Southern Company

Technology Inclusive Risk Informed Change Evaluation (TIRICE)
For Non-Light Water Reactors

Change Control Scope and Process
For a Reactor Licensed in Accordance with the NEI 18-04 Guidance

Document Number
SC-16166-107
Revision ~~B~~D

Battelle Energy Alliance, LLC
Contract No. 221666
SOW-16166

~~May~~July 2022

Prepared for:
U.S. Department of Energy (DOE)
Office of Nuclear Energy
Under DOE Idaho Operations Office
Contract DE-AC07-05ID14517

Technology Inclusive Risk Informed Change Evaluation (TIRICE)
For Non-Light Water Reactors

Change Control Scope and Process
For a Reactor Licensed in Accordance with the NEI 18-04 Guidance

Document Number
SC-16166-107
Revision ~~B~~D

Battelle Energy Alliance, LLC
Contract No. 221666
SOW-16166

Issued for Collaborative Review by:

____ ________________________

Amir Afzali, Next Generation Licensing and Policy Director Date
Southern Company Services

Disclaimer

Abstract

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 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 paper provides supplemental guidance for determining if NRC approval is required before implementing certain facility changes to advanced 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 an exemption, in part, to 10 CFR 50.59, this guidance should allow advanced reactor licensees to implement appropriate change control programs for the operation of their reactors.

Commented [A1]: The term "non-LWRs" was replaced throughout the document with the word "advanced". However, the cover page still refers to "non-LWRs". The NRC understands that Is TIRICE intended to be applicable to non-LWRs only at this time, so should all cases of "advanced reactors" be changed to "non-LWRs"?

Table of Contents

Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.
Error! Hyperlink reference not valid.

Error! Hyperlink reference not valid.

Error! Hyperlink reference not valid.

1.0 Introduction 1

1.1 Purpose and Scope 1

1.2 Regulatory Approach 2

1.3 Background .... 3~~2~~

1.3.1 NEI 96-07 "Guidelines for 10 CFR 50.59 Implementation" .... 3~~2~~

1.3.2 NEI 18-04 "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development" .... 5~~4~~

1.3.3 NEI 21-07 "Technology Inclusive Guidance for Non-Light Water Reactors - Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology" .... 6~~5~~

1.4 Application of this Guidance .... 7~~6~~

2.0 NEI 96-07 Introductory Material .... 9~~8~~

2.1 Introduction (NEI 96-07 Section 1.0) .... 9~~8~~

2.2 Defense-in-Depth Design Philosophy and 10 CFR 50.59 (NEI 96-07 Section 2.0) .... 9~~8~~

2.3 Definitions and Applicability of Terms (NEI 96-07 Section 3.0) .... 10~~9~~

2.3.1 Accident Previously Evaluated in the FSAR (as Updated) (NEI 96-07 Section 3.2) .... 10~~9~~

2.3.2 Change (NEI 96-07 Section 3.3) .... 10~~9~~

2.3.3 Malfunction of an SSC Important to Safety (NEI 96-07 Section 3.9) .... 11~~10~~

2.3.4 Safety Analyses (NEI 96-07 Section 3.12) .... 11~~10~~

3.0 Implementation Guidance .... 12~~11~~

3.1 Applicability (NEI 96-07 Section 4.1) .... 15~~12~~

3.1.1 Applicability to Licensee Activities (NEI 96-07 Section 4.1.1) .... 16~~12~~

3.1.2 Maintenance Activities (NEI 96-07 Section 4.1.2) .... 16~~12~~

3.1.3 UFSAR Modifications (NEI 96-07 Section 4.1.3) .... 16~~12~~

3.1.4 Changes to Procedures Governing the Conduct of Operations (NEI 96-07 Section 4.1.4) .... 16~~12~~

3.1.5 Changes to Approved Fire Protection Programs (NEI 96-07 Section 4.1.5) .... 16~~12~~

3.1.6 Changes to the Probabilistic Risk Assessment (PRA) .... 16~~13~~

3.1.7 Changes to the State of Knowledge .... 17~~13~~

3.2 Screening .... 18~~14~~

3.2.1 Change to the Facility or Procedures as Described in the UFSAR (NEI 96-07 Section 4.2.1) .... 18~~14~~

3.2.2 Changes to the Facility as Described in the UFSAR (NEI 96-07 Section 4.2.1.1) .... 19~~15~~

3.2.3 Changes to Procedures as Described in the UFSAR (NEI 96-07 Section 4.2.1.2) .... 19~~15~~

3.2.4 Changes to UFSAR Methods of Evaluation (NEI 96-07 Section 4.2.1.3) .... 19~~15~~

3.2.5 Test or Experiment Not Described in the UFSAR (NEI 96-07 Section 4.2.2) .... 19~~15~~

3.3 Evaluation .... 20~~16~~

3.3.1 Evaluation Criteria .... 20~~16~~

3.3.2 Evaluation Process .... 26~~21~~

4.0 Documentation and Reporting (NEI 96-07 Section 5.0) .... 31~~26~~

5.0 Summary .... 32~~27~~

Appendix A Probabilistic Risk Assessment A-1

Appendix B Terminology and Definitions B-1

List of Abbreviations

AOO	Anticipated Operational Occurrence
ARCAP	Advanced Reactor Content of Application Project
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
BDBE	Beyond Design Basis Event
DBA	Design Basis Accident
DBE	Design Basis Event
CFR	Code of Federal Regulations
COL	Combined construction and operating license
CP	Construction Permit
DBE	Design Basis Event
DID	Defense-in-Depth
FSAR	Final Safety Analysis Report
LBE	Licensing Basis Event
LMP	Licensing Modernization Project
LWR	Light water reactor
NEI	Nuclear Energy Institute
non-LWR	Non-light water reactor
NRC	Nuclear Regulatory Commission
NSRST	Non-Safety-Related with Special Treatment
NUREG	Nuclear Regulatory Commission technical report designation
~~PDC~~OL	~~Principal Design Criteria~~Operating license
PRA	Probabilistic Risk Assessment
SAR	Safety Analysis Report
SR	Safety-Related
SSCs	Structures, Systems, and Components
UFSAR	Updated Final Safety Analysis Report

Commented [A2]: The acronym COL is typically used to refer to a "combined license", which is a defined term in 10 CFR 52.1 for a "combined construction permit and operating license with conditions for a nuclear power facility issued under subpart C of [part 52]." It would be better to use "combined license" as the term corresponding to the acronym COL.

1.0 INTRODUCTION

1.1 Purpose and Scope

The purpose of this paper is to describe a proposed process for determining if prior regulatory approval is necessary for changes to certain advanced reactors licensed for power production and/or other uses under 10 CFR Part 50 or to 10 CFR Part 52 for a ~~COL~~combined construction and operating license (COL) without an associated design certification or an early site permit. The process is applicable only to advanced reactor licensees that implemented NEI 18-04, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," consistent with Regulatory Guide 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." The NEI 18-04 methodology is also referred to as the Licensing Modernization Project (LMP) methodology.

10 CFR 50.59 (also applicable to 10 CFR Part 52) permits licensees to make changes to the facility without prior Nuclear Regulatory Commission (NRC) approval, provided the requirements in the regulation are met. Change control guidance is mature and in place for currently-operating light water reactors (LWRs~~.~~). However, the existing change control guidance is tailored for the physical characteristics of LWRs and the terminology and approach of a traditional, deterministically-derived safety case. Advanced reactors may elect to follow NEI 18-04 for selection of licensing basis events (LBEs); safety classification of structures, systems, and components (SSCs) and associated special treatments; and determination of Defense-in-Depth (DID) adequacy. The resulting LMP-based affirmative safety case is substantially different from the traditional deterministic, compliance-based safety cases in place for LWRs licensed by NRC. The attributes of the LMP-based affirmative safety case require additional guidance for efficient application of 10 CFR 50.59

The objectives of this guidance include:

- Provide regulatory confidence that the threshold for regulatory review of changes to the facility as described in the final safety analysis report (FSAR) (as updated) will be effectively established and efficiently managed
- Minimize the ~~unnecessary~~ burden to the regulator and operators for determining if changes require a license amendment
- 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

Licensees that follow NEI 18-04 and RG 1.233 are also expected to conform to NEI 21-07, "Technology Inclusive Guidance for Non-Light Water Reactors – Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology~~.~~" and DG 1404. The NEI 18-04 methodology relies on information from a comprehensive probabilistic risk assessment (PRA), and the NEI 21-07 guidance anticipates that for non-LWRS the PRA will conform to

Commented [A3]: The word "to" here should probably be "under" in order to match the usage with "licensed ... under 10 CFR Part 50 ..." as extended to "licensed ... under 10 CFR Part 52...."

In addition, it would be better to use the defined term "combined licenses (COLs)" from 10 CFR 52.1 rather than "combined construction and operating license", which omits the word "permit" and reference to the potential for conditions included in the 52.1 definition. Suggest the use in the plural rather than the singular to match the usage of "certain advanced reactors" earlier in the sentence as it would not make sense to have multiple ones licensed under a single COL.

Commented [A4]: This might be better as "facilities" to match the usage of "licensees" earlier in the sentence.

Commented [A5]: Consider using "conditions" rather than "requirements".

Commented [A6]: This phrasing indicates that this is an open list that might have other objectives as well. Is that the intent?

Commented [A7]: This might be better focused on confidence in the implementation of the threshold for NRC approval of changes to the facility. Even changes that a licensee is permitted to make without obtaining a license amendment undergo a regulatory review, though that review is accomplished by the licensee and periodically reported to the NRC and overseen by inspection rather than by an NRC licensing action. It's also not entirely clear what is meant by "regulatory confidence".

Commented [A8]: The sentence conveys the idea just as well if "unnecessary" is deleted.

Commented [A9]: For completeness add reference to RGs.

Commented [A10]: Is the use of "licensees" correct here? It is a bit odd to have an expectation that licensees will conform to guidance for applicants. The idea that this document is applicable to licensees that follow NEI 18-04, NEI 21-07 and ASME/ANS RA-S-1.4-2021 is captured by the final sentences of this paragraph, so this sentence may not be necessary.

ANSI/ASME/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). The guidance in this white paper 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 advanced LWR would need to address its approach for its PRA.

Commented [A11]: This sentence also seems unnecessary given the limitations expressed in the remainder of the paragraph.

NEI 21-07 provides guidance for developing advanced reactor SARs for certain licensing pathways: 10 CFR Part 52 ~~combined construction and operating license (COL)~~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 white paper does not address the design certification pathway, so its scope is limited to the 10 CFR Part 52 COL (no design certification or early site permit) and the 10 CFR Part 50 CP/OL.

10 CFR 50.59 is only one of many processes that apply to nuclear power reactors. The regulation addresses the retention of records of changes and the need for prior NRC approval for certain changes to a facility that is licensed under 10 CFR Part 50 or 10 CFR Part 52. Other regulatory processes address areas such as operability, reportability, corrective action, and changes in the state of knowledge.

Commented [A12]: 10 CFR 50.59 is a regulation, not a process. In any case, it isn't entirely clear what value this paragraph as a whole is intended to add to the discussion.

Commented [A13]: It also addresses the maintenance of records of all changes whether requiring prior NRC approval or not.

This paper supports the Technology Inclusive Risk Informed Change Evaluation (TIRICE) Project, which will produce a change control guidance document for advanced reactors implementing the NEI 18-04 methodology. TIRICE is a follow-on activity to the Technology Inclusive Content of Application Project or TICAP, which led to the development of NEI 21-07. An additional follow-on project is planned to address broader aspects of change control for advanced reactors beyond the regulatory process associated with 10 CFR 50.59.

Commented [A14]: This sentence reflecting a future action would need to be removed from the version submitted to NRC for TIRICE endorsement.

1.2 Regulatory Approach

~~At this point, two options are being considered for the incorporation of this~~This new guidance ~~into the regulatory framework. The first option is to utilize this guidance to interpret the application of 10 CFR 50.59 for advanced~~ will be applied to proposed changes that may impact the licensing basis of reactors that were licensed using the ~~methodologies in~~ methodology of NEI 18-~~-~~04. ~~This supplemental guidance would be used in conjunction with existing guidance in NEI 96-07 to comply with the existing 10 CFR 50.59 regulation. This~~ It is anticipated that this approach ~~should allow advanced reactor licensees to implement appropriate change control programs for the operation of their reactors, and it would require no additional enabling regulatory actions. The second option is functionally equivalent to the first, i.e., to use this guidance in conjunction with the existing guidance in NEI 96-07 for implementation of change control programs. However, the second option would~~will be ~~invoked by~~implemented via a condition ~~that can be~~ incorporated into the operating license, likely coupled with an exemption under 10 CFR 50.12 to the applicability, in whole or in part, of 10 CFR 50.59. ~~Recommendations on the regulatory approach will be provided outside of this paper and following discussions with NRC.~~

1.3 Background

1.3.1 NEI 96-07 "Guidelines for 10 CFR 50.59 Implementation"

10 CFR 50.59 is a lynchpin in the current regulatory framework supporting the operation of the nuclear power plant fleet. It determines the regulatory threshold for when NRC must review and approve a proposed change to the facility before its implementation.

Expanding upon that purpose, 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.

The 10 CFR 50.59 rule was initially promulgated in 1962. However, by 1999 numerous opportunities for improvement had been identified. As such, the regulation underwent a major revision in 2000. The purposes of this revision were to:

- Establish clear definitions to promote a common understanding of the rule's requirements
- Clarify the criteria for determining when changes, tests, and experiments require prior NRC approval
- Provide greater flexibility to licensees, primarily by allowing changes that have minimal safety impact to be made without prior NRC approval
- Clarify the threshold for "screening out" changes that do not require full evaluation under 10 CFR 50.59, primarily by the adoption of key definitions

Significant changes to the regulation included clarification of many fundamental concepts, insertion of the word "minimal" into the evaluation of impacts, and incorporation of the concept of screening into the regulation.

In order to ensure effective and consistent implementation of this expansive change, NRC Regulatory Guide 1.187, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, And Experiments,'" was issued in 2000 and linked to the rule's implementation. Regulatory Guide 1.187 has been revised three times since being issued, most recently in June 2021. In addition, NRC endorsed NEI 96-07, an industry guidance document addressing change control, and focused on the 2000 revision of 10 CFR 50.59.

NEI 96-07 provides detailed guidance for the three major sub-processes that comprise the larger 10 CFR 50.59 process as it applies to LWRs. These sub-processes are applicability determination, screening, and evaluation.

The applicability determination sub-process addresses a provision of the 2000 revision that excludes proposed changes controlled by other, more specific regulations. This provision ensures that 10 CFR 50.59 is applied to proposed activities for which it is suited and allows the entire spectrum of regulations to more effectively control other activities. As an example, consistent with this provision, 10 CFR 50.59 would not be applied to any aspect of corrective action.

Commented [A15]: This misstates the outcome somewhat - 50.59 sets the threshold for when the NRC must issue a license amendment before the implementation of a change, test, or experiment.

Commented [A16]: This should be "obtaining a license amendment" rather than "prior NRC approval". There are some change control processes that could be satisfied by prior NRC approval rather than license amendment.

Commented [A17]: *General comment:* this document continues to misstate the regulation's determination of whether or not a license amendment is needed. This might be a minor issue, but RG 1.187 follows the wording in 50.59

Commented [A18]: Should a revision number be added here?

Commented [A19]: Is this example necessary to the discussion? Have we validated that it is true in all cases for any aspect of corrective action?

The screening sub-process provides for an upfront determination that an activity has no potential for requiring prior NRC review and approval. Activities that are "screened out" do not have to undergo the more resource-intensive evaluation process.

The evaluation sub-process is a more detailed review and evaluation of proposed activities that "screen in." The evaluation sub-process implements the 10 CFR 50.59(c)(2) criteria for evaluating the need for prior NRC review and approval for an activity. It involves addressing specific questions associated with the licensing basis of the facility and is structured around the licensing framework as described below.

As defined at the outset, 10 CFR 50.59 defines a regulatory threshold for obtaining prior NRC review and approval of proposed changes. As such, its structure replicates the licensing framework of the affected facilities. Specifically, this means that 10 CFR 50.59 is oriented around preserving these three licensing fundamentals:

1. The assumptions concerning the initiation, both frequency and type, of design basis events

2. The reliability and effectiveness of the mitigation systems

3. The acceptability of consequences (dose) by limiting increases in the dose results of the postulated design basis events

NEI 96-07 also has five appendices attached to the base document. A summary of each is provided below.

- Appendix A—The appendix consists of the text of 10 CFR 50.59.
- Appendix B—This appendix addresses the application of an analogous regulation for independent spent fuel storage installations (10 CFR 72.48). Appendix B has been superseded by NEI 12-04, "Guidelines for 10 CFR 72.48 Implementation."
- Appendix C—This appendix provides guidance for applying 10 CFR 50.59 to facilities licensed under 10 CFR 52. Regulatory Guide 1.187 now states that Appendix C is "… acceptable for use by licensees during formal NRC endorsement via the NRC's regulatory guide process."
- Appendix D—This appendix provides very specific guidance for applying 10 CFR 50.59 to digital modifications. This guidance builds upon the guidance contained in NEI 96-07 and is intended to be used in conjunction with the base document. Appendix D was endorsed in Revision 2 of Regulatory Guide 1.187 in June 2020.
- Appendix E—This appendix provides user guidance for 16 specific situations that are commonly encountered. It uses existing guidance from NEI 96-07 to address these situations. The appendix has not been formally endorsed by NRC.

Commented [A20]: Consider using "... as described in the following paragraphs..." rather than "below" because this word appears at the bottom of the page.

Commented [A21]: 50.59 defines criteria under which a licensee may implement changes, tests, and experiments without obtaining a license amendment and does not define a threshold for obtaining NRC review and approval of proposed changes.

Commented [A22]: This statement is unclear as to its meaning/intent.

Commented [A23]: While perhaps accurately reflecting the quotation in RG 1.187, it is a quote from the original letter (ML14113A529). This discussion would be could improved by quoting the original letter instead.

Commented [A24]: This is misleading - RG 1.187, revision 2, endorsed appendix D with clarifications as did RG 1.187, revision 3.

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

NEI 18-04 Revision 1 (August 2019) presents a technology-inclusive, risk-informed, and performance-based process for selection of LBEs; safety classification of SSCs and associated risk-informed special treatments; and determination of DID adequacy for advanced reactors including, but not limited to, molten salt reactors, high-temperature gas cooled reactors, and a variety of fast reactors at all thermal power capacities. NRC endorsed the methodology in Regulatory Guide 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" (June 2020).

Commented [A25]: It might be worth standardizing the method of citing references as well as including a listing of them.

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

- PRA plays a central role in the identification of LBEs, quantification of their frequency and consequences, and evaluation of their risk significance.
- 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.
- DBAs are defined using a set of deterministic rules that include the identification of Required Safety Functions. DBAs are derived from DBEs but rely upon only Safety-Related (SR) SSCs for performance of the Required Safety Functions, and the DBAs are evaluated conservatively with consequences compared against the same dose criteria applied to LWR DBAs.
- The remaining LBEs (AOOs, DBEs, and BDBEs) are evaluated as part of the PRA, using realistic assumptions and inputs consistent with the Non-LWR PRA Standard.
- A systematic process is used to ensure that plant capabilities and programs are sufficient to enable SSCs and associated human actions to perform safety-significant functions that

- provide adequate DID.
- Light water reactor general design criteria from 10 CFR 50 Appendix A, including the single failure criterion, are not imposed on the design. However, as discussed in DG 1404, each applicant using the methodology described in NEI 18-04 and NEI 21-07 must develop a set of design-specific Principal Design Criteria (PDCs) to define the safety attributes of the design. Reliability and capability targets and ~~defense-in-depth~~DID are used in lieu of the single failure criterion to ensure that SSCs and supporting human actions provide reasonable assurance of adequate protection of public safety. Therefore, redundancy and diversity are not required in the traditional sense, but they may be used by the designer to meet the performance targets.

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

1.3.3 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 (February 2022) describes one acceptable means of developing portions of the Safety Analysis Report (SAR) content for advanced reactor applicants that utilize NEI 18-04. The guidance describes eight chapters of an advanced reactor 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 methodology 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.
- 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 the analytical details are in the PRA design records rather than the SAR.

NRC is in the process of generating a regulatory guide that will address the acceptability of using NEI 21-07 to develop portions of an advanced reactor SAR. NRC also plans to issue guidance for developing the remaining portions of the SAR (i.e., those portions not covered by NEI 21-07)

Commented [A26]: There appears to be an extra carriage return in the middle of this bullet that resulted in separating this portion as a separate bullet.

Commented [A27]: The GDCs are not limited to LWRs - they are applicable to all water-cooled nuclear power plants (see Appendix A Introduction)

Commented [A28]: Should mention PDCs and consider them in any change control decision (see Table 1). Consider referencing 50.34(a)(3) as well.

Commented [A29]: There is no such thing.

Commented [A30]: This parenthetical muddies the waters because 50.59 is not applicable to DCs. Does it need to be here?

Commented [A31]: This characterization is better left to the NRC to make as discussed in the first sentence below the bulleted list of attributes on this page.

Commented [A32]: It may be better for this document to describe events/activities that are controlled by industry, and not directly discuss what the NRC plans are. For example, this could be phrased as a discussion somewhere that NEI 21-07 was developed as industry input for the development of a regulatory guide on the subject. Similarly, the discussion of the ARCAP could be set up as on NEI participation in discussions with the NRC to support the development of guidance.

and for other elements of a license application as part of its Advanced Reactor Content of Application Project (ARCAP).[1]

1.4 Application of this Guidance

Sections 2, 3, and 4 of this document provide change control guidance for advanced reactors following NEI 18-04 and NEI 21-07. The guidance in this white paper is based on the existing change control guidance in NEI 96-07~~,~~ with appropriate additions and adjustments~~ as provided herein~~.

Section 2 of this document addresses the introductory material in Sections 1, 2, and 3 of NEI 96-~~-~~07.

Section 3 of this document addresses the implementation guidance in NEI 96-07 Section 4. This section covers the three major areas of applicability, screening, and evaluation.

Section 4 of this document addresses documentation and reporting as covered in NEI 96-07 Section 5.

Section 5 of this document provides an overall summary.

In applying this guidance, it is important to keep in mind the purposes of the relevant guidance documents and the relationships among them.

- NEI 18-04 provides guidance for the development and maintenance of the LMP-based affirmative safety case.
- NEI 21-07 provides guidance for the documentation of the LMP-based affirmative safety case and thereby the establishment of the plant licensing basis.
- This white paper addresses the evaluation of changes to the facility once the LMP-based affirmative safety case has been baselined, documented, and approved by the NRC.
- In addition to establishing the LMP-based affirmative safety case described in the initial license application, NEI 18-04 is also relevant to evaluating changes to the facility and the resulting impacts on the ~~LMP-based affirmative~~ safety case.

The general process that would be followed for facility changes is outlined below.

- Prior to performing an evaluation of a proposed facility change to determine if it requires prior NRC review and approval (i.e., 10 CFR 50.59 or an approved alternative process), the licensee would evaluate the proposed change to determine its impact on the LMP-

Commented [A33]: The discussion shifts from the plant licensing basis in the second bullet to changes to the facility in the third bullet. Continuity of the discussion would be improved by aligning the terms being used.

Commented [A34]: This discussion doesn't seem to recognize that there are changes to a facility for which 50.59 is inapplicable because of the existence of other more specific change processes (e.g., 50.54(p) and (q), 50.150, etc.).

[1] Slides from the February 25, 2021, NRC Advanced Reactor Stakeholder Meeting provide information on the ARCAP project and its relationship to NEI 21-07. See ML21055A541 pp. 91-105.

based affirmative safety case. This evaluation would be based on the NEI 18-04 methodology.

- The change would not proceed "as is" if it would involve unacceptable impacts on plant safety.[1]

- In some cases, the licensee will identify other compensating facility changes to maintain risk at an acceptable level and to maintain ~~defense-in-depth~~DID adequacy.

- Once this technical evaluation is complete, if the change is deemed warranted the licensee would proceed with a licensing screening and evaluation of the proposed change, using the criteria outlined in this white paper, to determine if prior approval of the change by the NRC is needed.

- If prior NRC approval is determined to be necessary, the licensee would develop, submit and obtain NRC approval of a license amendment prior to implementing the change.

- If prior approval is determined not to be necessary, the licensee would proceed with the change and make the associated changes to licensing basis documentation and plant records.

Commented [A35]: 18-04 and 21-07 do not prescribe a process for making changes so what process would describe the need for this step? So how much of 21-07 would need to be repeated for a given change?

Commented [A36]: As laid out in this discussion, the technical evaluation of the proposed change would seem to be accomplished in all cases before the determination of applicability of 50.59, resulting in the licensee knowing the impact on the overall risk of, for example, changes to the Emergency Preparedness plans or the Security Plans. Would that be used as an input to the determination of reduction of effectiveness under the change control schemes for those items?

This would be an important consideration because those change control schemes do not have the same "more than minimal" criteria. I am not certain whether there would be a direct one-to-one correspondence between the PRA result changes on the F-C plot (if there are such changes) and the potential reductions in (safeguards) effectiveness for a change to the Emergency Preparedness (Security) Plans. If there isn't a relationship in mind, it might make sense to perform the applicability check before the technical evaluation.

Commented [A37]: This discussion of performing a technical evaluation of a proposed change to determine its impact on the LMP-based "affirmative safety case" is not supported by the process as laid out in the implementation section of this document (Section 3). To be more specific, the first block of Figure 1 is "identify proposed activity", then it proceeds to "is 50.59 applicable". Shouldn't the impact on the safety case be evaluated between these two blocks? One can't evaluate impacts without identifying the proposed activity. Also, is Figure 1 the only location where this step should appropriately referenced or applied?

Commented [A38]: What is considered an unacceptable impact and how does it relate to "minimal increase" in 50.59 or "minimal adverse effect" as used below with respect to DID?

[1] Note that there are other considerations associated with a plant change such as impact on plant availability, cost, and environmental impacts that could influence the licensee decision on whether or not to proceed with the change.

2.0 NEI 96-07 INTRODUCTORY MATERIAL

2.1 Introduction (NEI 96-07 Section 1.0)

The information in NEI 96-07 Section 1.0 is applicable to reactors with an LMP-based affirmative safety case licensed under 10 CFR Part 50 or 10 CFR Part 52.

2.2 Defense-in-Depth Design Philosophy and 10 CFR 50.59 (NEI 96-07 Section 2.0)

Section 2.0 of NEI 96-07 discusses the philosophy of DID for LWRs, the role of the General Design Criteria for LWRs documented in 10 CFR 50 Appendix A, and the importance of the updated final safety analysis report (UFSAR) accident analyses.

The NEI 96-07 Section 2.0 discussion of DID is not directly relevant to an advanced reactor with an LMP-based affirmative safety case. There are important differences between the treatment of DID in 10 CFR 50.59 and NEI 96-07, on the one hand, and the NEI 18-04 definition and evaluation of DID, on the other. The former focuses on the performance of fission product barriers, including fuel, coolant pressure boundary, and containment. The three-barrier LWR DID model is specific to the current generation LWR technology and may not apply to advanced reactor designs. In contrast, NEI 18-04 uses a layers-of-defense concept that addresses plant capabilities, programs, and a risk-informed, performance-based evaluation of DID.

The 10 CFR 50 Appendix A, General Design Criteria are written explicitly for LWRs and are not applicable to advanced non-LWRs. Principal Design Criteria for LWRs are generally derived from 10 CFR 50 Appendix A. In contrast, for advanced non-LWRs, NEI 21-07 SAR Chapter 5 describes a systematic approach for deriving Principal Design Criteria. Therefore, the discussion of General Design Criteria in NEI 96-07 Section 2.0 is not applicable to advanced reactors that ~~conform~~follow to NEI 21-07.

NEI 96-07 states, “The UFSAR presents the set of limiting analyses required by NRC.” Typically, these analyses are deterministic in nature and follow the NRC’s Standard Review Plan for LWR accident analyses. In contrast, NEI 18-04 provides for a systematic approach to developing LBEs for advanced reactors.

The fundamental conclusion of NEI 96-07 Section 2 is that:

> Changes to plant design and operation and conduct of new tests and experiments have the potential to affect the probability and consequences of accidents, to create new accidents and to impact the integrity of fission product barriers. Therefore, these activities are subject to 10 CFR 50.59.

As discussed above, there are a number of elements of NEI 96-07 Section 2 that are not applicable to advanced reactors. However, the fundamental conclusion of the section holds for advanced reactors, with one caveat. Reactors with an LMP-based affirmative safety case use a layers-of-defense approach to safety that is more holistic than the LWR approach, which focuses on three fission product barriers to provide DID. From a practical standpoint, this requires an adjustment to how the 10 CFR 50.59(c)(2)(vii) criterion related to fission product barriers is implemented. The adjustment is addressed in Section 3.3.1.

2.3 Definitions and Applicability of Terms (NEI 96-07 Section 3.0)

The definitions and applicability criteria presented in NEI 96-07 Section 3.0 are applicable to reactors with an LMP-based affirmative safety case, with the caveats and clarifications provided below. These caveats and clarifications should be applied to all phases of implementation guidance (applicability, screening, and evaluation).

2.3.1 Accident Previously Evaluated in the FSAR (as Updated) (NEI 96-07 Section 3.2)

Reference is made in the definition of "accidents, such as those typically analyzed in FSAR Chapters 6 and 15 of the UFSAR …." That is appropriate for a currently-operating LWR, but NEI 21-07 provides an alternate organization of material for a reactor with an LMP-based affirmative safety case. The appropriate reference for a reactor following NEI 18-04 would be to SAR Chapters 2 and 3 per NEI 21-07.

The discussion states that the term accidents includes "anticipated (or abnormal) operational transients and postulated design basis accidents" as well as "other events for which the plant is required to cope and that are described in the UFSAR …" For a reactor with an LMP-based affirmative safety case, the first category of accidents is defined as the LBEs (AOOs, DBEs, BDBEs, and DBAs), which, as noted above, are documented in SAR Chapters 2 and 3 per NEI 21-07. The second category remains the same for advanced reactors, to the extent the other events are applicable per the regulations.

2.3.2 Change (NEI 96-07 Section 3.3)

The definition of change as presented in NEI 96-07 is also applicable to a reactor with an LMP-based affirmative safety case. However, the discussion under the definition in NEI 96-07 addresses the terms "design functions" and "design bases functions." The systematic nature of the NEI 18-04 process allows for a much more straightforward approach to delineating design bases functions and design functions.

For the purpose of evaluating changes to a reactor with an LMP-based affirmative safety case, "design bases functions" correspond to Required Safety Functions per NEI 21-07 SAR Section 5.2. "Design functions" are considered to be composed of the design bases functions (Required Safety Functions), 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.

Special treatments are applied to SR and Non-Safety-Related with Special Treatment (NSRST) SSCs to ensure they are capable of accomplishing their design functions. Therefore, any non-administrative change to a special treatment constitutes a change.

Commented [A39]: Should mention capability and availability / reliability

2.3.3 Malfunction of an SSC Important to Safety (NEI 96-07 Section 3.9)

The definition implies that SSCs important to safety are those with "… design functions described in the UFSAR (whether or not classified as safety-related in accordance with 10 CFR 50, Appendix B)." For the purpose of evaluating changes to a reactor with an LMP-based affirmative safety case, SSCs important to safety ~~is~~ are interpreted to be the population of SSCs that are either ~~safety-related~~SR or NSRST SSCs, as defined by NEI 18-04. This population of SSCs is also referred to as the safety-significant SSCs.

2.3.4 Safety Analyses (NEI 96-07 Section 3.12)

The definition of safety analyses notes that containment, emergency core cooling system, and accident analyses in Chapters 6 and 15 of the UFSAR clearly fall within the meaning of safety analyses, recognizing that safety analyses are not limited to those two chapters. Per the discussion in Section 2.3.1 above, those particular types of analyses (if applicable to an advanced reactor with an LMP-based affirmative safety case) would be found in SAR Chapters 2 and/or 3 as defined in NEI 21-07.

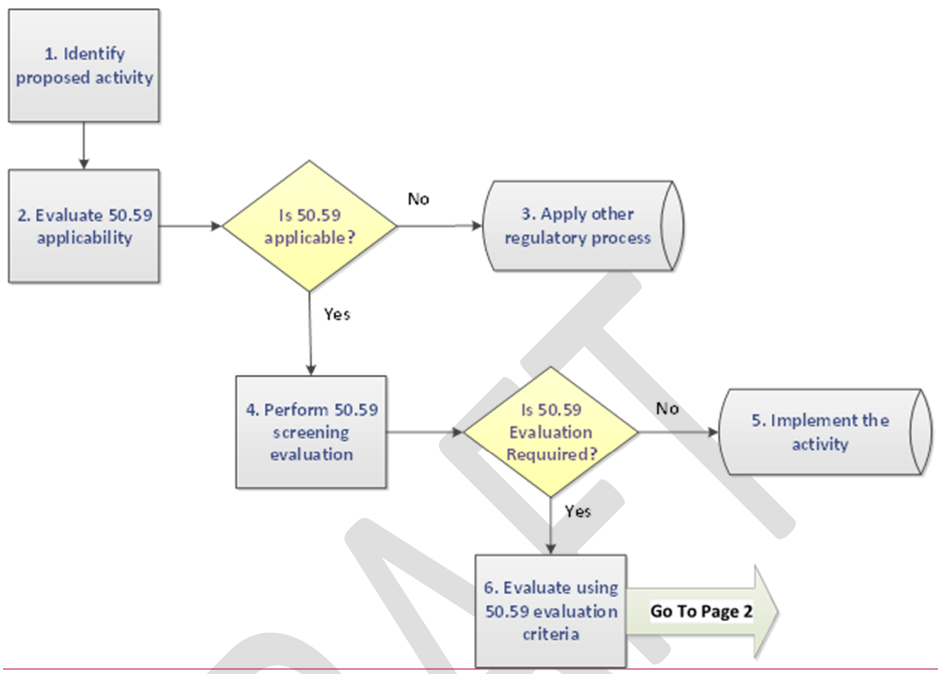
3.0 IMPLEMENTATION GUIDANCE

The process for 10 CFR 50.59 is shown in Figure 1 of NEI 96-07. This document assumes that a similar process is followed for an advanced reactor but that elements of the process are adjusted to reflect the different nature of the reactor and the safety case. The remainder of this section addresses the necessary adjustments to the three facets of the 10 CFR 50.59 process: applicability, screening, and evaluation. Figure 1 of this document shows the process for an LMP-based affirmative safety case, with the specific evaluation criteria summarized.

NEI 96-07 Section 4 provides implementation guidance for 10 CFR 50.59, and necessary ~~modifications~~adjustments to the guidance are addressed in ~~Section~~Chapter 3.0 of this white paper.

Commented [A40]: As commented earlier, this section doesn't discuss first performing the technical evaluation of a proposed change to see its effect on the LMP safety case

Commented [A41]: This section and its associated Figure 1 are confusing regarding the depiction of similarities and differences from 50.59. The figure seems to highlight two key aspects from the 50.59 process (applicability, evaluation required) for comparison, but then the text in 3.1, 3.2, and 3.3 addresses three topics (applicability, screening, evaluation).


1. Identify proposed activity
2. Evaluate 50.59 applicability
Is 50.59 applicable?
No
3. Apply other regulatory process
Yes
4. Perform 50.59 screening evaluation
Is 50.59 Evaluation Requuired?
No
5. Implement the activity
Yes
6. Evaluate using 50.59 evaluation criteria
Go To Page 2

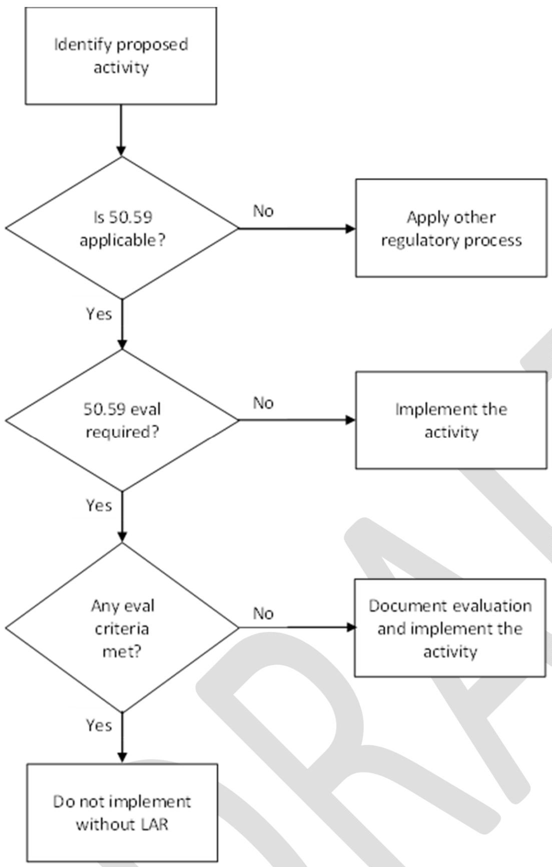
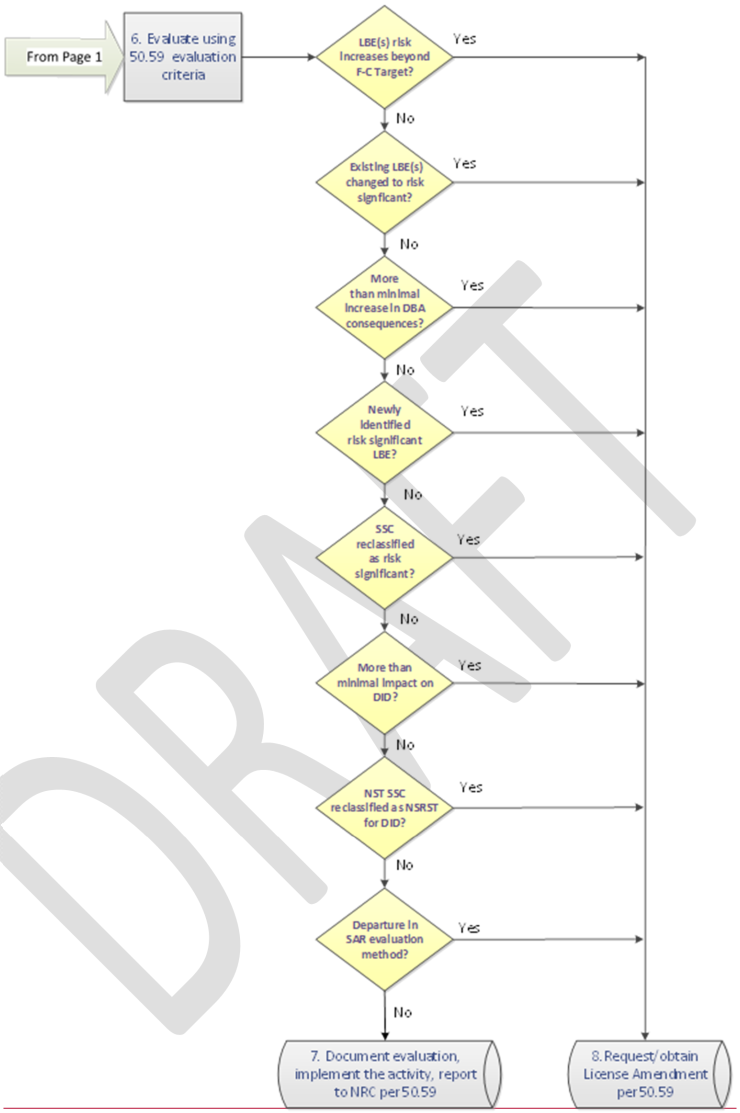


Figure 1. 10 CFR 50.59 Process for a Reactor with an LMP-based Affirmative Safety Case



~~Figure 1 (Cont'd)~~

3.1 Applicability (NEI 96-07 Section 4.1)

Section 4.1 of NEI 96-07 addresses applicability. 10 CFR 50.59 is applicable to advanced reactors licensed under 10 CFR Part 50 or 10 CFR Part 52, including those with an LMP-based affirmative safety case, for which this additional guidance is provided.

In general, the existing guidance provided in NEI 96-07 Section 4.1 is applicable to advanced reactors with an LMP-based affirmative safety case. However, there may be portions of the guidance that are not applicable due to the characteristics of (i) the reactor or (ii) the reactor's safety case. It is not possible to identify in advance all potential instances in which the NEI 96--07 guidance is not appropriate or cannot be applied. However, this section highlights examples where the application of NEI 96-07 Section 4.1 will need to be modified.

3.1.1 Applicability to Licensee Activities (NEI 96-07 Section 4.1.1)

NEI 96-07 makes it clear that certain licensee activities are controlled by other parts of the regulation and are excluded by 10 CFR 50.59(c)(4). This exclusion also applies to a reactor with an LMP-based affirmative safety case. One of the exclusion examples provided in NEI 96-07 is 10 CFR 50.46, the emergency core cooling system regulation. The regulation specifically applies to "boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircaloy or ZIRLO cladding." It is likely advanced non-LWRs will not use zircaloy or ZIRLO cladding. The NEI 18-04 guidance was written for advanced non-LWRs, so it can be assumed that this example exclusion from 10 CFR 50.59 will not be applicable to most reactors with an LMP-based affirmative safety case.

3.1.2 Maintenance Activities (NEI 96-07 Section 4.1.2)

The NEI 96-07 Section 4.1.2 guidance in its entirety is applicable to reactors with an LMP-based affirmative safety case.

3.1.3 UFSAR Modifications (NEI 96-07 Section 4.1.3)

The NEI 96-07 Section 4.1.3 guidance in its entirety is applicable to reactors with an LMP-based affirmative safety case.

3.1.4 Changes to Procedures Governing the Conduct of Operations (NEI 96-07 Section 4.1.4)

The NEI 96-07 Section 4.1.4 guidance in its entirety is applicable to reactors with an LMP-based affirmative safety case.

3.1.5 Changes to Approved Fire Protection Programs (NEI 96-07 Section 4.1.5)

The NEI 96-07 Section 4.1.5 guidance in its entirety is applicable to reactors licensed under 10 CFR Part 50 with an LMP-based affirmative safety case. 10 CFR Part 52 licensees should refer to the guidance provided in NEI 96-07 Appendix C Section 4.1.

3.1.6 Changes to the Probabilistic Risk Assessment (PRA)

PRAs for currently-licensed LWRs are not subject to change control under 10 CFR 50.59. The same approach is retained for advanced reactors that follow NEI 18-04. As described in Section

1.2.2, the PRA plays a much more significant role in the LMP-based affirmative safety case than it does in the licensing basis of LWRs licensed under 10 CFR Part 50 and 10 CFR Part 52. The PRA is a living plant model that is kept up to date for many reasons, including to ensure that it adequately represents both the probability and the consequences of the AOO, DBE, and BDBE licensing basis events.

It is neither desirable nor necessary to evaluate changes to the PRA under 10 CFR 50.59. Instead, this guidance assumes that the licensee has committed to following the Non-LWR PRA Standard,[1] which is the controlling document for changes to the PRA. If a licensee does not follow the Non-LWR PRA Standard, then it is incumbent on the licensee to establish with the NRC an acceptable alternative for PRA change control.

It is important to note that the change control process described in this white paper is applicable to methods of evaluation described in the UFSAR for DBA analyses even if the method of evaluation is also used in the PRA. DBA analyses are not part of the PRA; if the licensee elects to use a method of evaluation for DBAs that it also used in the PRA, that does not obviate the need to address changes to the DBA method of evaluation. Other LBE analyses – AOOs, DBEs, and BDBEs – are performed as part of the PRA. Accordingly, a method of evaluation that is used for an AOO – but not a DBA – would not be subject to the change control process described in this white paper.

Commented [A42]: is?

Further discussion of changes to the PRA is provided in Appendix A. As noted in Section 1.1, a follow-on project to TIRICE addressing change control in a broader manner is planned, and that project will address PRA change control, among other topics.

3.1.7 Changes to the State of Knowledge

New information relevant to a reactor safety case may be obtained at any time. This is true of currently-licensed LWRs, but these types of changes for new advanced non-LWRs may be more common, at least initially, than for LWRs as a result of refinements in the knowledge of new advanced non-LWRs from operating experience, experiments, and testing. Changes to the state of knowledge are not potential facility changes that are being contemplated; instead, they are actual changes to the best understanding of reality that have already occurred. There is nothing elective about them, and there is nothing to submit to the NRC for approval. Changes to the state of knowledge may impact the regulatory process in other ways, and they may lead to other changes that are subject to a 10 CFR 50.59 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 a change in the state of knowledge, and a plant modification to take advantage of margin gained by a change in the state of knowledge). However, a change to the state of knowledge, in and of itself, is not subject to a 10 CFR 50.59 review.

[1] ANSI/ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants," American Society of Mechanical Engineers and American Nuclear Society, approved January 28, 2021.

3.2 Screening

Section 4.2 of NEI 96-07 addresses screening. Once it has been determined that 10 CFR 50.59 is applicable to a proposed activity (see Section 3.1 above), screening is performed to determine if the activity should be evaluated against the evaluation criteria of 10 CFR 50.59(c)(2). If so, the evaluation should be performed as provided for in Section 3.3 below.

The guidance provided in NEI 96-07 Section 4.2 is generally applicable to advanced reactors with an LMP-based affirmative safety case. With that being said, the documentation of the safety case in a SAR that follows the guidance in NEI 21-07 should enable a relatively straightforward determination of whether or not the criteria associated with "screening a change in" (50.59 evaluation required) are satisfied. If not, the activity "screens out," and a 50.59 evaluation is not needed. This section highlights those aspects of the LMP-based affirmative safety case and associated SAR documentation that are particularly pertinent to screening.

Commented [A43]: Since NEI 21-07 is limited to the first 8 chapters of the SAR, it would be helpful to include some discussion that the 50.59 process applies to the entire SAR not just those portions informed by NEI 21-07 (see ARCAP Roadmap ISG). It would be ideal to avoid creating the impression that 50.59 is just limited to the first 8 chapters of an LMP-based SAR. Perhaps the statement needs to add references to the TICAP RG and ARCAP RG. Additionally, this comment could apply to all references to NEI 21-07. Perhaps a global statement in the front of the document would be appropriate.

The introductory material of NEI 96-07 addresses whether elements of a proposed activity are to be screened collectively or separately. The existing guidance provides for considering elements of an activity together if they satisfy one of the following two criteria.

(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.

For reactors with an LMP-based affirmative safety case, a third interdependency criterion is added.

(3) One or more of the elements are planned to ensure that the overall change preserves DID adequacy [see criterion (h) in Section 3.3.1 (Table 1) 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 incorporated to address what might otherwise be an undesirable result for criterion (h).

3.2.1 Change to the Facility or Procedures as Described in the UFSAR (NEI 96-07 Section 4.2.1)

In screening, an essential step is "to determine whether or not a proposed activity affects a design function, method of performing or controlling a design function or an evaluation that demonstrates that design functions will be accomplished …" For the LMP-based affirmative safety case, design functions should be documented in Chapter 5 of the SAR per NEI 21-07: a Required Safety Function 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. See Section 2.3.2 of this document for additional discussion.

3.2.2 Changes to the Facility as Described in the UFSAR (NEI 96-07 Section 4.2.1.1)

SSCs that are relied upon to carry out design functions are documented in the NEI 21-07 SAR in Section 5.4 (~~safety-related or~~ SR) and Section 5.5 (~~non-safety-related with special treatment or~~ NSRST). However, as addressed in Section 4.2.1.1, changes to other SSCs (i.e., no special treatment or NST) 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, 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 10 CFR 50.59 evaluation would be required.

Commented [A44]: This explanation seems too narrow. What about a change that removes or decreases the effectiveness of a special treatment? NEI 96-07 includes changes that "have adverse effects on design functions" as screened in.

3.2.3 Changes to Procedures as Described in the UFSAR (NEI 96-07 Section 4.2.1.2)

Procedures should be screened in only if they affect design functions (see Sections 2.3.2 and 3.2.1 above). 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).

In an analogous manner to facility changes discussed in Section 3.2.2 above, if a proposed change to a procedure results in a safety-significant SSC being unable to meet its reliability or capability target, then the change would "screen in" and a full 10 CFR 50.59 evaluation would be required.

3.2.4 Changes to UFSAR Methods of Evaluation (NEI 96-07 Section 4.2.1.3)

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 Analyses). Adverse changes to DBA methods would screen in. Methods of evaluation associated with the remaining LBEs (AOOs, DBEs, and BDBEs) should be addressed in the PRA and are therefore not applicable to further screening or evaluation (see Section 3.1.6 above). Methods of evaluation not associated with LBEs 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. Adverse changes to non-LBE methods of evaluation would screen in.

Commented [A45]: Changes to AOO, DBEs, or BDBE analysis methodology would be screened out from this process? NEI 96-07 describes "Adverse changes to elements of a method of evaluation included in the UFSAR, or use of an alternative method" as being screened in. The question is "how did the licensee implement the PRA standard'"? The licensee decides how a given event sequence is assembled. So if that sequence is altered to accommodate a design change, shouldn't that be screened in?

Commented [A46]: Also, changes in analysis assumptions is an important factor in the Changes to UFSAR Methods of Evaluation criteria. A change in analysis assumptions (that were accepted by the NRC staff at licensing) might not be screened in under this guidance.

3.2.5 Test or Experiment Not Described in the UFSAR (NEI 96-07 Section 4.2.2)

Tests or experiments described in the SAR may 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). If already described in the SAR, whether in the ~~aforementioned~~ these sections or other sections, the tests or experiments would screen out.

Commented [A47]: Plain English is preferred.

3.3 Evaluation

If a planned change has reached the evaluation portion of the 10 CFR 50.59 process, an applicability evaluation has determined that 10 CFR 50.59 is applicable to the proposed activity (see Section 3.1). In addition, screening has determined the activity is (i) a test or experiment not described in the UFSAR or (ii) a modification, addition, or removal (i.e., change) that adversely 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 (see Section 3.2). At this point, the licensee would perform a detailed evaluation of the adverse effect of the activity against the eight criteria of 10 CFR 50.59(c)(2).

It is in the evaluation portion that the most significant changes arise relative to the existing NEI 96-07 guidance for light water reactors with a traditional deterministic safety case. The risk-informed, performance-based approach to establishing an LMP-based affirmative safety case is very conducive to the 10 CFR 50.59 evaluation. Elements of the LMP-based affirmative safety case, such as risk significance and DID, enable an objective evaluation against the eight criteria, as described in this section. However, the evaluation process is modified somewhat from the approach of the existing NEI 96-07 guidance, as described in the remainder of this section. The need to modify the process stems from the differences in terminology and substance between an LMP-based affirmative safety case and a traditional deterministic safety case.

3.3.1 Evaluation Criteria

As shown in Table 1, evaluation criteria derived from NEI 18-04 have been established that enable the licensee to determine whether or not the intent of the evaluation criteria in 10 CFR 50.59(c)(2) are met. These alternative criteria based on NEI 18-04 are necessary to account for the risk-informed and performance-based nature of an LMP-based affirmative safety case. The eight evaluation criteria listed in 10 CFR 50.59(c)(2) are listed in the first column of Table 1. These criteria have been reordered and grouped into three categories to put them into the context of an LMP-based affirmative safety case. The second column of Table 1 provides the functionally equivalent criteria for a licensee following NEI 18-04. These criteria are referred to as "LMP 50.59 criteria." Changes to the facility that satisfy any one of the LMP 50.59 criteria would require NRC approval prior to implementation. The third column of Table 1 provides explanatory comments. Guidance on application of the criteria is provided in Section 3.3.2.

The first category of criteria covers changes that impact the frequency or consequences of accidents [criteria (i), (iii), and (v)]. The second category addresses changes that impact SSCs [criteria (ii), (iv), (vi), and (vii)]. The third category consists of criterion (viii) - changes to evaluation methods. Due to the integrated nature of the LMP-based affirmative safety case, changes that impact a criterion in one category may well impact other criteria in another category as well. For example, a change that involves a substantial impact on LBE frequency [LMP 50.59 criterion (a)] would result in a re-evaluation of the DID baseline per NEI 18-04 Sections 5.9.6 and 5.9.7, with implications for LMP 50.59 criterion (~~f~~h).

The LMP 50.59 criteria in Table 1 refer to LBEs, which are composed of AOOs, DBEs, BDBEs, and DBAs. The term “accident” is not used in NEI 18-04 or the Non-LWR PRA standard.

Table 1. 10 CFR 50.59 Evaluation Criteria for an LMP-based Affirmative Safety Case

10 CFR 50.59(c)(2) Criteria	**LMP 50.59 Criteria for an LMP-based Affirmative Safety Case**	**Comments**
	Category 1 - Accidents	
(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); (iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated); [See NEI 96-~~9~~07 Sections 4.3.1 and 4.3.3, respectively]	(a) Result in a change to the frequency 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 the NEI 18-04 Frequency-Consequence Target ~~or change~~. (b) Change an LBE from non-risk significant to risk significant according to NEI 18-04 LBE risk significance criteria. ~~(b) Result in more than a minimal increase in the consequence of a Design Basis Accident documented in the final safety analysis report (as updated).~~	~~Risk~~Comparison to the F-C target and risk significance of an LBE in the LMP context and in the Non-LWR PRA standard ~~requires~~[i.e., criteria (a) and (b)] require the consideration of the combination of frequency and consequence effects. There are no criteria to evaluate these components of risk separately. ~~LMP DBAs are evaluated conservatively, like LWR accidents. Therefore, determining if a change leads to a "more than minimal increase" in DBA consequences should follow the existing NEI 96-07 Section 4.3.3 guidance.~~

Formatted Table

Formatted: Space After: 24 pt

10 CFR 50.59(c)(2) Criteria	**LMP 50.59 Criteria for an LMP-based Affirmative Safety Case**	**Comments**
	(c) Result in more than a minimal increase in the consequence of a Design Basis Accident documented in the final safety analysis report (as updated).	LMP DBAs are evaluated conservatively, like "Chapter 15" accidents for currently-licensed LWRs. Therefore, determining if a change leads to a "more than minimal increase" in DBA consequences [i.e., criterion (c)] should follow the existing NEI 96-07 Section 4.3.3 guidance.
v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated); [See NEI 96-07 Section 4.3.5]	(~~c~~d) Result in one or more AOO, DBE, or BDBE that is (i) not previously evaluated in the UFSAR and (ii) classified as risk significant according to NEI 18-04 LBE risk significance criteria.	Newly identified LBEs or changes to LBE frequencies and consequences that are not risk significant should be documented in the next final safety analysis report update, but the associated change does not require prior NRC review.
	(~~d~~e) Result in a change to any of the NEI 18-04 cumulative risk metrics that exceeds the cumulative risk targets in Section 3.3.5 of NEI 18-04.	Cumulative risk from LBEs is an important element of the LMP-based affirmative safety case~~. In the Rev A version of this table, it was implicitly covered by the Category 2 criterion on defense-in-depth~~, but ~~it is appropriate to highlight it separately here~~there are no corresponding cumulative risk criteria in 10 CFR 50.59.
Category 2 - SSCs		
(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	(~~e~~f) Result in an increase in the frequency or consequences of a malfunction of any SSC that would change the classification of the SSC	10 CFR 50.59(c)(2) criteria (ii), (iv), (vi), and (vii) are addressed collectively by LMP 50.59 criteria (e) and (f).

Formatted Table

Formatted Table

Formatted: Don't keep with next

Formatted Table

Commented [A49]: (f) and (g)?

10 CFR 50.59(c)(2) Criteria	LMP 50.59 Criteria for an LMP-based Affirmative Safety Case	Comments
previously evaluated in the final safety analysis report (as updated); (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); [See NEI 96-07 Sections 4.3.2 and 4.3.4, respectively] (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); [See NEI 96-07 Section 4.3.6]	from non-risk significant to risk-significant. (~~f~~g) Result in ~~an increase~~a change in safety classification from NST to NSRST or Safety-Related or from NSRST to Safety-Related. (h) Result in a change to the ~~frequency or consequences of a malfunction of~~performance a safety-significant SSC that would have a more than minimal adverse effect on defense-in-depth adequacy ~~or lead to a change in safety classification from NST to NSRST to maintain adequate defense-in-depth.~~ .	Reclassification as addressed by (g) could be required if a change would otherwise adversely impact defense-in-depth, cumulative risk, or DBA consequences. Like cumulative risk, DID is an important element of the LMP-based affirmative safety case not addressed in 10 CFR 50.59.
(vii) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; [See NEI 96-07 Section 4.3.7]	~~No specific criterion~~ Results in non-compliance with any PDC.	The DID provided by LWR fission product barriers is addressed in a holistic manner in NEI 18-04. There is no need to single out fission product barriers in LMP 50.59 criteria; instead, impacts of changes on all safety-significant SSCs (not just fission product barriers) and DID are addressed by LMP 50.59 criteria (e) and (f).
Category 3 – Methods of Evaluation		

Formatted Table

Commented [A48]: Does this capture the NEI 96-07 criteria "more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC to perform its design function....departures from the design, fabrication, construction, testing and performance standards as outlined in the General Design Criteria (Appendix A to Part 50) are not compatible with a "no more than minimal increase" standard"? What does this mean: "more than minimal adverse effect on defense-in-depth adequacy"?

Commented [A50]: Shouldn't compliance with the PDCs be a criterion for any change? It is difficult to come up with a case where NRC would approve a change through a license amendment that results in noncompliance with any PDC, so listing it here implies that it could be possible.

10 CFR 50.59(c)(2) Criteria	LMP 50.59 Criteria for an LMP-based Affirmative Safety Case	Comments
(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. [See NEI 96-07 Section 4.3.8]	(~~g~~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~~, with the exception of LBE evaluation methods under the change control of the Non-LWR PRA Standard. ~~.	Evaluation of changes to methods of evaluation should follow NEI 96-07 Section 4.3.8 guidance. ~~Note that methods of evaluation used in the PRA are not addressed by 10 CFR 50.59 (see Section 3.1.6 of this guidance). Such methods are instead managed by New Methods and Configuration Control requirements in the Non-LWR PRA Standard ASME/ANS RA-S-1.4-2021. These include methods of evaluation for AOOs, DBEs, and BDBEs.~~

Formatted Table

Formatted Table

3.3.2 Evaluation Process

~~The~~For potential changes that may impact the LMP-based affirmative safety case, the process for evaluating a potential change to a facility to determine the need for prior NRC approval is described in this section. The process addresses the LMP 50.59 criteria listed in the center column of Table 1. If none of the criteria are satisfied, then the change may be implemented without prior NRC approval. If any LMP 50.59 criterion is satisfied, then the proposed activity requires prior NRC approval. The two potential outcomes of the evaluation are described further in NEI 96-07 Section 4.5.

The licensee must address all LMP 50.59 criteria (the entire center column of Table 1) in order to substantiate ~~that~~ a conclusion that prior NRC approval is not required. The evaluation can be performed in any order, but this guidance assumes the licensee will step through the criteria in Categories 1, 2, and 3, respectively, as provided in Section 3.3.1. Thus, the licensee would first consider LBE impacts, then SSC impacts, and finally methods of evaluation impacts. Further guidance for the application of the criteria is provided below.

Category 1 – Accidents

10 CFR 50.59(c)(2)(i) and (iii) refer to the frequencies and consequences, respectively, of accidents. Under current NEI 96-07 guidance "accidents" include AOOs, DBAs, and other events added to the licensing basis and reflected in the SAR such as anticipated transients without scram and station blackout. NEI 18-04 systematically identifies a range of LBEs that include AOOs, DBEs, BDBEs, and DBAs. In order to meet the requirements of the Non-LWR PRA Standard, the AOOs, DBEs, and BDBEs involve all credible combinations of safety system successes and failures, including consideration of common cause failures of the type involved in anticipated transient without scram and station blackout-type sequences. They also include, as appliable, event sequences involving multiple reactors and radionuclide sources. For the purpose of ~~evaluating~~addressing criteria (i) and (iii) in Category 1, this guidance addresses all four types of NEI 18-04 LBEs.

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 ~~safety-related~~SR SSCs in the performance of Required Safety Functions and are evaluated conservatively – the DBAs have no associated frequency. For the purpose of evaluating LBEs against the Category 1 LMP 50.59 criteria, AOOs, DBEs, and BDBEs are addressed in terms of frequency, consequence, and risk, whereas DBAs are addressed deterministically.

In the NEI 18-04 methodology, frequencies and consequences of AOOs, DBEs, and BDBEs are not evaluated separately but rather against risk criteria that consider the combination of frequency and consequences. As shown on NEI 18-04 Figure 3-1, AOOs, DBEs, and BDBEs are expected to be to the left of the Frequency-Consequence (F-C) Target, and are classified as either risk significant or non-risk-significant. For AOOs, DBEs, and BDBEs the term "more than minimal increase" is interpreted in the context of the risk significance criteria and the F-C Target. These criteria are clearly stated, performance-based, and unambiguous to apply.

For application of LMP 50.59 criterion (a) in Table 1, the ~~changes are deemed to have "more than a minimal increase" in frequency or consequences if an existing AOO, DBE, or BDBE changes its risk classification from non-risk-significant to risk-significant or~~criterion is satisfied if 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, ~~Tasks 7a and 7c).~~ Task 7a). For application of LMP 50.59 criterion (b) in Table 1, 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).[1] NEI 18-04 Figure 3-4 provides a graphical representation of the risk significant region and the F-C target. The evaluation of LMP 50.59 ~~criterion~~criteria (a) and (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. ~~It is noted that a proposed change may also result in changing one or more LBEs from risk significant to non-risk significant. Such a result would not satisfy LMP 50.59 criterion (a) and would therefore not translate to a requirement for prior NRC review of the proposed change.~~

LMP 50.59 criterion (~~b~~c) impacts NEI 18-04 DBAs only. Such DBAs are analyzed in a manner consistent with LWR Chapter 15 events, i.e., they are evaluated in a conservative manner against the same consequence criteria as in the current regulations, 10 CFR 50.34 and 10 CFR 100. Therefore, the language in criterion 50.59(c)(2)(iii) is applicable to DBAs, and it has been retained in LMP 50.59 criterion (~~b~~c). If the proposed change affects the plant response to an NEI 18-04 DBA, the effect of the change on the DBA should be assessed consistent with the guidance in NEI 96-07 Section 4.3.3 to determine if there is a "more than a minimal" increase in the consequences. Note that criterion (~~b~~c) addresses only consequences and not frequencies of DBAs. Because DBAs are derived from DBEs, LMP criterion (a) implicitly addresses the frequency of the underlying LBE, and no additional treatment is necessary for DBA frequency.

~~Changes~~ Potential changes that ~~may~~could introduce newly identified LBEs are addressed by LMP 50.59 criterion (~~c~~d). Such changes should be evaluated by revisiting the NEI 18-04 process for identifying LBEs ~~after quantifying the risk significance of the new LBE using the PRA~~. The evaluation of the change should determine whether there are new initiating events introduced by the change or 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 (~~c~~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 LMP-based affirmative safety case, so the change would not require prior NRC review. Also, because a new DBA would require a new DBE, LMP 50.59 criterion (~~c)~~d) implicitly covers DBAs as well as AOOs, DBEs, and BDBEs.

LMP 50.59 criterion (~~d~~e) 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 updated SAR in accordance with NEI 21-07 SAR Section 4.1. This criterion provides

[1] A proposed change could result in changing one or more LBEs from risk significant to non-risk significant. Such a result would not satisfy LMP 50.59 criterion (b) and would therefore not translate to a requirement for prior NRC review of the proposed change.

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.

Category 2 – SSCs

The next category of evaluation criteria addresses changes that impact the performance of SSCs identified in the UFSAR. 10 CFR 50.59(c)(2) includes several criteria associated with SSCs that are deemed "important to safety (ITS)." As discussed in Section 2.3.3 of this document, NEI 18--04 does not use important to safety but rather uses two SSC categories that collectively are regarded as "safety significant:" SR and NSRST. NSRST SSCs are so classified when the SSC functions either meet SSC risk significance criteria or provide functions that are deemed necessary for adequate DID. The SSC criteria of this change control guidance address safety-significant SSCs, and in doing so, address DID adequacy as well.

Criteria 10 CFR 50.59(c)(2)(ii), (iv), and (vi) address the likelihood and consequence of SSC malfunctions separately. NEI 18-04 SSC risk significance criteria define SSC risk significance based on a combination of frequency or probability of occurrence and consequences of failure. Note that this is consistent with the holistic treatment of LBE risk significance which was addressed above under Category 1. Therefore, the 10 CFR 50.59 criteria for SSCs that correspond to "more than minimal increase" in the likelihood of failure or consequences of an SSC malfunction are evaluated using LMP 50.59 criterion (~~e~~f) (based on NEI 18-04 SSC risk significance~~)~~), LMP 50.59 criterion (g) (based on NEI 18-04 SSC safety classification), and LMP 50.59 criterion (~~f~~h) (based on NEI 18-04 ~~defense-in-depth~~DID).[1]

Changes that may impact SSC risk significance or safety classification 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.

LMP 50.59 criterion (~~f~~h) addresses adverse effects on DID adequacy. DID ~~is~~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?

[1] It is noted that the concept of linking "more than minimal increase" to risk significance thresholds is being used in some of the draft language of 10 CFR Part 53 that addresses change control.

- 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 LMP 50.59 criteria (a) and (b) from Table 1, 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 ~~is~~per criterion (h) should be on the integrated DID evaluation as documented in ~~NEI 21-07~~ SAR Section 4.2.3, which addresses ~~the adequacy of~~both plant capability and programmatic DID. ~~NEI 21-07 SAR Section 4.2.3 addresses actions to establish DID adequacy described in NEI 18-04 Section 5.9.3.~~

Any changes which result in a more than minimal adverse effect on DID adequacy would require prior NRC approval. ~~The meaning of "more than minimal" necessarily varies with the design of the plant, the nature of the safety case, and each facet of DID being evaluated. It~~More than minimal 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. However, it is intended that the license applicant would, where feasible, establish guidelines up front in NEI 21-07 SAR Section 4.2.3 and the design records~~, to~~. Those guidelines would assist in performing the LMP 50.59 criterion (~~f~~h) evaluation (i.e., assist in answering the question of whether a change has a more than minimal effect on ~~each facet of integrated DID).~~ DID adequacy). It may be appropriate to enhance the guidance in NEI 21-07 to clarify the expectation that the licensee consider change control upfront when establishing the initial DID baseline [i.e., include guidelines to assist in the application of LMP 50.59 criterion (h)].

Commented [A51]: Define?

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 10 CFR 50.59 evaluation. It is anticipated that many changes will be simple and limited in scope such that the evaluation against ~~the~~ LMP 50.59 ~~criteria~~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 Integrated Decision-Making Process review of DID, including the possibility of utilizing an Integrated Decision-Making Panel, as described in NEI 18-04 Chapters 4 and 5. Once the LMP 50.59 criterion (~~f~~h) determination is made, the basis for the determination must be documented as discussed in Section 5 of NEI 96-07. If necessary, there should be an update of the DID baseline evaluation in the SAR and plant records.

~~Note that this approach requires upfront consideration of change control when the DID baseline is established and documented in the SAR and plant records. It may be appropriate to enhance the guidance in NEI 21-07 to clarify this expectation and ensure it will be accomplished during the establishment of the initial licensing basis.~~

Consistent with Section 3.2 of this white paper, the licensee may include additional 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.

As a general statement, examples of the application of the LMP 50.59 criteria should be very helpful to those seeking to apply the criteria for the first time. This is especially true of criterion (h) for DID, because DID involves a number of qualitative aspects that have no applicable precedent in the body of knowledge associated with conventional 10 CFR 50.59 change control.

Commented [A52]: I'd suggest different terminology that more clearly reflects what this means, making it more consistent with other text in the document.

There is no LMP 50.59 criterion explicitly addressing 10 CFR 50.59(c)(2)(vii), which focuses on design basis limits for fission product barriers. There are important differences between the treatment of DID in 10 CFR 50.59 and NEI 96-07, on the one hand, and the NEI 18-04 definition and evaluation of DID, on the other. The former focuses on the performance of fission product barriers, including fuel, coolant pressure boundary, and containment. The three-barrier LWR DID model is specific to the technology of current generation LWRs and may not apply to advanced reactor designs. In contrast, NEI 18-04 uses a layers-of-defense concept that addresses plant capabilities, programs, and a risk-informed, performance-based evaluation of DID. Accordingly, in NEI 18-04, fission product barriers are addressed as part of the safety classification and performance requirements included in the SAR for SSCs in general. Although a traditional LWR fission product barrier may be classified as SR or NSRST under NEI 18-04, its treatment in the LMP-based affirmative safety case is not elevated above other types of SSCs. LMP 50.59 criteria (~~e~~f), (g), and (~~f~~h) address SSCs in a comprehensive manner, including fission product barriers to the extent they are applicable, so there is no need to include an explicit fission product barrier LMP 50.59 criterion.

Category 3 – Evaluation Methods

For an LMP-based affirmative safety case, LMP 50.59 criterion (~~g~~i) for evaluation methods is consistent with the 10 CFR 50.59(c)(2)(viii).

Note that changes in evaluation methods used in the PRA, including those used for AOO, 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 3.1.6 above). However, if a method of evaluation used in the PRA is also described in the UFSAR for application to an analysis other than an AOO, DBE, or BDBE, then a change to that method of evaluation for the non-PRA application would require prior NRC approval if criterion (i) is met.

Commented [A53]: What about changes to assumptions used in the PRA? I did not see this item addressed in this guidance. Altering assumptions previously made in evaluating LBEs is something that should be evaluated. NRC license approval may have been based on a set of assumptions.

4.0 DOCUMENTATION AND REPORTING (NEI 96-07 SECTION 5.0)

Licensees using the guidance for an LMP-based affirmative safety case should follow the documentation and reporting guidance in Section 5 of NEI 96-07. In documenting the evaluation, the licensee should use the criteria shown in the middle column of Table 1 rather than the standard criteria as worded in 10 CFR 50.59(c)(2). ~~As discussed in Section 3 above, for a licensee following NEI 18-04, the LMP-based criteria are functionally equivalent to the criteria provided in the regulations.~~

5.0 SUMMARY

An effective change control program is necessary to ensure that a nuclear power reactor will operate in a safe and efficient manner. This document addresses the application of 10 CFR 50.59, the NRC's requirements for prior approval of facility changes, to advanced reactors with an LMP-based affirmative safety case. The document addresses the three key aspects of the current guidance for LWR change control as discussed in NEI 96-07: applicability, screening, and evaluation. To the extent possible, this guidance takes advantage of the risk-informed, performance-based attributes of reactors which follow the methodologies and guidance provided by NEI 18-04 and NEI 21-07.

Appendix A Probabilistic Risk Assessment

The PRA is a representation of important elements of the nuclear power plant facility, and it plays a key role in the NEI 18-04 methodology. The integrated PRA model is actually hundreds of separate models, including system models, event tree models, top logic models, data, etc., supporting each of the hazard models as applied to each of the analyzed plant operating states. Among the many elements of the PRA are the AOO, DBE, and BDBE probability and consequence analyses that comprise a subset of the LBEs for the plant.

The PRA can change due to periodic updates or as a result of changes in knowledge about the various models. For example, industry data on the reliability of a component may evolve as additional data on it is gathered, and such a change could impact the probability of an event sequence that is one of the plant's AOOs, DBEs, and BDBEs. Another example would be a change to the consequence model associated with an AOO, DBE, or BDBE. Yet another would be a decision to model a particular aspect of the plant in additional detail instead of relying on simplified assumptions. It is important that the operator keep the PRA up-to-date, which means modifying it to reflect significant new information and incorporating accurate and reliable models of plant performance.

For the purposes of this guidance, it is assumed that the licensee has committed to follow the Non-LWR PRA standard.[1] The standard provides comprehensive guidance for maintaining and updating the PRA. The scope of the information in the PRA makes it both impractical and undesirable for the PRA to be under 10 CFR 50.59 change control. Instead, licensees should be required to follow the Non-LWR PRA standard when updating the PRA, and those activities will be subject to NRC audit and inspection.

With this approach, changes to methods of analyses for AOOs, DBEs, and BDBEs will not be addressed by 10 CFR 50.59. However, such changes will be addressed by a comprehensive and industry-accepted program – the Non-LWR PRA standard – which is expected to be endorsed by an NRC regulatory guide. It should also be noted that DBAs will be analyzed with a traditional conservative "Chapter 15" approach to show conformance to dose limits, and those methods of analyses will be subject to 10 CFR 50.59 change control. All in all, advanced reactors that conform to NEI 18-04 will have a more systematic and comprehensive safety case than is provided by the traditional LWR approach.

The PRA tool is a fundamental part of the LMP-based affirmative safety case. In fact, as discussed elsewhere in this white paper, a PRA evaluation of potential plant changes will be a key factor in determining if prior NRC approval for the change is required. PRA results are provided in various sections of a SAR that follows NEI 21-07. If such PRA results change, they will be reflected in the periodic SAR updates.

[1] ANSI/ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants," American Society of Mechanical Engineers and American Nuclear Society, approved January 28, 2021.

Appendix B Terminology and Definitions

NEI 18-04 and NEI 21-07 use terminology and definitions specific to reactors approved for operation based on an LMP-based affirmative safety case.

Table B-1 provides the definitions of key terms from the aforementioned documents.

Table B-2 describes how some terms from NEI 96-07 are applied in change control for a reactor following the NEI 18-04 and NEI 21-07 methodology.

Table B-1. Terminology and Definitions

Term	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 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 and NEI 21-07
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 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 and NEI 21-07
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
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 and NEI 21-07

Commented [A54]: Should "Plant" be added to this list, since its multi-reactor use in LMP is different from the historical single reactor concept of 50.59. For instance, the LMP definition of AOO is:
Anticipated event sequences expected to occur one or more times during the life of a nuclear power plant, which may include one or more reactor modules.

Formatted Table

Term	Definition	Source
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 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 and NEI 21-07
Design Basis Hazard Level (DBHL)	A design specification of the level of severity or intensity of a hazard for which the SR SSCs are designed to withstand with no adverse impact on their capability to perform their Required Safety Functions.	NEI 21-07 but corrected by removing "external."
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 and NEI 21-07
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 and NEI 21-07
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 and NEI 21-07
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 and NEI 21-07
Required Functional Design Criteria (RFDC)	Reactor design-specific functional criteria that are necessary and sufficient to meet the Required Safety Functions.	NEI 18-04 and NEI 21-07
Required Safety Function	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 and NEI 21-07
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 and NEI 21-07

Formatted Table

Term	Definition	Source
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 and NEI 21-07
Safety-Related SSCs (SR SSCs)	SSCs that are credited in the fulfilment of Required Safety Functions and are capable to perform their Required Safety Functions in response to any Design Basis Hazard Level.	NEI 18-04 and 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). The population of Safety-Significant SSCs is made up of SR SSCs and NSRST SSCs.	NEI 18-04 and NEI 21-07, embellished for this document

Formatted Table

Table B-2. Corresponding Terms

NEI 96-07	Change Control for an LMP-Based Affirmative Safety Case
<u>Accident Previously Evaluated in the FSAR (As Updated)</u> 'Accident previously evaluated in the FSAR (as updated) means a design basis accident or event described in the UFSAR including accidents, such as those typically analyzed in Chapters 6 and 15 of the UFSAR, and transients and events the facility is required to withstand such as floods, fires, earthquakes, other external hazards, anticipated transients without scram (ATWS) and station blackout (SBO). The term "accidents" refers to the anticipated (or abnormal) operational transients and postulated design basis accidents that are analyzed to demonstrate that the facility can be operated without undue risk to the health and safety of the public.'	The concept is the same for an LMP-based affirmative safety case. However, Chapters 6 and 15 have a different meaning for an advanced reactor following the SAR guidance in NEI 21-07. The term "typically analyzed in Chapters 6 and 15 of the SAR" corresponds to all LBEs (AOOs, DBEs, BDBEs, and DBAs) for a reactor that uses the NEI 18-04 methodology.
<u>Design Function</u> 'Design functions are UFSAR-described design bases functions and other SSC functions described in the UFSAR that support or impact design bases functions. Implicitly included within the meaning of design function are the conditions under which intended functions are required to be performed, such as equipment response times, process conditions, equipment qualification, and single failure. Design bases functions are functions performed by systems, structures, and components (SSCs) that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, orders, or technical specifications, or (2) credited in licensee safety analyses to meet NRC requirements.'	For the purpose of addressing change control in a reactor with an LMP-based affirmative safety case, design functions are considered to be Required Safety Functions per NEI 21-07 SAR Section 5.2, risk-significant functions per NEI 21-07 SAR Section 5.5.1, or a safety function required for adequate DID in NEI 21-07 SAR Section 5.5.2.

NEI 96-07	Change Control for an LMP-Based Affirmative Safety Case
<u>SSCs Important to Safety</u> 'The term "malfunction of an SSC important to safety" refers to the failure of structures, systems and components (SSCs) to perform their intended design functions—including both non-safety-related and safety-related SSCs.' Thus, an important safety SSC is one that carries out a design function (see above), but is not necessarily safety-related.	For the purpose of addressing change control in a reactor with an LMP-based affirmative safety case, ~~safety-related~~<u>SR</u> SSCs and NSRST SSCs, taken together, are considered to be equivalent to SSCs important to safety.
<u>Methods of Evaluation</u> 'Methods of evaluation means the calculational framework used for evaluating behavior or response of the facility or an SSC.'	The concept is the same for an LMP-based affirmative safety case. However, in the NEI 18-04 methodology, many of the LBEs are evaluated as part of the plant PRA. For such methods of evaluation, changes are controlled by the Non-LWR PRA Standard, and as such, those methods of evaluation are outside the scope of 10 CFR 50.59.
<u>Updated Final Safety Analyses Report (UFSAR)</u> UFSAR refers to the safety analysis report (SAR) of a plant that has (i) received its operating license and (ii) updated to reflect the current state of knowledge.	The concept is the same for an LMP-based affirmative safety case. However, the more general term SAR is often used in the NEI 18-04 and NEI 21-07 guidance documents, which were written with applicants in mind rather than licensees. Where the term SAR is used in this document, it can be interpreted as UFSAR.