prior NRC approval provided that the changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire, and
2. Alter specific features of the approved program provided such changes do not otherwise involve a change to the license or technical specifications or require an exemption.

Adoption of the standard fire protection license condition provided a more consistent approach to evaluating changes to the facility, including those associated with the fire protection program. Originally, changes to the fire protection program under the fire protection license condition were also subject to this screening and evaluation process; however, this created confusion as to which regulatory requirement governed fire protection program changes.

It is important to note that when applicable regulations establish more specific criteria for controlling certain changes, this screening and evaluation process does not also apply. Consistent with this intent, the standard fire protection license condition establishes specific criteria for control of fire protection changes and falls outside the scope of Section 4.3. Thus, applying this screening and evaluation process to fire protection program changes is not required.

Commented [A11]: This section is written to sound like all applicants within the scope of this guidance will have the standard fire protection license condition. It doesn't mention the possibility of the implementation of components of NFPA 805 in accordance with the draft ARCAP Fire Protection (Operations) ISG. Additionally, applicants may use 50.59, or another proposed process and associated license condition. Suggest revising this section to account for the scope of applicants that will be using this guidance.

Commented [A12]: "this screening and evaluation process" seems to refer to the 50.59 process and not TIRICE. Not sure if a historical statement like this is necessary.

Changes to the fire protection program should be evaluated for impacts on other design functions, and this screening and evaluation process should be applied to the non-fire protection related effects of the change, if any.

Consistent with current practice, determinations made under the standard fire protection license condition should be based on a written evaluation that remains available for NRC review for the life of the plant. These written evaluations should provide the basis for the licensee's conclusion that changes to the fire protection program do not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire. An evaluation performed in accordance with the license condition should include an assessment of the impact of the change on the existing fire hazards analysis for the area, as is current practice. The assessment should address the effects on combustible loading and distribution and should consider whether circuits or components, including associated circuits, for a train of equipment needed for safe shutdown could be affected, or whether a new element could be introduced into the area.

Under the standard license condition, approved fire protection program documents (e.g., fire hazards analysis) are incorporated in the UFSAR, and as such, changes to this information are subject to 10 CFR 50.71(e) reporting requirements.

4.1.6 New Information

New Information is routinely acquired as a natural part of the design, operation, and maintenance of nuclear facilities. New information for new reactor designs is expected to be identified as a result of the compilation of the knowledge from operating experience, experiments, and testing.

It is recognized that new information could impact the licensing basis and would be subject to other regulatory controls (e.g., 10 CFR Part 50 Appendix B, 10 CFR 50.150 and 10 CFR 50.155). In that regard, new information may lead to changes that are subject to an activity screening and potentially evaluation (e.g., a change to a method of evaluation due to an evolution of the understanding of a particular physical phenomenon, a plant modification to regain margin loss due to the availability of new information, and a plant modification to take advantage of margin gained by the availability of new information). However, new information, in and of itself, is not subject to review using this guidance.

The most commonly encountered approach for dealing with new information is expected to be corrective action pursuant to 10 CFR Part 50 Appendix B. If corrective action is taken to resolve this condition, then this guidance would not be applicable.

4.2 Activity Screening

Once it has been determined that this activity screening and evaluation process is applicable to a proposed activity, screening is performed to determine if the activity should be evaluated against the nine evaluation criteria in Sections 4.3.1 through 4.3.9.

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 this activity screening and evaluation. Activities that are screened out from further evaluation under this activity screening and evaluation 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; (2) they are performed collectively to address a design or operational issue; or (3) one or more of the elements are planned to ensure that the overall change preserves DID adequacy (see Criterion (h) in Section 4.3 of this document). To state it another way, it is allowable to include an additional element or elements in the screening and evaluation of a proposed change if that additional element or elements are being performed to address what might otherwise be an undesirable result for Criterion (h).

An example of the first criterion is a pump upgrade modification may also necessitate a change to a support system, such as cooling water. An example of the second criterion is reinforcing structural members in support of the installation of a heavier component. An example of the third criterion is a change in special treatment that is linked to preserving a single safety function identified in order to maintain adequate DID.

If concurrent changes are being made that are not linked, each must be screened separately and independently of each other. If, however, there are changes to the DID baseline that are made to offset any adverse impacts of a change to DID adequacy through applying the change process in NEI 18-04 Sections 5.9.6 and 5.9.7, such concurrent changes are considered linked.

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

Specific guidance for applying this activity screening and evaluation process 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 USFAR?

To determine whether 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. For the LMP-based affirmative safety case, design functions should be documented in Chapter 5 of the SAR per NEI 21-07—a RSF in Section 5.2, a risk-significant function in Section 5.5.1, and a safety function required for adequate DID in Section 5.5.2. 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 or capability of an SSC design function, including either functions whose failure would initiate a transient/ LBE or functions that are relied upon for mitigation?

- Does the activity reduce 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 ability of the SSC to withstand design basis hazards (e.g., seismic) or environmental qualification of the SSC?

- Does the activity adversely affect other units at a multiple unit site?

- 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, this guidance 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, this activity evaluation process should be performed. NEI 98-03 provides guidance for determining whether additions to the facility and procedures should be reflected in the UFSAR per 10 CFR 50.71(e).

Consistent with historical practice, changes affecting SSCs or functions not described in the UFSAR must be screened for their effects (so-called “indirect effects”) on UFSAR-described design functions. This activity screening and evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.

4.2.1.1 Screening for Adverse Effects

An activity screening is required for changes that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished (i.e., “adverse changes”). Changes that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new LBEs or otherwise meet the evaluation criteria delineated in Sections 4.3.1 through 4.3.9.

Per the definition of "design function," 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 LBE would be considered to adversely affect a design function and would screen in. In this regard, changes that would relax the manner in which code requirements are met for certain SSCs should be screened for adverse effects on design function. Similarly, changes that would introduce a new type of LBE or malfunction would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and an activity screening and evaluation performed in accordance with this guidance. 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 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 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 activity screenings, and evaluations, which focus on whether changes meet any of the nine criteria in Sections 4.3.1 through 4.3.9. Technical/engineering information (e.g., design evaluations) 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. Alternatively, nonconservative changes to inputs/assumptions in design analysis or calculations used to demonstrate compliance with safety criteria should be screened in. Furthermore, i~~I~~f 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 RSFs and design requirements are met, the change is considered to be adverse and must be screened in. The revised safety analyses may be used in support of the required evaluation of such changes.

Commented [A13]: In Section 4.2.1.5 below, Example 3 describes a change to a steamline break mass and energy release calculations that would screen out as a methodology change because the proposed activity involved a change to an input parameter (% power) and not a methodology change. This discussion goes on to state that 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 Section 4.3.9 Criteria (a) through (h). However, it is not clear in Section 4.2.1.1 that such a change would be considered a change in the facility.

Suggest adding text to this section that describes situations where nonconservative charges to inputs/assumptions to analysis or calculations should be screened in.

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 main control room isolation dampers reduces the calculated dose to operators, 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 main control room, not to demonstrate that applicable dose limits continue to be met. A change that would adversely affect the design function of the dampers (isolation of the main control room) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that applicable dose limits continue to be met. The revised analyses would be used in support of the change evaluation to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between activity screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the Emergency Core Cooling System (ECCS) analyses is for the diesel to start within 12 seconds. This change would screen out because it is apparent that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's start time to 13 seconds would screen in because the change adversely effects the design function (to start in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all RSFs supported by the diesel (core heat removal, containment isolation, containment cooling, etc.) are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of RSFs and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of activity screening reviews. Thus, an activity evaluation would be required. The revised safety analyses would be used in support of the activity evaluation to determine whether any of the 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 Sections 4.2.1.2 and 4.2.1.3, respectively.

4.2.1.2 Screening of Changes to the Facility as Described in the USFAR

Screening to determine whether a change 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.

SSCs that are relied upon to carry out design functions are documented in the NEI 21-07 SAR in Section 5.4 (SR SSCs) and Section 5.5 (NSRST SSCs). However, as addressed in Section 4.2.1.1, changes to other SSCs (i.e., NST SSCs) should be considered for potential adverse effects on any SR or NSRST SSC design function, method of performing or controlling the design function, or an evaluation demonstrating that the intended design functions will be accomplished.

In accordance with NEI 18-04~~,~~ and NEI 21-07, reliability and capability targets are documented in ~~NEI 21-07~~ SAR Sections 6.2 and 7.1 for SR and NSRST SSCs, respectively. If a proposed change to the facility results in a safety-significant SSC being unable to meet its reliability or capability target, then the change would screen in, and a full evaluation in accordance with Section 4.3 would be required.

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 an activity change 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 an activity evaluation is required.

Another important consideration is that a change to NST 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 non-safety-related heat exchanger could compromise the cooling system's ability to cool safety-related equipment.

Seismic qualification, missile protection, flooding protection, fire protection, environmental qualification, high energy line break and masonry block walls are some of the areas where changes to NST SSCs, whether or not described in the UFSAR, can affect the UFSAR-described design function of safety-significant 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 equivalence assessments, e.g., consideration of performance/operating characteristics and other factors, may thus form the basis for screening determinations that no activity change 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 an activity evaluation. Changes that have positive or no effect on design functions may generally be screened out.

The following examples illustrate the screening process as applied to proposed facility changes.

Example 1

A licensee proposes to replace a relay in the overspeed trip circuit of an emergency diesel generator with a nonequivalent relay. The relay is not described in the UFSAR, but supports the design functions of the overspeed trip circuit and the emergency diesel generator which are described in the UFSAR. Based on engineering/technical information supporting the change, the licensee determines that replacing the relay would adversely affect the design function of the overspeed trip circuit and therefore requires an activity change evaluation. Conversely, if the licensee were to conclude that the change would not adversely affect the UFSAR-described design function of the circuit, then this determination would form the basis for screening out the change, and an activity change evaluation would not be required. This example demonstrates where replacing a relay that supports a design function has a functional impact even though the SSC being changed is beneath the level detail in the UFSAR description.

Example 2

A licensee proposes a nonequivalent change to the operator for a safety injection accumulator isolation valve. The UFSAR describes that these isolation valves are open with their circuit breakers open during normal operation. These are motor operated, safety-related valves required for pressure boundary integrity and to remain open so that flow to the reactor coolant system will occur during a Loss of Coolant Accident (LOCA) as reactor coolant system pressure drops below ~600 psi. They are remotely closed during a normal shutdown so as to not inject when not required. Technical/engineering work supporting this change confirmed that the replacement operator is capable of performing the functions of the existing operator and will not adversely affect the connected Class 1E bus or diesel. This change would screen out because (1) the valve operator does not perform, support, or impact the UFSAR-described design function (to ensure pressure boundary integrity and remain open when required) that supports safety injection performance credited in the safety analyses, and (2) the change does not adversely affect other SSC design functions (e.g., of the Class 1E bus).

If the proposed change was to configure the valve as a normally closed valve that automatically opens on loss of reactor coolant system pressure, an activity change evaluation would be required because the change would adversely affect the reliability of the safety injection 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. The UFSAR-described design function of this valve is to maintain the integrity of the system boundary when closed. The vent/drain function of the valve does not relate to design functions credited in the safety analyses, and the licensee has determined that a ball valve is adequate to support the vent/drain function and is superior to the globe valve in terms of its isolation function. Thus, the proposed change affects the design of the existing vent/drain valve—not the design function (pressure boundary integrity) that supports system performance credited in the safety analyses—and an activity change evaluation/reporting 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.

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.

Example 5

A waste processing system includes a trap designed to collect radionuclides. An inadvertent release of the trap's contents has been evaluated as a BDBE. A proposed procedure change would extend the interval at which the trap is replaced. The service life of the trap has been evaluated and allows extending the replacement interval by a factor of two. Such an extension would result in the postulated radioactive release increasing by the same factor due to a larger source term. The change has a potential to adversely affect the design function since the safety analyses assumptions may no longer be conservative. Therefore, the proposed activity screens in for further evaluation.

4.2.1.3 Screening of Changes to Procedures as Described in the UFSAR

Procedure changes are screened in (i.e., require a change 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) (see Sections 3.3 and 4.1.1). Proposed changes that are determined to have positive or no effect on how SSC design functions are performed or controlled may be screened out. Required operator actions should be addressed in the SAR documentation of the associated SSCs, provided in NEI 21-07 SAR Chapter 6 (SR SSCs) and NEI 21-07 SAR Chapter 7 (NSRST SSCs).

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

The following examples illustrate the activity screening process as applied to proposed changes affecting how SSC design functions are performed or controlled.

Example 1

If the UFSAR description of the reactor start-up 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 start-up, the change would screen out.

Example 2

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 change evaluation to be performed.

Example 3

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 high energy line breaks 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 high energy line breaks. Therefore, this change screens in, and an activity change evaluation is required.

4.2.1.4 Screening of Changes that Impact Operator Actions

Certain plant changes have the potential to impact the safety significance of SSC functions supported by operator actions and should be screened in as requiring evaluation. Examples of such changes include:

- Changes to the implementation of a safety function from being executed automatically via the plant control and protection systems to requiring operator action(s) to initiate the execution of a safety function.

- Changes to the implementation of a safety function from relying on operator action to relying on automatic action via the plant control and protection systems. Operator actions to support the safety function may be available as a backup in this case.

- Changes to the design of the main machine interface that has the potential to influence the reliability of an operator action that supports the implementation of a safety function.

Commented [A14]: Should this be "man-machine"?

As discussed in Section 5 of the UFSAR, developed in accordance with NEI 21-07, the LMP methodology treats the safety significance of operator actions by linking them to the SSC functions they support rather than by separately classifying the safety significance of operator actions. SSC safety functions classified as safety significant include those associated with the performance of RSFs, risk significant functions, or functions needed for DID adequacy.

Operator actions that support a given safety function will typically be triggered by alarms, sensors, and control room indications that are needed to alert the operator of the conditions and to signal the operator to implement the action. Hence if the change results in increased reliance on operator action, the change can also potentially impact the SSC safety classification for SSCs that are necessary to enable the performance of the operator action.

The application of the evaluation criteria is the same for each of these types of changes. The discussion provided by this section can be used to inform the evaluation of the individual criteria discussed more fully in section 4.3.

4.2.1.5 Screening Changes to UFSAR Methods of Evaluation

As discussed in Section 3.9, 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 3.9) is considered to be a change that is controlled by this guidance 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 Criterion (i) of Section 4.3.9 to determine if prior NRC approval is required. Changes to methods of evaluation (only) do not require evaluation against the first eight criteria. Methods of evaluation associated with DBAs should be addressed in NEI 21-07 SAR Sections 2.2 (Source Term), 2.3 (DBA Analytical Methods), and 3.6 (Design Basis Accidents). Adverse changes to DBA methods utilized to demonstrate that design limits are met for SSCs that provide functions that support the retention of radioactive material would screen in. Methods of evaluation not associated with DBAs may be addressed in NEI 21-07 SAR Section 2.4 (Other Methodologies and Analyses) or in other parts of the SAR not covered by NEI 21-07 guidance. Methods of evaluation associated solely with the remaining LBEs (AOOs, DBEs, and BDBEs) should be addressed in the PRA in accordance with ASME/ANS PRA Standard for Advanced Non-LWRs (ASME/ANS-RA-S-1.4-2021) and are outside the scope and applicability of this guidance (see Section 4.1.1).

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. If a method of evaluation is used in the PRA and is also included in the UFSAR for a DBA analysis, then it would screen in for the other UFSAR analysis.

Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not subject to activity screening and evaluation in accordance with this guidance unless the UFSAR states they were used for specific analyses used in establishing the design bases or in the safety analyses.

Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation using this guidance if the changes are outside the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or 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.

If the proposed activity involves a change to an input parameter or assumption in the analysis that is nonconservative and the input parameter or assumption was integral to the NRC approval of the methodology, then that change would not screen out.

Commented [A15]: This proposed text addition is based on Example 4 below.

Proposed use of an alternative method is considered an adverse change that must be evaluated under Section 4.3.9 Criterion (i).

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 containment performance analyses, with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated topical report and SER. A change that goes beyond restrictions on the use of the method would be considered adverse and evaluated under Section 4.3.9 Criterion (i) to determine if prior NRC approval is required.

Example 2

The UFSAR describes the methods used for atmospheric heat transfer and containment pressure response calculations contained within the CONTEMPT computer code. The code is also used for developing long-term temperature profiles (post-recirculation phase of LOCA) for environmental qualification through modeling of the residual heat removal system. Neither this application of the code nor the analysis method is discussed in the UFSAR. A revision to CONTEMPT to incorporate more dynamic modeling of the residual heat removal system transfer of heat to the ultimate heat sink would screen out because this application of the code is not described in the UFSAR as being used in the safety analyses or to establish design bases. Changes to CONTEMPT that affect the atmospheric heat transfer or containment pressure predictions may not screen out (because the UFSAR describes this application in the safety analyses) and may require an activity evaluation.

Example 3

The steamline break mass and energy release calculations were originally performed at a power level of 105% of the nominal power (plus uncertainties) in order to allow margin for a future power uprate. The utility later decided that it would not pursue the power uprate and wished to use the margin to address other equipment qualification issues. The steamline break mass and energy release calculations were reanalyzed, using the same methodology, at 100% power (plus uncertainties). This change would screen out as a methodology change because the proposed activity involved a change to an input parameter (% power) and 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 Section 4.3.9 Criteria (a) through (h).

Example 4

The mass and energy release calculations for events involving a breach of the reactor coolant system were originally performed at a power level of 105% of the nominal power, plus uncertainties. Some of the assumptions in the analysis were identified as nonconservative, but NRC concluded in the associated SER that the overall analysis was conservative because of the use of the higher initial power. The utility later decided that it would not pursue the power uprate and wished to use the margin to address other equipment qualification issues. The associated break mass and energy release calculations were reanalyzed, using the same methodology, at 100% power (plus uncertainties). This change would not screen out because the proposed activity involved a change to an input parameter that was integral to NRC approval of the methodology.

Commented [A16]: I think this example should be incorporated into the discussion above. See proposed changes above.

Example 5

Due to fuel management changes, core physics parameters change for a particular reload cycle. The topical report and associated 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 add or remove discretionary conservatism via use of 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 SER.

Example 6

A new version of computer software is available that is used for modeling the peak fuel and cladding temperature as part of the analyses for LBEs that are not DBAs. The new version of the software more accurately models the physical phenomena inside the reactor core and results in peak temperatures being lower than currently analyzed. The proposed activity is a change to a PRA-related method of evaluation but it is not associated with DBA analyses. Therefore, the proposed activity involves a change to a PRA method not associated with DBA analyses which is outside of the scope of the changes evaluated by this guidance.

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

As discussed in Section 3.14, tests or experiments not described in the UFSAR are 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.

As discussed in Section 4.1.2, testing associated with maintenance is assessed and managed under 10 CFR 50.65(a)(4) and is not subject to activity screening and evaluation in accordance with this guidance.

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. Tests or experiments described in the SAR would likely be located in NEI 21-07 SAR Chapter 2, NEI 21-07 SAR Section 6.3 (SR SSCs), and NEI 21-07 SAR Section 7.2 (NSRST SSCs).

Examples of tests that would screen in at this step include the following[12]:

- Operation with fuel demonstration assemblies beyond what is allowed by Technical Specifications
- Disabling automatic transfer to alternative power sources to assess core response
- Cleaning of fuel cladding crud while at power

12Assuming the tests were not described in the UFSAR. Note that the flexibility to apply an alternative regulation does not extend to “test or experiments not described in the UFSAR.” Thus, even if such an extreme activity is also controlled by another regulation, this change process also would control.

Examples of tests that would screen out are:

- Steam generator moisture carryover tests (provided such testing is described in the UFSAR)
- Balance-of-plant heat balance test
- Information gathering that is nonintrusive to the operation or design function of the associated SSC

4.2.3 Screening Documentation

The following record-keeping requirements apply to activity evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with plant procedures of screenings that conclude a proposed activity may be screened out (i.e., that an activity 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. Typically, the screening documentation is retained as part of the change package. This documentation does not constitute the record of changes required by this guidance, and thus is not subject to associated documentation and reporting requirements delineated in Section 5. Screening records need not be retained for activities for which an evaluation was performed or for activities that were never implemented.

4.3 Evaluation Process

Once it has been determined that a given activity requires an activity evaluation, the written evaluation must address the applicable criteria of Sections 4.3.1 through 4.3.9. These nine criteria are used to evaluate the effects of proposed activities on LBEs, and malfunctions previously evaluated in the UFSAR and their potential to cause LBEs or malfunctions whose effects are not bounded by previous analyses.

Criteria (a) through (h) are applicable to activities other than changes in methods of evaluation. Criterion (i) 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. Sections 4.3.1 through 4.3.9 provide guidance and examples for evaluating proposed activities against the nine change evaluation criteria.

Each element of a proposed activity must undergo an activity screening and 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; (2) they are performed collectively to address a design or operational issue; or (3) one or more of the elements are planned to ensure that the overall change does not result in a change to the defense-in-depth adequacy determination. For example, a pump upgrade modification may also necessitate a change to a support system, such as cooling water. Another example are discrete elements linked to preserving a single RSF feature which may have been identified as necessary for adequate DID.

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 should be assessed against each of the applicable evaluation criteria separately. Evaluations should consider the effects of the proposed activity on operator actions.

Specific guidance for applying activity screening and evaluation to temporary changes proposed as compensatory actions for degraded or nonconforming conditions is provided in Section 4.4.

Information on LBE frequency and consequence is developed in the PRA and is provided in the SAR for AOOs, DBEs, and BDBEs. DBAs are defined using a set of deterministic rules that involve the selection of SR SSCs in the performance of RSFs and their consequences are evaluated conservatively; the DBAs have no documented frequency as part of the licensing basis. For the purpose of evaluating LBEs against the change evaluation criteria delineated in Section 4.3, AOOs, DBEs, and BDBEs are addressed in terms of frequency, consequence, and risk, whereas DBA consequences are addressed deterministically based on consequences.

Special treatments for safety significant SSCs are documented in the UFSAR Sections 6.2 and 7.1 for SR and NSRST SSCs, respectively according to the guidance in NEI 21-07. The evaluation criteria presented below include criteria for changes that impact the definition, frequency, and consequences of LBEs and the likelihood and consequences of malfunctions of safety significant SSCs. Any changes to special treatments documented in the UFSAR are evaluated on the basis of the impacts on these metrics as illustrated in the examples presented with the criteria. Changes to special treatments that do not impact these metrics do not require NRC prior approval.

The nine criteria to be considered during the evaluation process are listed below and described in more detail in the Sections 4.3.1 through 4.3.9. Examples are provided to illustrate the application of the criteria. It is important to note that while all criteria must be considered when evaluating a proposed change, the examples are written to address only one criterion. Therefore, while an example may conclude that a proposed change is permitted by the specific criterion being evaluated, the proposed change would still have to be evaluated against the other criteria before it could be concluded that the proposed change may be implemented without an amendment to the operating license.

Criterion (a)— *Result in a change to the frequency and/or consequences of one or more AOOs, DBEs, or BDBEs documented in the final safety analysis report (as updated) in a manner that would exceed (i) the NEI 18-04 Frequency-Consequence Target; or (ii) an NEI 18-04 Cumulative Risk Target.*

Criterion (b)—*Change an AOO, DBE or BDBE from non-risk significant to risk significant according to NEI 18-04 LBE risk significance criteria.*

Criterion (c)—*Result in more than a minimal increase in the consequences of a Design Basis Accident.*

Criterion (d)—*Result in identifying one or more AOOs, DBEs, or BDBEs that are (i) not previously evaluated in the UFSAR and (ii) classified as risk significant according to NEI 18-04 LBE risk significance criteria.*

Criterion (e)—*Result in (i) the inability of a Safety-Related SSC to meet a Safety-Related Design Criterion as described in the FSAR (as updated) or (ii) a change to a Safety-Related Design Criterion as described in the FSAR (as updated).*

Criterion (f)—*Result in an increase in the frequency and/or consequences of a malfunction of any safety-significant SSC that would change the classification of the SSC from non-risk significant to risk-significant.*

Criterion (g)—*Result in a change of any SSC from (i) No Special Treatment to Safety-Related; or (ii) Non-Safety Related with Special Treatment to Safety-Related; or (iii) Safety-Related to Non-Safety Related with Special Treatment; or (iv) Safety-Related to No Special Treatment.*

Criterion (h)—*Result in a change to the performance of a safety-significant SSC that would change the overall evaluation of defense-in-depth adequacy.*

Criterion (i)—*Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.*

4.3.1 Criterion (a)

(a) Result in a change to the frequency and/or consequences of one or more AOOs, DBEs, or BDBEs documented in the final safety analysis report (as updated) in a manner that would exceed (i) the NEI 18-04 Frequency-Consequence Target; or (ii) an NEI 18-04 Cumulative Risk Target.

Commented [A17]: For LBEs that are already risk-significant, it would appear that Criterion (b) wouldn't apply, only Criterion (a). Is a change that moves from the far left side of the risk-significant region to the far right of the same region (i.e., close to the F-C target line) considered as not needing NRC approval? Has this type of change been considered when developing this guidance?

In evaluating Criterion (a)(i), the first step is to identify the LBEs that have been evaluated in the UFSAR that are affected by the proposed activity. Then a determination should be made as to whether the change increases the risk such that the AOO, DBE, or BDBE exceeds the Frequency-Consequence (F-C) target (see NEI 18-04 Section 3.2.2, Task 7a). The evaluation of Criterion (a)(i) may be performed by using the PRA to evaluate the effect on the frequency and consequences of the event consistent with NEI 18-04.

Criterion (a)(ii) addresses the impact of a proposed change to cumulative risk. The cumulative risk metrics are defined in NEI 18-04 Section 3.3.5 and would be documented in the UFSAR in accordance with NEI 21-07 SAR Section 4.1. This criterion provides confidence that an accumulation of changes over time, each of which is acceptable from an individual LBE perspective, does not lead to unacceptable cumulative risk.

The following examples illustrate the implementation of Criterion (a)(i).

Example 1

A high-temperature gas-cooled reactor plant proposes to raise the administrative, procedural limit related to the steam generator nominal wall thickness tube plugging criteria. This change will allow tubes with more significant defects to remain in service where previously they would have been required to be plugged. One of the likely effects of this change is an increased probability of a steam generator tube rupture (SGTR) DBE. A technical evaluation established an upper bound value for the amount that the SGTR initiating event frequency would increase due to the change. The evaluation demonstrated that allowing tubes to remain in service with more significant defects did not result in exceeding the NEI 18-04 F-C Target. Therefore, Criterion (a)(i) does not require prior NRC approval for the change (see Figure 2~~Figure 2~~). Note that multiple LBEs would likely be assessed as part of this evaluation, but the example is focusing only on one LBE sequence for demonstration purposes.

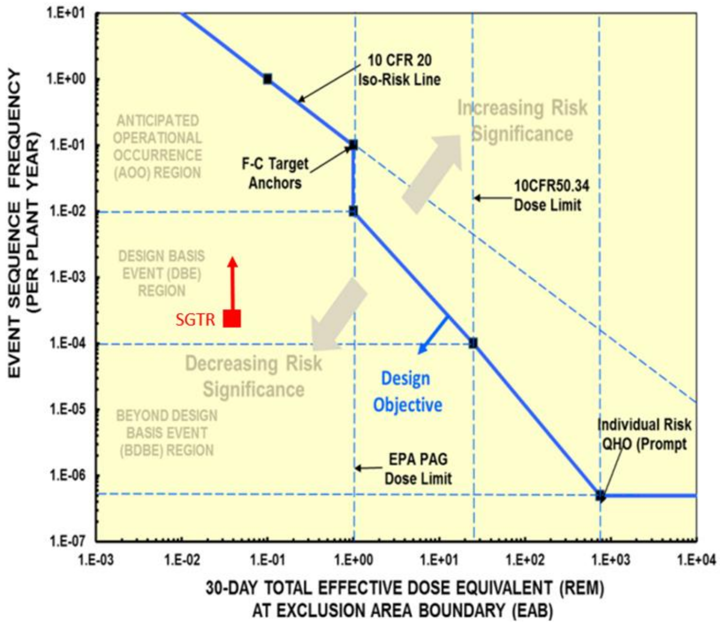

Figure 2. Overall Plant Performance Change in Example 1

Example 2

The state emergency management agency requests that the nuclear operator provides for additional communications beyond what is in the existing emergency plan. This communicator function would need to be performed by a control room operator. The performance of the additional duties raises the operator's human error probability for performing steam generator (SG) cooldown in response to the SGTR event, which is necessary to limit primary-to-secondary leakage and prevent SG overfill. Management requests plant staff evaluate the proposed change to assist in decision-making. The potential impact to the emergency plan will be evaluated under 10 CFR 50.54(q) and is not subject to the TIRICE process. The potential impact to the LMP-based affirmative safety case does screen into the TIRICE process as requiring evaluation. Although the proposed change results in increased consequences (for the one event sequence depicted), it does not exceed the F-C target and would not exceed Criterion (a)(i). Therefore, Criterion (a)(i) does not require prior NRC approval for the change (see Figure 3~~Figure 3~~).

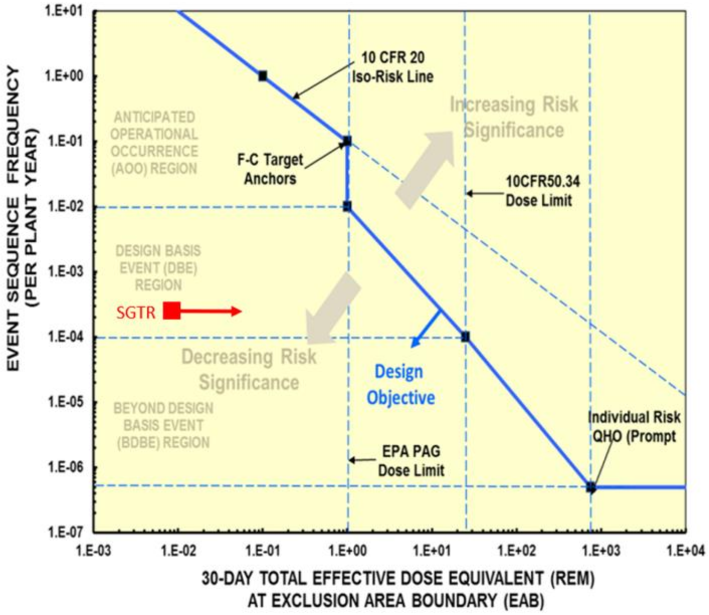

Figure 3. Overall Plant Performance Change in Example 2

The following examples illustrate the implementation of Criterion (a)(ii).

Example 3

One of the components used to circulate primary coolant during normal operation is degrading. Plant procedures limit the component's out of service time to no more than seven days before requiring a unit shutdown. However, the maintenance is expected to take longer than seven days and the plant is evaluating the option to stay online to support increased demands on the power grid. The proposed activity is to extend the procedurally allowed out of service time before requiring a plant shutdown. An analysis was conducted by extending the component's out of service time in the PRA model. The purpose of the analysis was to evaluate the impact of extending the allowed out of service time to accomplish the repair during normal operation. The study concluded that the proposed activity would not result in a change that exceeds the cumulative risk targets in Section 3.3.5 of NEI 18-04. Therefore, the proposed activity does not require prior NRC approval for the change per Criterion (a)(ii).

Commented [A18]: Although this text refers to "plant procedures', it seems to be talking about a Technical Specifications and associated AOTs. If that's the case, then this example seems to allow licensees to change AOTs without prior NRC approval.

Please provide more clarity on whether this references Technical Specifications, TRM, plant procedures, etc.

Example 4

A design issue has been discovered that affects the installed fuel. Specifically, a rapid down-power/runback maneuver induces unacceptable stress on the fuel. This stress is likely to result in the release of fission products. This runback-induced stress is associated with multiple AOOs. Consideration is being given to an "accept as-is" response to the situation, which involves permanent acceptance of the design issue and entry into this change process. Revised analyses have demonstrated that the release of fission products during all of the impacted AOOs during one year would result in an off-site

Commented [A19]: What's meant by "unacceptable stress" ? Inside or outside of AOO assumptions and related limitations?

dose of 110 mrem. Thus, the off-site dose impact of these multiple high-frequency events exceeds the criteria cited in Section 3.3.5 of NEI 18-04, which states in part:

> *The total frequency of exceeding a site boundary dose of 100 mrem from all LBEs should not exceed 1/plant-year.*

As a result, the proposed activity would require prior NRC approval for the change per Criterion (a)(ii).

4.3.2 Criterion (b)

(b) Change an AOO, DBE or BDBE from non-risk significant to risk significant according to NEI 18-04 LBE risk significance criteria.

The criterion is satisfied if an existing AOO, DBE, or BDBE changes its risk classification from non-risk-significant to risk-significant (see NEI 18-04 Section 3.2.2, Task 7c). NEI 18-04 Figure 3-4 provides a graphical representation of the risk significant region and the F-C target. The evaluation of Criterion (b) may be performed by using the PRA to evaluate the effect on risk significance and the F-C target consistent with NEI 18-04. This criterion is not applicable to DBAs because risk significance applies only to AOOs, DBEs, and BDBEs

The following examples illustrate the implementation of Criterion (b).

Example 1

A plant utilizes an air-operated valve to perform a function that has been identified as part of establishing adequate DID. The design utilizes one solenoid valve to port air into the actuator to open the air-operated valve. The current configuration has caused plant transients due to spuriously opening at power. A design change is being implemented to add a second solenoid valve in series using a redundant signal. The proposed configuration was modeled in the PRA for the purposes of evaluating whether prior NRC approval is needed. The addition of the second solenoid valve would reduce the probability that the air-operated valve would spuriously open but would raise the probability of a failure to open on demand. However, the overall risk impact did not change any LBE from non-risk significant to risk significant in accordance with the NEI 18-04 risk significance criteria as depicted in Figure 4. Therefore, Criterion (b) does not require prior NRC approval for the change.

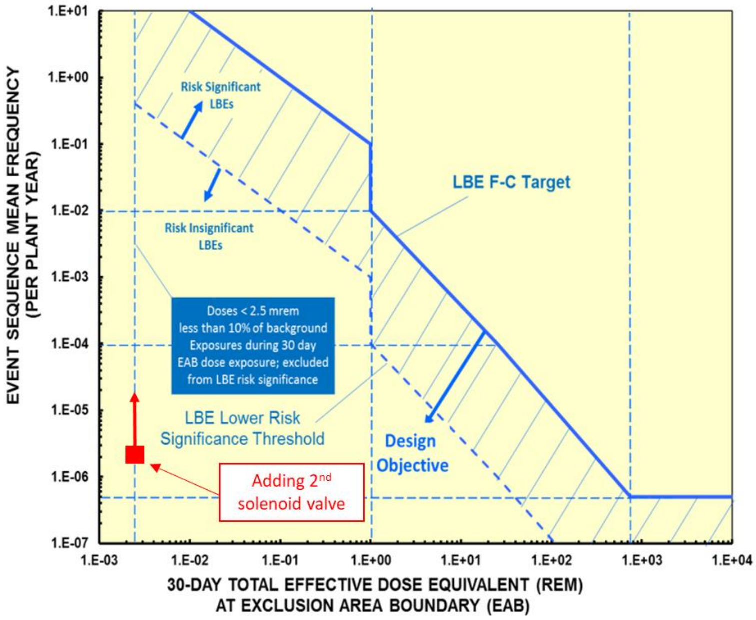

Figure 4. Modification to Add Second Solenoid Valve in Example 1

Example 2

A pump is classified as NSRST and during a PRA update which incorporated new evidence from plant specific service experience, it is determined that the pump is more reliable than previously assessed in the PRA. This increased reliability leads to consideration of a change in the special treatment requirements defined in the UFSAR, which specified monthly surveillance testing of the pump. In applying the Integrated Decision Process in NEI 18-04 it was determined that the surveillance testing interval could be increased from monthly to quarterly while maintaining confidence that the reliability targets and design functions could be met. In applying Criterion (b) it is determined that there is no change to the risk significance of any LBE in which the pump provides a prevention or mitigation function. Therefore, Criterion (b) does not require prior NRC approval for the change to the special treatment.

4.3.3 Criterion (c)

(c) Result in more than a minimal increase in the consequences of a Design Basis Accident.

The criterion addresses DBAs, which are analyzed in a conservative manner against the same consequence criteria as in the current regulations, 10 CFR 50.34 and 10 CFR 100. Note that Criterion (c) addresses only consequences because the selection of DBAs in the LMP framework is not based on frequency of occurrence or risk but rather by application of deterministic rules to convert DBEs to DBAs while crediting only SR SSCs in the performance of RSFs.

In NEI 18-04 and NEI 21-07 the consequences of DBAs are assessed in terms of public dose at the site boundary. The only activities affecting on-site dose consequences that may require prior NRC approval that are relevant to the LMP-based safety case are operator actions that may be required to perform one or more RSFs as identified in Section 5.4 of the UFSAR per NEI 21-07. The onsite doses to consider in this respect are limited to those dose exposures during the time frames that the operator actions need to be performed to execute the RSFs. For changes affecting the dose to operators performing required actions outside the control room, an increase is considered more than minimal if the resultant “mission dose” exceeds applicable limits for dose to control room operators The guidance in the remainder of this section applies to evaluation of effects of changes on main control room and off-site doses.

The evaluation should determine the dose that would likely result from DBAs 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 DBA, 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 so that an individual located at any point on the outer boundary of the zone would meet the relevant criteria set forth in 10 CFR 50.34(a)(1) for the radiological dose consequences of postulated accidents. It should be noted that the regulatory requirements for control room dose are outside the scope of LMP and should be addressed in ARCAP.

Therefore, for a given DBA, calculated or bounding dose values for that DBA would be identified in the UFSAR. These dose values should be within the applicable regulatory limits. 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% of the difference between the current calculated dose value and the regulatory limit. The current calculated dose values are those documented in the most up-to-date analyses of record.

In determining if there is more than a minimal increase in consequences, the first step is to determine which DBAs 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:

- Will the proposed activity change, prevent, or degrade the effectiveness of actions described or assumed in a DBA discussed in the UFSAR?
- Will the proposed activity alter assumptions previously made in evaluating the radiological consequences of a DBA described in the UFSAR?
- Will the proposed activity play a direct role in mitigating the radiological consequences of a DBA 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 DBAs evaluated in the UFSAR. If it is determined that the proposed activity does have an effect on the radiological consequences of any DBA analysis described in the UFSAR, then either:

- Demonstrate and document that the radiological consequences of the DBA 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

- 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 Criterion (c). 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 Criterion (i) as discussed in Section 4.3.9.

Example 1

The calculated dose to the control room operators following a loss of coolant DBA is 4 rem total effective dose equivalent (TEDE). A change is proposed to the control room ventilation system such that the calculated dose would increase to 4.5 rem. The regulations dictate that the control room doses are to be controlled to less than 5 rem. Although the new calculated dose is less than the regulatory limits, the incremental increase in dose (0.5 rem) exceeds the value of 10% of the difference between the previously calculated value and the regulatory value or 0.1 rem [10% of (5 rem - 4 rem)]. This change would require prior NRC review because the increase in consequences exceeds the minimal standard Criterion (c).

Example 2

The calculated public dose consequence for a particular steam generator tube rupture accident is 2 rem TEDE at the exclusion area boundary. As a result of a proposed change, the calculated dose consequence would increase to 3 rem. The increase is not more than minimal because the new calculated dose does not exceed the applicable guideline of 25 rem TEDE, nor does the incremental change in consequences (1 rem) exceed 10% of the difference between the previous calculated value and the regulatory limit of 25 rem TEDE. Ten percent of the difference between the regulatory limit (25 rem) and the calculated value (2 rem) is 2.3 rem (10% of 23). Since 1 rem is less than 2.3 rem, this change does not cause more than a minimal increase in consequences therefore Criterion (c) does not require prior NRC approval for the change.

4.3.4 Criterion (d)

(d) Result in identifying one or more AOOs, DBEs, or BDBEs that are (i) not previously evaluated in the UFSAR and (ii) classified as risk significant according to NEI 18-04 LBE risk significance criteria.

Potential changes that could introduce newly identified LBEs are addressed by Criterion (d). Such changes should be evaluated by revisiting the NEI 18-04 process for identifying LBEs.

The evaluation of the change should determine whether the change alters the event sequence plant response model in a manner that introduces a new event sequence or event sequence family. It is important to note that Criterion (d) is satisfied only when any new LBEs exceed the risk significance criteria in NEI 18-04 based on mean values of frequency and consequence. If a newly identified LBE is not risk significant, it has no material impact on the safety analysis based on the methodology endorsed in RG 1.233, so the change would not require prior NRC review. Also, because a new DBA would require a new DBE, and thus Criterion (d) implicitly covers DBAs as part of its scope of AOOs, DBEs, and BDBEs.

Commented [A20]: Could a new DBA be related to a new non-risk significant DBE? When looking at Task 6 in NEI 18-04, the deterministic DBAs are taken from all DBEs (not just the risk-significant ones determined in Task 7c). A new DBA through this pathway would not seem to be covered by criterion (d) or any other criterion herein.

Commented [A21R20]: In addition, could there be a scenario where a DBA was selected to address several DBEs (event families) and later it is determined to introduce a new DBA - not on the introduction of a new DBE but to address some operational or analysis issue - related to the performance of specific SR SSCs?

A potential change that affects the frequency of an LBE could cause it to move from one category to another (e.g., the frequency of a BDBE increases enough to make it a DBE). Such an event should be treated as a “not previously evaluated” licensing basis event. If it is classified as risk significant, Criterion (d) would be satisfied, and prior NRC approval would be required before implementing the change.

The following examples illustrate the implementation of Criterion (d).

Example 1

The station desires to install a new process heat plant to make commercial quantities of hydrogen. The proposed location of the process heat plant for making the hydrogen is close enough for blast effects to interrupt normal operation and potentially damage equipment relied upon for normal cooling. The modification is in the conceptual stage; however, the change would likely result in one or more additional risk significant LBEs that are not evaluated in the UFSAR. Therefore, the change would require prior NRC approval per Criterion (d).

Example 2

A change to the plant has been proposed to provide additional cooling capacity to a system by upgrading an existing heat exchanger. The heat exchanger was originally installed during plant construction and a replacement project would necessitate removal of a nearby concrete wall. The permanent removal of the wall is being included as a part of the change in order to provide flexibility for maintenance activities or enable additional upgrades in the future. Upon evaluation, it was determined that the concrete wall serves as a flooding barrier between two cooling water pumps. As a result, the removal of the wall would result in a new risk-significant DBE due to flooding. Therefore, the proposed activity (i.e., permanent removal of the concrete wall) would require prior NRC approval for the change per Criterion (d) (See Figure 5).

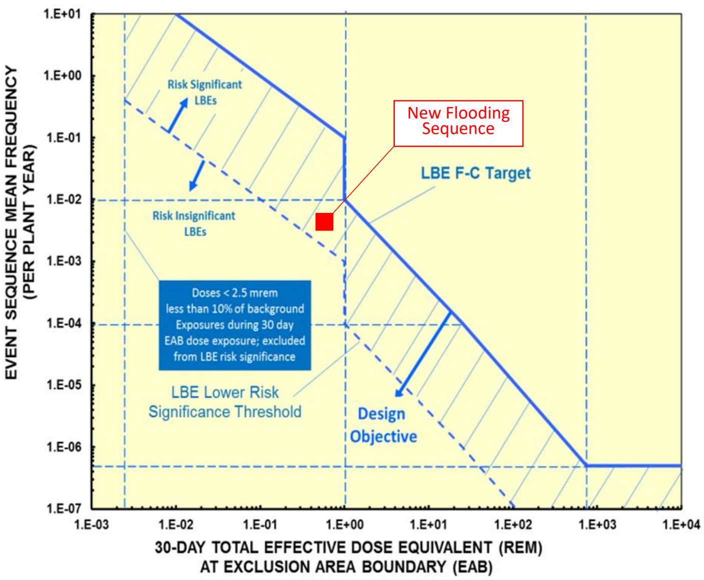

Figure 5. Identification of a New Risk-Significant Flooding Sequence in Example 2

4.3.5 Criterion (e)

(e) Result in (i) the inability of a Safety-Related SSC to meet a Safety-Related Design Criterion as described in the FSAR (as updated) or (ii) a change to a Safety-Related Design Criterion as described in the FSAR (as updated).

The first part of the criterion addresses changes that affect UFSAR analyses of the ability of a SR SSC to meet its safety-related design criteria, including analyses demonstrating that the SR SSC can withstand DBHLs. If a change renders a SR SSC incapable of meeting one of its safety-related design criteria, then the activity would require prior NRC approval. Safety-related design criteria for SR SSCs are documented in NEI 21-07 SAR Section 6.1.2. Criterion (e) directly controls the SRDC, which are expected to rely, in part, upon commitments to regulatory guides, nationally recognized industry consensus standards, UFSAR-described-design processes for Natural Phenomena and NRC-approved Topical Reports.

If the change to a commitment to compliance to a code, standard, or other UFSAR-described-design processes for Natural Phenomena or NRC-approved Topical Reports does not impact the ability to satisfy the SRDC documented in Section 5 of the UFSAR per NEI 21-07, then prior NRC approval would not be required as result under this Criterion (e)(i).

Compliance with Criterion (e) for instances where regulatory guides, codes or standards are not directly cited requires a slightly different approach than that described above. For these cases, compliance with SRDC is centered on a critical part of the definition of Design Function, Section 3.2, which states, “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, and equipment qualification." This element ensures that performance of a design function is subject to the additional margins required to accommodate limiting design conditions.

Therefore, assessing ongoing adherence to UFSAR-described-design processes for Natural Phenomena and NRC-approved Topical Reports is informed by focusing upon this standard (i.e., the design function is subject to the additional margins required to accommodate limiting design conditions). That is, Criterion (e) may be answered "no" if the required Design Function remains available under the intended design conditions. These "conditions under which the intended functions are required to be performed" are identified by examination of the design processes in use.

If a change is being evaluated which would require changing an SRDC, NRC prior approval would be required via a license amendment prior to changing the SRDC.

The following example illustrates the implementation of Criterion (e).

Example 1

A larger, more massive flywheel is being installed to enhance the capability of the internal Reactor Coolant System (RCS) sodium pump. This larger flywheel and pump shaft connects with the internal RCS pumps through a flange that is part of the RCS vessel. The increased flywheel mass increases the postulated seismic loadings on the RCS vessel flange.

Examination of the UFSAR-described SRDC identifies that the design of the RCS vessel flange is to the ASME code for a DBHL seismic event at 1×10^{-4} occurrence frequency.

The increased seismic loading on the RCS vessel flange during a DBE seismic event has been evaluated to continue to meet the ASME code requirement with reduced margin above the code allowable stresses. Changes in margin to code requirements, as long as the code requirements and applicable SRDC continue to be met do not require prior NRC prior approval per Criterion (e)(i).

Example 2

A reactor houses a safety-related pump inside a hardened building designed to withstand tornado-driven missiles. Protection against natural phenomena hazards, including tornado-driven missiles, is a SRDC for the safety-related pump. A planned maintenance activity would involve removing one of the walls of the building for 120 days during the middle of an operating cycle, which is a Temporary Alteration in Support of the maintenance activity. Because the maintenance would last more than 90 days, the activity screens in for change control evaluation. Removal of the wall would leave the safety-related pump subject to damage during a tornado, so the design criterion of protection from natural phenomena hazards would not be satisfied. For this example, Criterion (e)(i) requires prior NRC approval for the change.

Example 3

The vibratory ground motion peak ground acceleration is established at 0.4 g for a safety-related valve. The ability of a valve to withstand the peak ground acceleration is summarized in a UFSAR analysis. A proposed change to the valve operator would significantly change the weight of the valve and operator such that the analysis no longer demonstrates the valve could carry out its design bases function during a seismic event with that peak ground acceleration. For this example, Criterion (e)(i) requires prior NRC approval for the change; a redesign may be in order per Section 4.5.

Example 4

A design change to a gas-cooled reactor is proposed that would increase the capacity of the primary loop relief valve by 15%. One of the effects of the change would be to increase the amount of helium released to the reactor building during several LBEs such that the peak reactor building pressure would be 11 psig. The previously calculated peak reactor building pressure was 7 psig.

The decay heat removal system (DHRS) is a safety-related SSC located in the reactor building. The DHRS has an SRDC that in the event of a LBE that involves a loss of primary coolant pressure boundary integrity, the DHRS shall be capable of withstanding the resulting differential pressure with no loss of DHRS function. The interior of the DHRS would be at atmospheric pressure during such LBEs, and the maximum differential pressure for which the DHRS is designed is 10 psig. The proposed change would result in a differential pressure of 11 psig, which would result in the inability to meet a safety-related design criterion as described in the SAR (as updated). Accordingly, the proposed change would require prior NRC approval per Criterion (e)(i).

4.3.6 Criterion (f)

(f) Result in an increase in the frequency and/or consequences of a malfunction of any safety-significant SSC that would change the classification of the SSC from non-risk significant to risk-significant.

Criterion (f) is based on NEI 18-04 SSC safety classification. Changes that may impact SSC risk significance should be evaluated by revisiting the pertinent processes in NEI 18-04 Section 3.2.2 after quantifying the impact on risk using the PRA.

The following examples illustrates the implementation of Criterion (f).

Example 1

A pump that is classified as NSRST is equipped with an automatic start feature. The automatic start feature is credited in the analyses of several LBEs, none of which are DBAs. A change is being considered to incorporate a new action to manually start the pump in lieu of the automatic start feature. The proposed activity will revise operating procedures to incorporate the new action and will implement a design change to delete the circuitry of the automatic start feature. The PRA model was revised for the purposes of analyzing the proposed activity; the change did not result in the identification of any new risk significant SSCs. As a result, the proposed activity does not require prior NRC approval for the change per Criterion (f).

Example 2

A design change is proposed that will impact the heat transfer capacity for the Reactor Cavity Cooling System (RCCS) by reducing the surface area and volume of the RCCS standpipes. The RCCS provides the RSF of Control Heat Removal and the proposed design change reduces the heat transfer capability from the reactor core to the ultimate heat sink such that the fuel experiences higher temperatures during DBEs and BDBEs. As such, the proposed design change does increase the frequency and consequence of a malfunction of RCCS. Additionally, the total frequency of LBEs that involve the degradation of the

Control Heat Removal RSF contributes more than 1% of the LMP cumulative risk target of meeting the NRC safety goal QHO individual risk of latent cancer fatality. As such, the proposed design change results in an increase in the frequency and consequence of a malfunction of a safety-significant SSC that changes the classification from non-risk significant to risk-significant according to the SSC risk significance criteria in NEI 18-04. As a result, the proposed activity requires prior NRC approval for the change per Criterion (f).

4.3.7 Criterion (g)

(g) Result in a change of any SSC from (i) No Special Treatment to Safety-Related; or (ii) Non-Safety Related with Special Treatment to Safety-Related; or (iii) Safety-Related to Non-Safety Related with Special Treatment; or (iv) Safety-Related to No Special Treatment.

It is possible that a change might lead to a reclassification of an SSC from NST or NSRST to SR, although such changes are expected to be infrequent. For example, if a change introduces a new hazard that was not addressed in the existing classification, it may be determined that it is more cost effective to select and reclassify an existing NST or NSRST SSC to SR to perform a RSF to protect against that hazard than to impose new design criteria on an existing SR SSC to protect against that hazard. Per this criterion, changing the classification from NST or NSRST to SR requires a license amendment. Additionally changing the classification of an SR SSC to an NST, or NSRST SSC, also requires a license amendment.

In other situations, for certain changes, it may be necessary to reclassify an SSC from NST to NSRST to maintain the adequacy of DID. If the affected SSC was originally NST and the SSC is subsequently reclassified as NSRST then Criterion (g) does not require prior NRC approval for the change.

The following examples illustrate the implementation of Criterion (g).

Example 1

An air-cooling system is classified as NST. A proposed activity is being considered to incorporate a debris filtration screen on the system’s intake to reduce the potential for internal fouling. However, the screen would result in an increased potential for flow restriction during some postulated events. The proposed modification is modeled in the PRA, and it is determined that the new failure mode (i.e., clogged screen) would cause the system to be less reliable. In order to maintain reliability at an acceptable level special treatment is needed to periodically inspect and clean the screen and results in changing the system’s safety classification from NST to NSRST. Therefore, the proposed activity does not require prior NRC approval for the change per Criterion (g).

Example 2

A design change is proposed to install a steam-methane reforming system to produce and store hydrogen. The proposed location of the new system is adjacent to the nuclear island auxiliary building and the conventional island, which currently houses the turbine generator and other balance of plant SSCs. The new system produces hydrogen by combining high temperature steam coming off the main steam lines downstream of the steam generator with methane. Because the proposed system involves both methane and hydrogen, it introduces a new hazard (i.e., explosion) for the safety case to consider. After analyzing the hydrogen and methane initiating event and the resulting impact, the mean frequency of the initiating event is 2×10^{-3}/plant-year and both the nuclear island auxiliary building and the conventional island civil structures, to include the SSCs inside those structures, would be damaged by the explosion. The nuclear island auxiliary building and associated SSCs are classified as NSRST and the conventional island building and associated SSCs are classified as NST. The hydrogen and methane explosion and associated impact on the nuclear island auxiliary building does impact the reactor building, which is classified as Safety-Related (SR). Specifically, the nuclear island auxiliary building would be damaged by the explosion in a manner that would restrict the intake and exhaust flow of the Reactor Cavity Cooling System (RCCS) thus preventing its capability to adequately provide the RSF of Control Heat Removal. As such, the modification to the auxiliary building is needed which involves re-classification of the nuclear island auxiliary building civil structure from an NSRST SSC to an SR SSC. As a result, the proposed activity requires prior NRC approval for the change per Criterion (g)(i).

4.3.8 Criterion (h)

(h) Result in a change to the performance of a safety-significant SSC that would change the overall evaluation of defense-in-depth adequacy.

Criterion (h) addresses adverse effects on DID adequacy that change the DID adequacy determination. DID has an important, formalized role in the LMP-based affirmative safety case as addressed in Chapter 5 of NEI 18-04 and Chapter 4 of NEI 21-07. Elements of the DID baseline may relate to plant capability (e.g., SSCs) or be programmatic in nature (e.g., testing). DID elements will vary among technology types, specific designs, and the nature of the safety case, so the DID baseline for one reactor may be very different from another.

NEI 18-04 Section 5.9.6 sets forth specific questions associated with the consideration of plant changes, repeated below.

- Does the change introduce a new LBE for the plant?
- Does the change increase the risk of LBEs previously considered to be of no/low risk significance to the point that it will be considered risk-significant after the change is made?
- Does the change reduce the number of layers of defense for any impacted LBEs or materially alter the effectiveness of an existing layer of defense?
- Does the change significantly increase the dependency on a single feature relied on in risk-significant LBEs?

The first and second bullets are addressed by Criteria (a) and (b), respectively. The third and fourth bullets relate directly to DID and are addressed by Criterion (h).

NEI 18-04 Section 5.9.3 describes how DID adequacy is confirmed in establishing the DID baseline. NEI 21-07 specifies that SAR Section 4.2.3 will document the integrated DID evaluation by addressing the confirmatory DID criteria in NEI 18-04 Section 5.9.3. Thus, the focus of the evaluation of the effect of a proposed change on DID adequacy per Criterion (h) should be on the integrated DID evaluation as documented in SAR Section 4.2.3, which addresses both plant capability and programmatic DID.

Any changes which would alter the conclusion of the DID adequacy determination would require prior NRC approval. In this instance, the adverse effect of the change relates to the design function the SSC is intended to accomplish in support of DID adequacy. Some of the confirmatory DID criteria are amenable to quantitative assessment (e.g., performance targets for SSC reliability and capability are identified), while others require a qualitative evaluation (e.g., prevention/mitigation balance is sufficient). Given the potential for variability in the DID baselines for different designs, it is not practical for guidance to specify, in advance, finite change control acceptance criteria for all considerations related to DID adequacy. The evaluation will be based on the DID baseline information in NEI 21-07 SAR Section 4.2.3 and the design records.

The nature of the change and its impact on the LMP-based affirmative safety case will impact the approach taken to carrying out the DID portion of the change evaluation. It is anticipated that many changes will be simple and limited in scope such that the evaluation against Criterion (h) will be relatively straightforward, using the information and criteria documented in the SAR and the plant records. However, some changes may require a more comprehensive IDP review of DID adequacy, including the possibility of utilizing an Integrated Decision-Making Process Panel (IDPP), as described in NEI 18-04 Chapter 5.

Consistent with Section 4.2, the licensee may include additional compensatory elements in the change in order to maintain DID adequacy and preclude the need for prior NRC approval. DID is interwoven with many parts of the LMP-based affirmative safety case, and it is important to provide licensees with flexibility to address it holistically provided overall DID adequacy is maintained.

Once the Criterion (h) determination is made, the basis for the determination must be documented as discussed in Section 5. In addition to updating plant records, if necessary, there should be an update of the DID baseline evaluation in the UFSAR.

Examples of Evaluation of DID Adequacy

The following examples illustrate the implementation of Criterion (h).

Example 1

A reactor relies on a passive safety-related heat removal system for removing decay heat if normal powered plant systems are lost. The passive system is highly reliable, but in order to provide for an independent layer of defense, an Auxiliary Heat Removal System (AHRS) is provided and classified as NSRST. The AHRS has its own dedicated power source that is designed to allow continued operation in the event of a loss of normal A/C electrical power.

SAR Section 5.5.2 identifies the AHRS as necessary for adequate DID. SAR Section 5.6 identified the Complementary Design Criteria for the AHRS - limit primary coolant temperature below 600°C for licensing basis events in which the system is operable. SAR Section 7.1 documents the reliability target for the AHRS: 98% overall and 90% for scenarios involving a loss of A/C electrical power in the plant. A proposed replacement of the AHRS dedicated power source would result in a reliability of 75% in the event of a loss of A/C electrical power. The proposed change screened in for evaluation because it would result in the safety-significant SSC not meeting its reliability target.

The integrated DID evaluation in SAR Section 4.2.3 documented the incorporation of the highly reliable AHRS to provide independent layers of defense and minimize challenges to the passive safety-related heat removal system. The proposed change would result in a reduction of more than 10% in the reliability of the AHRS relative to the established reliability target. Thus, the change materially alters the effectiveness of an existing layer of defense, and an IDP review is required to assess the impact on DID adequacy. Based on the IDP review, which included the existing DID baseline and the associated design records, it was not clear that DID adequacy would be maintained after the change. Therefore, the change requires NRC pre-approval per Criterion (h).

Example 2

A reactor uses an Auxiliary Reactivity Control System (ARCS) that injects a neutron poison material into the coolant system as a diverse means of controlling heat generation for certain scenarios. The ARCS is not required to mitigate any DBA, but it is identified as NSRST in SAR Section 5.5.2. SAR Section 5.6 identifies the Complementary Design Criteria for the ARCS—achieve and maintain a shutdown state in the event the primary reactivity control system does not function. At the beginning of plant operation, there was substantial uncertainty associated with the reliability of Component X in the ARCS. The original IDP review specified frequent testing of Component X as a special treatment to provide greater confidence in its reliability, as documented in SAR Section 6.3. The Component X tests are resource-intensive and have the potential for causing an undesired shutdown if performed incorrectly. Over time, data gathered from tests at the reactor and other reactors of the same design demonstrated that Component X is indeed highly reliable. The proposed change is to modify the procedure controlling the testing to allow for a frequency of no less than once per year rather than no less than once per 30 days. This would be a change in a special treatment for the ARCS. The proposed change was considered adverse and screened in for evaluation because it would decrease the ability to detect ARCS unavailability in the event Component X failed.

The evaluation determined that the accumulated data substantiates the high reliability of the ARCS component and demonstrates it should meet its reliability target as documented in SAR Section 7.1 without the additional confidence provided by more frequent testing. Therefore, the DID adequacy determination would not change. The SAR should be modified to reflect the change to the ARCS special treatment (test frequency). The proposed activity does not require prior NRC approval for the change per Criterion (h).

Example 3

Normal heat removal during operation of a reactor is accomplished by a conventional Rankine cycle, which includes a main feedwater (MFW) system, steam generator, turbine-generator, and condenser. The reactor vessel has a highly reliable passive safety-related heat removal system requiring no actuation to provide adequate heat removal in the event steam generator heat removal is not available.

In the event of a loss of MFW, there is an auxiliary feedwater (AFW) system that automatically actuates to provide cooling through the steam generator. AFW operation precludes the need for the passive safety-related heat removal system to operate. The AFW system is not safety-related, but it is identified in SAR Section 5.5.2 as necessary for adequate DID. SAR Section 5.6 6 identifies the Complementary Design Criteria for the AFW system – in the event of a loss of MFW, provide adequate flow to the steam generator such that the core temperature rise is limited to 150°C. SAR Section 7.1 documents the reliability target for the AFW system as 95%.

The proposed change is to remove automatic actuation for the AFW system and instead rely upon operator action to identify the need for AFW and actuate it manually. A system analysis indicates that AFW must be actuated within 10 minutes in order to limit the core temperature rise to 150°C. A human reliability analysis finds that the human error probability for accomplishing AFW actuation within 10 minutes is on the order of 50%, so the AFW system would not be close to achieving its reliability target established as part of the DID baseline. Therefore, it was concluded that the change would result in a situation in which DID adequacy is not maintained, and prior NRC approval is required for the change per Criterion (h).

At that point, a set of proposed additional instrumentation and control modifications were identified that would lower the human error probability for AFW actuation. With the additional instrumentation and control modifications in place, the AFW system would meet its 95% reliability target, including human actuation by 10 minutes. The set of proposed additional instrumentation and control modifications, by themselves, were determined not to require prior NRC approval for implementation. Therefore, the proposed additional instrumentation and control modifications were grouped with the change to replace automatic AFW actuation with manual actuation, and the additional compensatory elements were determined to maintain DID adequacy with the package of changes. Accordingly, the change to manual AFW actuation and the instrumentation and control modifications may be implemented together without prior NRC approval, consistent with Section 4.2. Therefore, the proposed activity, with the additional instrumentation and control I&C modifications, does not require prior NRC approval for the change per Criterion (h).

Example 4

A reactor relies on a passive heat removal system for removing decay heat if normal power plant systems are lost. This DHRS is classified as SR for performing the RSF of controlling core heat removal. The design of the system includes a shell and tube heat exchanger to transfer decay heat to the ultimate heat sink. Design to ASME Section III is one of the special treatments identified for the DHRS heat exchanger in SAR Section 6.3. Application of the pertinent portion of ASME Section III is a programmatic element of DID for ensuring adequate quality and reliability for the component.

Over the life of the plant, some heat exchanger tubes experienced degradation that was detected during routine in-service inspection. Some of those tubes exceeded ASME code limits and were plugged, reducing the capability of the DHRS. Other tubes experienced partial cracking but were allowed to remain in service per the code. The concern arose that, over time, additional tube plugging would reach the point that the heat exchanger could no longer meet its capability target.

Advanced testing was performed on the heat exchanger tube materials which, coupled with advanced fracture mechanics evaluations, demonstrated increased margin to tube failure during all LBEs for which the DHRS was required. Using this margin would allow tubes to operate at higher crack depths before tube plugging, extending the lifetime of the DHRS and delaying or avoiding a major component replacement project. A change to the Heat Exchanger Testing and Maintenance Program was proposed that would change the criterion for tube plugging from exceeding ASME code limits (current acceptance criterion) to exceeding the limits justified by the combination of advanced testing and fracture mechanics evaluations (new acceptance criterion).

In accordance with Criterion (h), the change was evaluated to determine whether or not the impact of the programmatic change would change the overall evaluation of DID adequacy. The technical evaluation indicated that operation of the DHRS tubes to the revised plugging limits would provide essentially the same DHRS tube integrity margin as was credited when the DID baseline (documented in SAR Section 4.2.3) was originally established. Therefore, an IDP evaluation of the impact of the change concluded that DID adequacy would be maintained following the change. Accordingly, it was concluded that Criterion (h) does not require prior NRC approval of the programmatic change to the Heat Exchanger Testing and Maintenance Program. If implemented, the change would result in the need to modify the safety-related SSC special treatments identified for the DHRS in SAR Section 6.3 and the codes and standards identified for the DHRS in SAR Section 6.4.1.

4.3.9 Criterion (i)

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

The UFSAR contains design and licensing basis information for a nuclear power facility, including description on how regulatory requirements for design bases are met and how the facility responds to various DBAs.

Commented [A22]: Why is this Criteria (i) limited to DBAs? It is not clear how the PRA change control process would evaluate changes to inputs/assumptions used in non-DBA analysis for prior NRC review. Nonconservative changes to inputs/assumptions that are important with respect to the demonstrations of performance that the analyses provide (i.e., analyses described, outlined or summarized in the UFSAR) should be evaluated for prior NRC approval. This is consistent with guidance in NEI 96-07 which does not limit this criterion to just DBA analysis.

Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and that the facility 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 this guidance 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 this process, specifically Criterion (i). 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 approved by NRC for the intended application.

If the proposed activity does not involve a change to a method of evaluation, then the activity evaluation should reflect that this criterion is not applicable. If the activity involves only a change to a method of evaluation, then the activity evaluation should reflect that Criteria (a) - (h) 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, or summarized in the UFSAR or are controlled by an alternative regulation. (Such changes may have been screened out as discussed in Sections 4.1.1 and 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 as providing results that are essentially the same as, or more conservative than, either the previous revision of the same methodology.

Commented [A23]: What does "either" refer to here?

Note that changes in evaluation methods used in the PRA, including those used for AOOs, DBEs, and BDBEs, do not normally require prior NRC approval because they are addressed through adherence to ASME/ANS RA-S-1.4-2021 (see Section 4.1.7). However, if a method of evaluation used in the PRA is also described in the UFSAR for application to an analysis that demonstrates that DBA limits are met for SSCs that support the retention of radioactive material than the method of evaluation would require prior NRC approval if Criterion (i) is met.

Commented [A24]: Should than be "then"?

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

The definition of “departure” provides licensees with the flexibility to make changes to methods of evaluation whose results are “conservative” or that are not important 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.

4.3.9.2 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. Such departures require prior NRC approval of the revised method. Analytical results obtained by changing any element of a method are “conservative” relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change from 45 psig to 48 psig in the result of a containment peak pressure analysis (with design basis limit of 50 psig) using a revised method of evaluation would be considered a conservative change when applying this criterion. In other words, the revised method is more conservative if it predicts more severe conditions given the same set of inputs. This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making potential physical or procedure changes without a license amendment.

In contrast, if the use of a modified method of evaluation resulted in a change in calculated containment peak pressure from 45 psig to 40 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 50 psig) for the licensee to make more significant changes to the physical facility or procedures.

The following examples illustrate the implementation of Criterion (i).

Example 1

A facility has a design basis containment pressure limit of 50 psig. The current worst-case design basis accident calculation results in a peak pressure of 45 psig within two minutes. The licensee revises the method of evaluation, and the recalculated result is 40 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 NRC and met all the terms and conditions of the method, a recalculated result of 40 psig would not require prior NRC approval.

Example 2

The UFSAR states that a damping value of 0.5% is used in the seismic analysis of safety-related piping. The licensee wishes to change this value to 2% to reanalyze the seismic loads for the piping. Using a higher damping value to represent the response of the piping to the acceleration from the postulated earthquake in the analysis 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 piping, 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% damping provided certain other assumptions were made, and the licensee used the NRC prescribed set of assumptions to perform its analysis, then the 2% damping under these circumstances would not be a departure because this method of evaluation is considered "approved by NRC for the intended application."

Example 3

A new version of the computer software is available that is used for modeling the peak fuel and cladding temperature as part of the DBA safety analyses. The new version of the software more accurately models the physical phenomena inside the reactor core and results in peak temperatures being lower than currently analyzed. The proposed method of analysis is considered nonconservative as it gains margin to the safety limits for the fuel and cladding. Therefore, prior NRC approval is required to adopt the new software before the results can be incorporated into the analyses of record.

4.3.9.3 "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 performed must be for the same set of plant 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.

The following example illustrate the implementation of Criterion (i).

Example 1

A licensee revises the seismic analysis described in the UFSAR to include an inelastic analysis procedure. This revised method is used to demonstrate that cable trays have greater capacity than previously calculated. This change would require prior NRC approval as it would not produce results that are essentially the same.

4.3.9.4 Guidance for Changing from One Method of Evaluation to Another

The definition of “departure” provides licensees with the flexibility to make changes by implementing this guidance from one method of evaluation to another provided that the new method is approved by NRC for the intended application. A new method is approved by 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 and several utilities have prepared and obtained NRC approval of topical reports that describe methodologies for the performance of a given type or class of analysis. Through an SER, NRC approved the use of the methodologies for a given class of power plants. In some cases, 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 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, NRC’s approval has typically been part of a plant’s licensing basis and limited to a given plant 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 NRC and the analysis owner that is referenced in the SER or associated transmittal letter.

It is incumbent upon the users of a new methodology—even one generically approved by 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 activity 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 if it is approved for use in the intended application, licensees should consult various sources, as appropriate. These include SERs, topical reports, and licensee correspondence with 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 NRC for the intended application."

The applicable terms and conditions for the use of a methodology are not limited to a specific analysis; the qualification of the organization applying the methodology is also a consideration. Through Generic Letter 83-11, Supplement 1,13 NRC has established a method by which licensees can demonstrate they are generally qualified to perform safety analyses. Licensees thus qualified can apply methods that have been reviewed and approved by NRC or that have been otherwise accepted as part of another plant's licensing basis, without requiring prior NRC approval. Licensees that have not satisfied the guidelines of Generic Letter 83-11, Supplement 1, may, of course, continue to seek plant-specific approval to use new methods of evaluation.

When considering the application of a methodology, it is necessary to adopt the methodology in 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 4.3.9.1.

4.3.9.5 Considerations for Determining if New Methods May be Considered "Approved by 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., plant-specific commitments)? Will the methodology supersede a methodology addressed by other regulations such as 10 CFR 50.55a or the plant technical specifications (Core Operating Limits Report or Pressure/Temperature Limits Report)? Is the methodology consistent with relevant industry standards?

- Does the application of the new methodology require an exemption(s) from regulations or a departure from plant-specific commitments, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with a facility's licensing basis? If so, then prior NRC approval may be required. The applicable change process must be followed to make the plant's licensing basis consistent with the requirements of the new methodology.

- Does the new method involve the use of a computer code, and if so, has the code been installed in accordance with applicable software quality assurance requirements? Has the plant-specific model been adequately qualified through benchmark comparisons against test data, plant 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?

- Is the computer code installation and plant-specific model qualification directly transferable from one organization to another? Has the installation and qualification been performed in accordance with the quality assurance program?

13 Generic Letter 83-11, Supplement 1, "Licensee Qualification for Performing Safety Analyses," June 24, 1999.

- Is the facility for which the methodology has been approved designed and operated in the same manner as the facility to which the methodology is to be applied? Is the relevant equipment the same? Does the equipment have the same pedigree (e.g., Class 1E, Seismic Category I, etc.)? Are the relevant failure modes and effects analyses the same? If the plant 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 plant design?
    - Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

Differences in the plant configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage plants may not include an analysis of the feedwater line break event that is required in later vintage plants. Some plants 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 NRC. Some plants may have pressurizer power-operated relief valves that are qualified for water relief; other plants do not. Plant 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.

The following examples illustrate the implementation of Criterion (i).

Example 1

Licensee X has received NRC approval for the use of a method of evaluation for performing steamline break mass and energy release calculations for environmental qualification evaluations. 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. Licensee Y has satisfied the guidelines of GL 83-11, Supplement 1. 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 plant, Licensee Y conducts an activity 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 NRC.

Example 2

NRC has approved the use of computer code and the associated analysis of a steamline break for use in the evaluation of component stresses. A licensee uses the same computer code and analysis methodology to replace its evaluation of the containment temperature response. This change would require prior NRC approval unless the methodology had been previously approved for evaluating containment temperature response.

4.4 Utilizing an Activity Evaluation to Assess Compensatory Actions to Address Nonconforming or Degraded Conditions

Three general courses of action are available to licensees to address non-conforming and degraded conditions. Whether or not this guidance must be applied, and the focus of an activity 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 accordance with 10 CFR Part 50, Appendix B (i.e., in a timely manner commensurate with safety). This activity is not subject to an activity evaluation.

- If an interim compensatory action is taken to address the condition and involves a temporary procedure or facility change, this guidance should be applied to assess 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, an activity evaluation should be performed for the proposed corrective action, unless another regulation applies, e.g., 10 CFR 50.55a. In these cases, the final corrective action becomes the proposed change that would be subject to an activity evaluation.

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 plant. 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.

Example 1

A level transmitter for one Reactor Coolant Pump (RCP) lower oil reservoir failed while at power. The transmitter provides an alarm function, but not an automatic protective action function. The transmitter and associated alarm are described in the UFSAR, as protective features for the RCPs, but no technical specification applies. Loss of the transmitter does not result in the loss of operability for any technical specification equipment. The transmitter fails in a direction resulting in a continuous alarm in the control room. The alarm circuitry provides a common alarm for both the upper and lower oil reservoir circuits, so transmitter failure causes a hanging alarm and a masking of proper operation of the remaining functional transmitter. Precautionary measures are taken to monitor lower reservoir oil level as outlined in the alarm manual using available alternate means. An interim compensatory action is proposed to lift the leads (temporary change) from the failed transmitter to restore the alarm function for the remaining functioning transmitter.

Lifting the leads is a compensatory action (temporary change) that is subject to an activity evaluation. The activity screening would be applied to the temporary change itself (lifted leads), not the degraded condition (failed transmitter), 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, and therefore not require an activity evaluation.

4.5 Disposition of Activity Evaluations

There are two possible conclusions to an activity evaluation:

- The proposed activity may be implemented without prior NRC approval.
- The proposed activity requires prior NRC approval.

Where an activity requires prior NRC approval, the activity must be approved by 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.

For example, a modification to a facility involved the replacement of a train of a safety system with one including diverse primary components (diesel-driven pump vice a motor-driven pump). The installation of the replacement train 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 commencing the modification. The licensee prepared an activity screening to support implementing the modification 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. This guidance should be applied to any aspects of the activity not adequately 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:

- Cancel the planned activity.
- Redesign the proposed activity so that it may proceed without prior NRC approval.

- 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 plant safety at the expense of a small adverse impact in a specific area. It is the responsibility of the utility to assure that proposed activities are safe, and it is the role of NRC to confirm the safety of those activities that are determined to require prior NRC review.

5 DOCUMENTATION AND REPORTING

The following documentation and recordkeeping are required.

The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made in accordance with this guidance. 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.

1. The licensee shall submit, as specified in 10 CFR Part 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.

2. The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR Part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.

The documentation and reporting requirements contained in this guidance apply to activities that require evaluation against the nine criteria of Sections 4.3.1 through 4.3.9 and are determined not to require prior NRC approval. This pertains to those activities that were evaluated against the nine 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 specified by this guidance is not required for activities that are canceled or that are determined to require prior NRC approval and are implemented via the license amendment request process.

Documenting Activity Evaluations

In performing an activity evaluation of a proposed activity, the evaluator must address the nine criteria in Sections 4.3.1 through 4.3.9 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. 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 activity 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 activity evaluation is completeness, the items considered by the evaluator must be clearly stated.

Each activity evaluation is unique. Although each applicable criterion must be addressed, the questions and considerations listed throughout this guidance 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 activity 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 activity 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 as defined in this guidance, and thus is not subject to the recordkeeping requirements of the rule.

Reporting to NRC

A summary of activity evaluations for activities implemented under this guidance must be provided to NRC. Activities that were screened out, canceled, or implemented via license amendment need not be included in this report. The reporting requirement (every 24 months) is identical to that for UFSAR updates such that licensees may provide these reports to NRC on the same schedule.

APPENDIX A. GLOSSARY OF TERMS

Term	Acronym	Definition	Source
Anticipated Operational Occurrence	AOO	Anticipated event sequences expected to occur one or more times during the life of a nuclear power plant, which may include one or more reactors. Event sequences with mean[14] frequencies of 1×10^{-2}/plant-year and greater are classified as AOOs. AOOs take into account the expected response of all SSCs within the plant, regardless of safety classification.	NEI 18-04 Modified for TICAP
Beyond Design Basis Event	BDBE	Rare event sequences that are not expected to occur in the life of a nuclear power plant, which may include one or more reactors, but are less likely than a DBE. Event sequences with mean[14]~~[10]~~ frequencies of 5×10^{-7}/plant-year to 1×10^{-4}/plant -year are classified as BDBEs. BDBEs take into account the expected response of all SSCs within the plant regardless of safety classification.	NEI 18-04 Modified for TICAP
Complementary Design Criteria	CDC	Design criteria for NSRST SSC that are necessary to satisfy the PRA Safety Function(s) associated with the SSC. The CDC may be defined at a functional level, or more specifically addressed to the NSRST SSC specific function(s). The CDC for the NSRST SSC are directly tied to the success criteria established in the PRA for the PRA Safety Function(s) responsible for the classification of the SSC as NSRST.	NEI 21-07
Defense-in-Depth	DID	An approach to designing and operating nuclear facilities that prevents and mitigates accidents that release radiation or hazardous materials. The key is creating multiple independent and redundant layers of defense to compensate for potential human and mechanical failures so that no single layer, no matter how robust, is exclusively relied upon. Defense-in-depth includes the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures.	NRC Glossary

[14] The classification of AOOs, DBEs, and BDBEs is based on the mean frequencies of the underlying uncertainty distributions. When the uncertainty band on the frequency defined by the 95th and 5th percentiles of the distribution straddle one of the frequency boundaries, the LBEs are evaluated on each side of the boundary, per NEI 18-04. For example, if a BDBE has a 95th percentile estimate above 1×10-4 per plant year, it is treated as a DBE for the purposes of defining the RSFs and defining the DBAs.

Term	Acronym	Definition	Source
Design Basis Accident	DBA	Postulated accidents that are used to set design criteria and performance objectives for the design of SR SSCs. DBAs are derived from DBEs based on the capabilities and reliabilities of SR SSCs needed to mitigate and prevent accidents, respectively. DBAs are derived from the DBEs by prescriptively assuming that only SR SSCs classified are available to mitigate postulated accident consequences to within the 10 CFR 50.34 dose limits.	NEI 18-04
Design Basis Event	DBE	Infrequent event sequences that are not expected to occur in the life of a nuclear power plant, which may include one or more reactors, but are less likely than AOOs. Event sequences with mean[14]~~[10]~~ frequencies of 1×10^{-4}/plant-year to 1×10^{-2}/plant-year are classified as DBEs. DBEs take into account the expected response of all SSCs within the plant regardless of safety classification. The objective and scope of DBEs form the safety design basis of the plant.	NEI 18-04 Modified for TICAP
Design Basis External Hazard Level	DBEHL	A design specification of the level of severity or intensity of an external hazard for which the SR SSCs are designed to withstand with no adverse impact on their capability to perform their RSFs	NEI 18-04
Design Basis Hazard Level	DBHL	Effectively synonymous with the DBEHL term from TICAP. However, the word “external” is removed to clarify that the intent is to include internal plant hazards as well as traditional external events.	NEI 21-07
Event Sequence	ES	A representation of a scenario in terms of an initiating event defined for a set of initial plant conditions (characterized by a specified plant operating state) followed by a sequence of system, safety function, and operator failures or successes, with sequence termination with a specified end state (e.g., prevention of release of radioactive material or release in one of the reactor-specific release categories). An event sequence may contain many unique variations of events (minimal cutsets) that are similar in how they impact the performance of safety functions along the event sequence.	ASME/ANS RA-S-1.4-2021[15]

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Term	Acronym	Definition	Source
Event Sequence Family	-	A grouping of event sequences with similar challenges to the plant safety functions, response of the plant in the performance of each safety function, response of each radionuclide transport barrier, and end state. An event sequence family may involve a single event sequence or several event sequences grouped together. Each release category may include one or more event sequence families. When event sequence models are developed in great detail, identification of families of event sequences with common or similar source, initiating event and plant response facilitates application of the event sequence modeling requirements in this Standard and development of useful risk insights in the identification of risk contributors. Each event sequence family involving a release is associated with one and only one release category.	ASME/ANS-RA-S-1.4-2021[15]~~[11]~~
Frequency-Consequence Target	F-C Target	A target line on a frequency-consequence chart that is used to evaluate the risk significance of LBEs and to evaluate risk margins that contribute to evidence of adequate Defense-in-Depth	NEI 18-04
Initiating Event	IE	A perturbation to the plant during a plant operating state that challenges plant control and safety systems whose failure could potentially lead to an undesirable end state and/or radioactive material release. An initiating event is defined in terms of the change in plant status that results in a condition requiring a response to mitigate the vent or to limit the extent of plant damage caused by the initiating event. An initiating event may result from human causes, equipment failure from causes internal to the plant (e.g., hardware faults, flood, or fires) or external to the plant (e.g., earthquakes or high winds), or combinations thereof.	ASME/ANS-RA-S-1.4-2021[15]~~[11]~~
Integrated Decision-Making Process	IDP	Risk-informed and performance-based integrated decision-making (RIPB-DM) process used for establishing special treatments and evaluating the adequacy of DID.	NEI 21-07 (based on NEI 18-04)
Layers of Defense	--	Layers of defense are those plant capabilities and programmatic elements that provide, collectively, independent means for the prevention and mitigation of adverse events. The actual layers and number are dependent on the actual source and hazard posing the threat. See Defense-in-Depth.	NEI 18-04

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Term	Acronym	Definition	Source
Licensing Basis Event	LBE	The entire collection of event sequences considered in the design and licensing basis of the plant, which may include one or more reactors. LBEs include AOOs, DBEs, BDBEs, and DBAs.	NEI 18-04 Modified for TICAP
Mechanistic Source Term	MST	The characteristics of a radionuclide release at a particular location, including the physical and chemical properties of released material, release magnitude, heat content (or energy) of the carrier fluid, and location relative to local obstacles that would affect transport away from the release point and the temporal variations in these parameters (e.g., time of release duration) that are calculated using models and supporting scientific data that simulate the physical and chemical processes that describe the radionuclide inventories and the time-dependent radionuclide transport mechanisms that are necessary and sufficient to predict the source term.	ASME/ANS-RA-S-1.4-2021[15]~~[11]~~
Mitigation Function	--	An SSC function that, if fulfilled, will eliminate or reduce the consequences of an event in which the SSC function is challenged. The capability of the SSC in the performance of such functions serves to eliminate or reduce any adverse consequences that would occur if the function were not fulfilled.	NEI 18-04
Non-Safety-Related with Special Treatment SSCs	NSRST SSCs	Non-safety-related SSCs that perform risk-significant functions or perform functions that are necessary for Defense-in-Depth adequacy	NEI 18-04
Non-Safety-Related with No Special Treatment SSCs	NST SSCs	All SSCs within a plant that are neither SR SSCs nor Non-Safety-Related with Special Treatment SSCs	NEI 18-04
Performance-Based	PB	An approach to decision-making that focuses on desired objective, calculable or measurable, observable outcomes, rather than prescriptive processes, techniques, or procedures. Performance-based decisions lead to defined results without specific direction regarding how those results are to be obtained. At NRC, performance-based regulatory actions focus on identifying performance measures that ensure an adequate	Adapted from NRC Glossary definition of performance-based regulation (page updated March 9, 2021) in order to

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Term	Acronym	Definition	Source
		safety margin and offer incentives and flexibility for licensees to improve safety without formal regulatory intervention by the agency.	apply to both design decisions and regulatory decision-making
Plant	--	The collection of the site, buildings, radionuclide sources, and SSCs seeking a single design certification or one or more OLs under the LMP framework. The plant may include a single reactor unit or multiple reactor units as well as non-reactor radionuclide sources.	NEI 18-04 Modified for TICAP
PRA Safety Function	PSF	Reactor design specific SSC functions modeled in a PRA that serve to prevent and/or mitigate a release of radioactive material or to protect one or more barriers to release. In ASME/ANS-Ra-S-1.4-2013 these are referred to as "safety functions." The modifier PRA is used in NEI 18-04 to avoid confusion with safety functions performed by SR SSCs.	NEI 18-04, ASME/ANS-RA-S-1.4-2021[15]~~[11]~~
Prevention Function	--	An SSC function that, if fulfilled, will preclude the occurrence of an adverse state. The reliability of the SSC in the performance of such functions serves to reduce the probability of the adverse state.	NEI 18-04
Required Functional Design Criteria	RFDC	Reactor design-specific functional criteria that are necessary and sufficient to meet the RSFs	NEI 18-04
Required Safety Function	RSF	A PRA Safety Function that is required to be fulfilled to maintain the consequence of one or more DBEs or the frequency of one or more high-consequence BDBEs inside the F-C Target	NEI 18-04
Risk-Informed	RI	An approach to decision-making in which insights from probabilistic risk assessments are considered with other sources of insights	Adapted from NRC Glossary definition of risk-informed regulation (page updated March 9, 2021) in order to apply to both design decisions and regulatory decision-making

Term	Acronym	Definition	Source
Risk-Informed and Performance-Based Integrated Decision-Making	RIPB-DM	The union of risk information and performance information to achieve performance-based objectives	NEI 18-04
Risk-Significant LBE	--	An LBE whose frequency and consequence meet a specified risk significance criterion. In the LMP framework, an AOO, DBE, or BDBE is regarded as risk-significant if the combination of the upper bound (95th percentile) estimates of the frequency and consequence of the LBE are within 1% of the F-C Target AND the upper bound 30-day TEDE dose at the EAB exceeds 2.5 mrem.	NEI 18-04
Risk-Significant SSC	--	An SSC that meets defined risk significance criteria. In the LMP framework, an SSC is regarded as risk-significant if its PRA Safety Function is: a) required to keep one or more LBEs inside the F-C Target based on mean frequencies and consequences; or b) if the total frequency LBEs that involve failure of the SSC PRA Safety Function contributes at least 1% to any of the LMP cumulative risk targets. The LMP cumulative risk targets include: (i) maintaining the frequency of exceeding 100 mrem to less than 1/plant-year; (ii) meeting the NRC safety goal QHO for individual risk of early fatality; and (iii) meeting the NRC safety goal QHO for individual risk of latent cancer fatality.	NEI 18-04
Safety-Related Design Criteria	SRDC	Design criteria for SR SSCs that are necessary and sufficient to fulfill the RFDC for those SSCs selected to perform the RSFs	NEI 18-04
Safety-Related SSCs	SR SSCs	SSCs that are credited in the fulfillment of RSFs and are capable to perform their RSFs in response to any Design Basis Hazard Level	NEI 18-04 Modified for NEI 21-07
Safety-Significant SSC	--	An SSC that performs a function whose performance is necessary to achieve adequate Defense-in-Depth or is classified as risk-significant (see Risk-Significant SSC)	NEI 18-04

Term	Acronym	Definition	Source
Special Treatment	--	Refers to the treatments beyond those typically provided for commercial grade equipment necessary to achieve the reliability and capability targets for SSCs in the performance of safety significant functions. In Regulatory Guide 1.201, the following definition of special treatment is provided: "…special treatment refers to those requirements that provide increased assurance beyond normal industrial practices that structures, systems, and components (SSCs) perform their design-basis functions."	NEI 18-04 and Regulatory Guide 1.201

APPENDIX B. RATIONALE FOR CHANGE CONTROL CRITERIA FOR REACTORS USING NEI 18-04

Overview

This document provides guidance for change control for reactors licensed based on the risk-informed methodologies of NEI 18-04 and NEI 21-07. The approach taken follows the general framework used by current LWRs, based on the regulation 10 CFR 50.59 and the guidance document NEI 96-07. However, there are numerous differences between this approach and NEI 96-07 that are a result of the differences in the safety cases for currently-licensed LWRs and the LMP-based affirmative safety case. Those differences are in large part reflected in the evaluation criteria presented in Section 4.3 of this report. This appendix provides the rationale and explanation for the criteria used in this report.

The fundamental goal of change control for reactors following NEI 18-04 is the same as for currently operating LWRs. That goal is to identify changes to the facility that require NRC approval prior to implementation, and to ensure proper documentation of changes deemed not to require prior NRC approval. The threshold for changes requiring prior NRC approval is that the changes could substantively affect the basis used by the NRC in the initial approval of the reactor operating license or subsequent approvals of amendments to the license. In order to determine if that threshold is met, this document provides evaluation criteria which may be applied by the licensee staff to potential changes.

In addition to explaining the rationale for the evaluation criteria used for reactors following NEI 18-04, this appendix addresses each of the change control criteria for current reactors (i.e., those enumerated in 10 CFR 50.59). Some of those criteria are analogous to the criteria in Section 4.3, while others are not necessary for reactors following NEI 18-04 due to the nature of the LMP-based affirmative safety case.

Each of the criteria from Section 4.3 is presented and discussed below.

Criterion (a): LBE Frequency-Consequence (F-C) Curve

Result in a change to the frequency and/or consequences of one or more AOOs, DBEs, or BDBEs documented in the final safety analysis report (as updated) in a manner that would exceed (i) the NEI 18-04 Frequency-Consequence Target; or (ii) an NEI 18-04 Cumulative Risk Target.

With respect to the first part of the criterion, NEI 18-04 establishes the F-C Curve as a target for the evaluation of the LBEs that are derived from the plant-specific PRA (see NEI 18-04 Section 3.2.1). The consequence limits are derived from NRC regulatory dose limits and Environmental Protection Agency Protective Action Guide limits. A facility change that causes the frequency and/or consequence of an LBE to increase such that the F-C curve is exceeded is deemed to be consequential enough to require prior NRC approval.

Part (i) of this criterion is related to 10 CFR 50.59(c)(2)(i) (more than minimal increase in the frequency of occurrence of an accident) and 10 CFR 50.59(c)(2)(iii) (more than minimal increase in the consequences of an accident). However, the risk-informed NEI 18-04 methodology considers frequency and consequences in tandem, rather than individually. Also, Criterion (a) evaluates the risk of individual LBEs against the F-C curve rather than looking at the relative change in the components of risk (frequency and consequence). Thus, the risk-informed NEI 18-04 methodology enables a quantitative and holistic approach to the evaluation of changes from the standpoint of individual LBEs. Finally, Criterion (a) addresses a broader range of events than current LWRs because LBEs includes Beyond Design Basis Accidents. Note that one class of LBEs – DBAs – are not covered by this criterion but are addressed by Criterion (c).

With respect to the second part of the criterion, comparison to cumulative risk targets is an important facet of the NEI 18-04 methodology, as discussed in NEI 18-04 Section 3.3.5. Similar to exceeding the F-C Curve for an individual LBE as discussed under part (i), a change that results in exceeding the cumulative risk targets would require prior NRC approval under this criterion. The cumulative risk targets address site boundary dose as well as exclusion area boundary doses at levels derived from the Quantitative Health Objectives of the NRC Safety Goals.

Part (ii) of Criterion (a) has no analogous criterion in 10 CFR 50.59. Quantification of cumulative risk requires PRA analyses which are central to the NEI 18-04 methodology but not part of the licensing basis of current LWRs.

Criterion (b): Change in LBE Risk Significance

Change an AOO, DBE or BDBE from non-risk significant to risk significant according to NEI 18-04 LBE risk significance criteria.

NEI 18-04 establishes a quantitative criterion for the risk significance of individual AOOs, DBEs, and BDBEs, which constitute a subset of LBEs (see NEI 18-04 Section 3.3.5). This gradation among LBEs allows for a focus of regulatory review on those that present the most risk. Accordingly, it is considered appropriate for NRC to have prior approval for facility changes that would increase the population of risk-significant LBEs.

There is no analogous criterion in 10 CFR 50.59 because there is no quantitative risk associated with individual accidents in the current licensing framework. All accidents are treated in the same manner, regardless of the potential of the individual accident to impact public health and safety. However, 10 CFR 50.59(c)(2)(i) (more than minimal increase in the frequency of occurrence of an accident) and 10 CFR 50.59(c)(2)(iii) (more than minimal increase in the consequences of an accident) may be addressed by Criterion (b).

Criterion (c): DBA Consequences

Result in more than a minimal increase in the consequences of a Design Basis Accident.

Criterion (c) requires prior NRC approval if a facility change results in a more than minimal increase in the consequences of a DBA. In the NEI 18-04 methodology, DBAs are a subset of LBEs; the DBAs have no frequencies associated with them and are analogous to the accidents evaluated in Chapter 15 of a current LWR UFSAR. Thus, the DBAs in NEI 18-04 provide an important traditional deterministic component to the overall LMP-based affirmative safety case. Criterion (c) ensures that changes impacting impact DBA consequences to a more than minimal extent receive NRC review before implementation.

The first part of Criterion (c) is directly analogous to 10 CFR 50.59(c)(2)(iii) (more than minimal increase in the consequences of an accident).

Criterion (d): Risk Significant AOO, DBE, or BDBE Not Previously Evaluated

Result in identifying one or more AOOs, DBEs, or BDBEs that are (i) not previously evaluated in the UFSAR and (ii) classified as risk significant according to NEI 18-04 LBE risk significance criteria.

A new and risk significant AOO, DBE, or BDBE would be a significant perturbation to the LMP-based affirmative safety case. As noted under Criterion (b) above, risk significance is a concept specific to NEI 18-04 that provides for a gradation of AOOs, DBEs, and BDBEs. This criterion takes advantage of that aspect of NEI 18-04 to focus regulatory scrutiny (in this case, prior NRC approval) on those new LBEs that also meet the risk significant criteria discussed in NEI 18-04 Section 3.3.5.

Criterion (d) is analogous to 10 CFR 50.59(c)(2)(v), which requires prior NRC approval for changes that result in a new accident not evaluated in the UFSAR.

Criterion (e): Failure to Meet an SRDC or Change to an SRDC

Result in (i) the inability of a Safety-Related SSC to meet a Safety-Related Design Criterion as described in the FSAR (as updated) or (ii) a change to a Safety-Related Design Criterion as described in the FSAR (as updated)

The first part of Criterion (e) requires prior NRC approval if a change results in a SR SSC being unable to meet a SRDC. In the NEI 18-04 methodology, the SR SSCs are the means for accomplishing Required Safety Functions, which among other things ensure that the plant mitigates DBAs with acceptable consequences. SRDC are documented in the UFSAR and provide specific criteria that help to ensure SR SSCs function as expected. Thus, meeting the SRDC is an important facet of providing reasonable assurance of adequate protection of public health and safety, and a change that impacts the ability to meet a SRDC would require prior NRC approval.

The first part of Criterion (e) requires prior NRC approval if there is a change to a SRDC. This precludes a situation in which the licensee changes SRDC to allow the first part of Criterion (e) to be satisfied. Taken together, the two parts of Criterion (e) ensure that the required and actual performance of SR SSCs remain consistent with the understanding presented as part of the LMP-based affirmative safety case.

If the first part of Criterion (e) is satisfied, there would likely be an adverse impact on the reliability or capability of the affected SR SSC. Therefore, Criterion (e) relates to 10 CFR 50.59(c)(2)(ii) (more than a minimal increase in the likelihood of occurrence of a malfunction of an important to safety SSC) and 10 CFR 50.59(c)(2)(iv) (more than a minimal increase in the consequences of a malfunction of an important to safety SSC). Criterion (e) also relates to 10 CFR 50.59(c)(2)(vi) (possibility of a malfunction of an important to safety SSC with a different result than previously evaluated) and 10 CFR 50.59(c)(2)(vii) (result in a design basis limit for a fission product barrier being exceeded or altered).

Criterion (f): SSC Classification Change to Risk Significant

Result in an increase in the frequency and/or consequences of a malfunction of any safety-significant SSC that would change the classification of the SSC from non-risk significant to risk-significant.

NEI 18-04 uses the concept of risk significance for SSCs as well as LBEs. As with LBEs, SSC risk significance enables a focus of regulatory scrutiny on those SSCs presenting the most risk. NEI 18-04 Section 4.2.2 addresses SSC risk significance. If a facility change were to change the classification of an SSC from non-risk significant to risk significant, NRC approval would be required prior to implementation. Thus, Criterion (f) addresses risk significance for SSCs in a manner similar to the way Criterion (b) addresses risk significance for LBEs.

There is no directly analogous criterion in 10 CFR 50.59. Current LWR licensing does not incorporate the concept of risk significance for SSCs. However, Criterion (f) relates to 10 CFR 50.59(c)(2)(ii) (more than a minimal increase in the likelihood of occurrence of a malfunction of an important to safety SSC), 10 CFR 50.59(c)(2)(iv) (more than a minimal increase in the consequences of a malfunction of an important to safety SSC), and 10 CFR 50.59(c)(2)(vi) (possibility of a malfunction of an SSC with a different result than previously evaluated).

Criterion (g): Change in SR SSC Classification

Result in a change of any SSC from (i) No Special Treatment to Safety-Related; or (ii) Non-Safety Related with Special Treatment to Safety-Related; or (iii) Safety-Related to Non-Safety Related with Special Treatment; or (iv) Safety-Related to No Special Treatment.

NEI 18-04 identifies a subset of SSCs to be SR. SR SSCs are selected because they (i) perform RSFs that mitigate the consequences of DBEs within the F-C Target, (ii) mitigate DBAs such that they meet 10 CFR 50.34 dose limits, or (iii) perform RSFs that prevent a BDBE frequency from increasing into the DBE region if its consequences would exceed the F-C Target for that region.

Parts (i) and (ii) of Criterion (g) requires prior NRC approval if a facility change results in a reclassification “upward” of an SSC to SR. Such a reclassification implies a need for augmented SSC performance to accomplish an RSF or mitigate a DBA, and this kind of modification to the LMP-based affirmative safety case should be done only with prior NRC approval.

Parts (iii) and (iv) of Criterion (g) require prior NRC approval if a facility change results in a reclassification “downward” of an SSC to NSRST or NST. Reclassification “downward” of one or more SSCs may be construed as a reduction in safety margin, and it is a perturbation of the LMP-based affirmative safety case that should not be done without prior NRC approval.

Criterion (h): Defense-in-Depth Adequacy

Result in a change to the performance of a safety-significant SSC that would change the overall evaluation of defense-in-depth adequacy.

Defense-in-depth is an important facet of the NEI 18-04 methodology, as discussed in NEI 18-04 Chapter 5. Relative to current LWRs, the implementation of defense-in-depth is very different for reactors licensed under NEI 18-04. Initial licensing will include a determination that defense-in-depth is adequate. Should a facility change impact that conclusion in an adverse manner, prior NRC approval is required.

Current LWRs handle defense-in-depth much differently than reactors licensed under NEI 18-04, which outlines a systematic process for establishing and documenting adequate defense-in-depth. For the current reactor fleet, regulatory requirements for defense-in-depth primarily originate in the General Design Criteria (10 CFR Part 50 Appendix A). Thus, there are no criteria in 10 CFR 50.59 that are directly analogous to Criterion (h). However, Criterion (h) relates to 10 CFR 50.59(c)(2)(ii) (more than a minimal increase in the likelihood of occurrence of a malfunction of an important to safety SSC) and 10 CFR 50.59(c)(2)(iv) (more than a minimal increase in the consequences of a malfunction of an important to safety SSC). Criterion (h) also relates to 10 CFR 50.59(c)(2)(vi) (possibility of a malfunction of an SSC with a different result than previously evaluated) and 10 CFR 50.59(c)(2)(vii) (result in a design basis limit for a fission product barrier being exceeded or altered).

Criterion (i): Departure from a Method of Evaluation Described in the FSAR

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

Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and that the facility response to accidents and events is acceptable. For reactors following NEI 18-04, the focus is on those methods described in the UFSAR and used for the analysis of DBAs (which are analogous to Chapter 15 events for current LWRs) and to show that safety significant SSCs are capable of withstanding design basis hazards such as earthquakes and floods. Section 4.3.9 provides guidance on determining if departures from such analytical methods require prior NRC approval.

Criterion (i) is analogous to 10 CFR 50.59(c)(2)(viii) except in one regard. Reactors with an LMP-based affirmative safety case use the plant PRA for a subset of the LBEs, i.e., AOOs, DBEs, and BDBEs. Methods of analysis used solely for those LBEs are addressed under PRA change control processes.

Commented [A25]: Still not clear how changes to inputs/assumptions used in LBE analysis would be properly screened for prior NRC review by the PRA change control process. This comment relates to the very first comment regarding a PRA change control process document.

10 CFR 50.59 Evaluation Criteria

The intent of the change control in Section 4.3 was not to attempt to replicate the criteria in 10 CFR 50.59. The safety case for a reactor following NEI 18-04 is fundamentally different from the safety case for a current LWR. In fact, the systematic nature of the analyses and documentation for reactors following NEI 18-04 is well-suited toward certain straightforward change control criteria that are not feasible to apply to current LWRs.

In this section, each 10 CFR 50.59 evaluation criterion is mapped to Section 4.3 criteria that may accomplish some or all of the goals associated with the 50.59 evaluation criterion. The purpose of the mapping is to provide insight into how the respective criteria accomplish similar goals through different methods. The results of the analysis are summarized in the following table.

10 CFR 50.59(c)(2) Criterion	Relationship to Criteria for Reactors Using NEI 18-04
(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);	Changes to risk (frequency times consequences) associated with AOOs, DBEs, and BDBEs are addressed through: • Criterion (a) - LBE Frequency-Consequence (F-C) Curve • Criterion (b) - Change in LBE Risk Significance

10 CFR 50.59(c)(2) Criterion	Relationship to Criteria for Reactors Using NEI 18-04
(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);	Changes to risk (frequency times consequences) associated with a non-risk significant but safety significant SSC are addressed through: • Criterion (f) - SSC Classification Change to Risk Significant Changes to SSC ability to accomplish design functions are addressed through: • Criterion (e) - Ability of SSCs to Meet SRDC • Criterion (h) - Defense-in-Depth Adequacy
iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);	Changes to risk (frequency times consequences) associated with AOOs, DBEs, and BDBEs are addressed through: • Criterion (a) - LBE Frequency-Consequence (F-C) Curve • Criterion (b) - Change in LBE Risk Significance Changes to DBA consequences are addressed through: • Criterion (c) DBA Consequences
(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);	Changes to risk (frequency times consequences) associated with a non-risk significant but safety significant SSC are addressed through: • Criterion (f) - SSC Classification Change to Risk Significant Changes to SSC ability to accomplish design functions are addressed through: • Criterion (e) – Ability of SSCs to meet SRDC • Criterion (g) - Change in SSC classification to or from SR • Criterion (h) - Defense-in-Depth Adequacy
v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);	Changes that lead to an AOO, DBE, or BDE not previously evaluated in the UFSAR are addressed through: • Criterion (d) - Risk Significant AOO, DBE, or BDBE Not Previously Evaluated

10 CFR 50.59(c)(2) Criterion	Relationship to Criteria for Reactors Using NEI 18-04
vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);	Changes to risk (frequency times consequences) associated with a non-risk significant but safety significant SSC are addressed through: • Criterion (f) - SSC Classification Change to Risk Significant Changes to SSC ability to accomplish design functions are addressed through: • Criterion (e) – Ability of SSCs to meet SRDC • Criterion (g) - Change in SSC classification to or from SR Criterion (h) - Defense-in-Depth Adequacy
vii) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered;	NEI 18-04 uses a layers of defense approach that does not elevate fission product barriers above other SSCs. With that being said, changes to SSC ability to accomplish design functions (such as retention of fission products) are addressed through: • Criterion (c) (second part) - Ability of SSCs to Meet SRDC • Criterion (h) - Defense-in-Depth Adequacy
viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.	Changes that would result in a departure from a method of evaluation described in the FSAR (as updated) are addressed by: • Criterion (i) - Departure from a Method of Evaluation Described in the FSAR

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