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Sent: Thursday, December 2, 2021 1:06 PM
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Subject: Transmittal of Draft White Paper titled, "Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors"
Attachments: TICAP - Draft Regulatory Guide DRG dec 2021 version.docx

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Mr. Afzali, Mr. Holtzman, and Mr. Draffin,

The purpose of this email is to provide you with the attached Draft White Paper titled, "Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors" The purpose of providing you this document is to support ongoing stakeholder interactions to develop technology inclusive content of application project (TICAP) guidance development. The attached document will be referenced in the meeting notice for the upcoming December 14, 2021, public meeting.

This email will be captured in ADAMS and the email will be made publicly available so that interested stakeholders will have access to the information prior to the meeting.

If you have questions regarding the attached documents please contact me or Eric Oesterle.

Sincerely,

Joe Sebrosky
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Advanced Reactor Policy Branch
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301-415-1132

Hearing Identifier: NRR_DRMA
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This draft staff white paper has been prepared and is being released to support ongoing public discussions. This draft white paper uses Regulatory Guide format because the staff is considering using this format to provide guidance in the near future to support the review of advanced reactor applications. This draft white paper is being issued in parallel with the NRC staff's review of draft industry guidance. The main purpose of this document at this early stage of advanced reactor guidance development is to engage stakeholders on the staff's initial high-level considerations on issues to be considered in such guidance.

This paper has not been subject to NRC management and legal reviews and approvals, and its contents are subject to change and should not be interpreted as official agency positions.

GUIDANCE FOR A TECHNOLOGY-INCLUSIVE CONTENT OF APPLICATION METHODOLOGY TO INFORM THE LICENSING BASIS AND CONTENT OF APPLICATIONS FOR LICENSES, CERTIFICATIONS, AND APPROVALS FOR ADVANCED REACTORS
Draft December 2021 Version

A. INTRODUCTION

Purpose

This regulatory guide (RG) provides the U.S. Nuclear Regulatory Commission (NRC) staff's guidance on using a technology-inclusive content of application methodology to inform specific portions of the safety analysis report (SAR) included as part of an advanced reactor license application. Specifically, this RG endorses the methodology described in Nuclear Energy Institute (NEI) 21-07, "Technology Inclusive Guidance for Non-Light-Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology" (Ref. 1), as one acceptable process for use when developing portions of an application for an advanced reactor construction permit, operating license, combined license, manufacturing license, standard design approval, or design certification under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 2), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 3). It is anticipated that this guidance will be updated for advanced nuclear reactor license and permit applications submitted under 10 CFR Part 53, "Licensing and Regulation of Advanced Nuclear Reactors," as that proposed regulation is finalized.

NEI 21-07 describes an approach to develop the scope and content of an application by implementing the licensing modernization project (LMP) methodology described in NEI 18-04, Revision 1, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development" (Ref. 4) as endorsed by the NRC in RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications For Licenses, Certifications, and Approvals for Non-Light-Water Reactors" (Ref. 5). The methodology in NEI 18-04 provides a systematic, risk-informed and technology neutral process for developing key inputs into the content of applications, to improve understanding of the safety and risk significance of system designs and their relationship to safety evaluations for a variety of non-light water reactor (LWR) designs. Even though the guidance described in NEI 18-04 is intended for non-LWRs, the NRC staff believes that the content and methodology described is also an acceptable approach to develop an application for the other categories of advanced reactors.

In this RG, the term "advanced reactor" is used in the context of the Nuclear Energy Innovation and Modernization Act (NEIMA). NEIMA included a definition for "advanced nuclear reactor" that was further refined by the Energy Act of 2020. The definition of advanced nuclear reactor found in the Energy Act of 2020 includes:

> (1) ADVANCED NUCLEAR REACTOR. —The term 'advanced nuclear reactor' means—
> (A) a nuclear fission reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (or successor regulations)), with significant improvements compared to reactors operating on the date of enactment of the Energy Act of 2020, including improvements such as—
> - (i) additional inherent safety features;
> - (ii) lower waste yields;
> - (iii) improved fuel and material performance;
> - (iv) increased tolerance to loss of fuel cooling;
> - (v) enhanced reliability or improved resilience;
> - (vi) increased proliferation resistance;
> - (vii) increased thermal efficiency;
> - (viii) reduced consumption of cooling water and other environmental impacts;
> - (ix) the ability to integrate into electric applications and nonelectric applications;
> - (x) modular sizes to allow for deployment that corresponds with the demand for electricity or process heat; and
> - (xi) operational flexibility to respond to changes in demand for electricity or process heat and to complement integration with intermittent renewable energy or energy storage; and
>
> (B) a fusion reactor.

In SECY 20-0032, "Rulemaking Plan On Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)" (Ref. 6), the staff further clarified its interpretation of the advanced reactors described in NEIMA to include LWR small modular reactors (SMRs), non-LWRs, and fusion reactor designs.

Although the technology-inclusive methodology described in NEI 21-07 provides a common approach to identifying and describing the scope and level of detail for the fundamental safety functions of a design (i.e., the safety case), the applicant or the licensee is still responsible for demonstrating compliance with all applicable regulations and may request exemptions as appropriate (i.e., the licensing case). The staff has provided guidance on which regulations are applicable to non-LWRs in Appendix D of the ARCAP roadmap interim staff guidance (ISG) document (Ref. 7) (*to be provided later*).

In addition, the staff notes that the applicability of specific technical requirements in NRC regulations or the need to define additional technical requirements for a particular design arising from the safety assessments will be made on a case-by-case basis for advanced reactors.

Applicability

This RG applies to nuclear power reactor designers, applicants, and licensees of advanced reactors[1] (non-LWR and SMR designs) applying for permits, licenses, certifications, and approvals under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities” (Ref. 2), and 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (Ref. 3). It is envisioned that the review approach described in this RG will also support the technology-inclusive, risk-informed and performance-based application content and level of detail expected in a future application submitted under the proposed Title 10 of the Code of Federal Regulations (10 CFR) Part 53, “Licensing and Regulation of Advanced Nuclear Reactors,” which is currently being developed.

Applicable Regulations

- 10 CFR Part 50 provides regulations for licensing production and utilization facilities.
    - 10 CFR 50.34, “Contents of applications; technical information,” describes the minimum information required for (a) preliminary safety analysis reports supporting applications for a construction permit and (b) final safety analysis reports supporting applications for operating licenses.
- 10 CFR Part 52 governs the issuance of early site permits, standard design certifications (DCs), combined licenses (COLs), standard design approvals (SDAs), and manufacturing licenses (MLs) for nuclear power facilities.
    - 10 CFR 52.47, “Contents of applications; technical information,” describes the information to be included in final safety analysis reports supporting applications for standard DCs.
    - 10 CFR 52.79, “Contents of applications; technical information in final safety analysis report,” describes the information to be included in final safety analysis reports supporting COLs.
    - 10 CFR 52.137, “Contents of applications; technical information,” describes the information to be included in final safety analysis reports supporting SDAs.
    - 10 CFR 52.157, “Contents of applications; technical information in final safety analysis report,” describes the information to be included in final safety analysis reports supporting MLs.

Related Guidance, Communications, and Policy Statements

- “Policy Statement on the Regulation of Advanced Reactors” (Volume 73 of the *Federal Register*, page 60612, October 14, 2008) (Ref. 8), establishes the Commission’s expectations related to advanced reactor designs to protect the environment and public health and safety and promote the common defense and security with respect to advanced reactors.

[1] Certain elements of this RG may also be applicable to Fusion reactors, as appropriate. However, the staff notes that options for the regulatory treatment of fusion reactors are currently being considered by the NRC staff which may result in the development of fusion-specific guidance.

- RG 1.70, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)” (Ref. 9), provides detailed guidance to the writers of safety analysis reports to allow for the standardization of information the NRC requires for granting construction permits and operating licenses.

- RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light Water Reactors” (Ref. 10), describes the NRC’s guidance on how the general design criteria in 10 CFR Part 50, Appendix A, “General Design Criteria for Nuclear Power Plants.” This guidance may be used by non-LWR reactor designers, applicants, and licensees to develop principal design criteria for any non-LWR designs, as required by the applicable NRC regulations for nuclear power plants. The RG also describes the NRC’s guidance for modifying and supplementing the general design criteria to develop principal design criteria that address two types of non-LWR technologies: sodium cooled fast reactors and modular high temperature gas-cooled reactors (MHTGRs).

- RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors” (Ref. 5), describes the NRC’s endorsement of the licensing modernization project (LMP) methodology described in NEI 18-04, Rev. 1, for selecting licensing basis events, classifying structures, systems, and components, and assessing defense-in-depth adequacy. This guidance may be used by non-LWR reactor designers, applicants, and licensees to develop the content of their applications. Specifically, use of LMP is the baseline methodology used by applicants to develop their applications in accordance with NEI 21-07.

Purpose of Regulatory Guides

The NRC issues RGs to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated events, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 50 and 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011 and 3150-0151. Send comments regarding this information collection to the Information Services Branch (T-6A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0011 and 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC20503; e- mail: oira_submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

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B. DISCUSSION

Reason for Issuance

This RG provides the U.S. Nuclear Regulatory Commission (NRC) staff's guidance on using a technology-inclusive content of application methodology to inform specific portions of the safety analysis report (SAR) included as part of an advanced reactor license application. Specifically, this RG endorses the methodology described in Nuclear Energy Institute (NEI) 21-07, "Technology Inclusive Guidance for Non-Light-Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology" (Ref. 1), as one acceptable process for use when developing portions of an application for an advanced reactor construction permit, operating license, combined license, manufacturing license, standard design approval, or design certification under Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 2), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 3).

Background

As the NRC prepares to review and regulate a new generation of advanced reactors, the staff has previously recognized the need to establish, and the benefits of having, a flexible regulatory framework. The NRC described efforts to prepare for possible licensing of non-LWR technologies in "NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness," (Ref. 11). The staff then developed "NRC Non-Light Water Reactor Near Term Implementation Action Plans" (Ref. 12), and "NRC Non-Light Water Reactor Mid-Term and Long-Term Implementation Action Plans" (Ref. 13), to identify specific activities that the NRC will conduct in the near-term, mid-term, and long term timeframes. Similarly, the Commission encouraged the use of a performance based, technology inclusive licensing framework for SMRs in SRM - COMGBJ-10-0004/COMGEA-10-0001, "Use of Risk Insights to Enhance Safety Focus of Small Modular Reactor Reviews," (Ref. 14) and SRM – SECY -11-0024, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews" (Ref. 15).

To ensure review readiness, a key element of this new and flexible regulatory framework is to standardize the development of content within an advanced reactor application to promote uniformity among applicants. A standardized content of application for advanced reactors also ensures review consistency and predictability from NRC staff, and presents a well-defined base from which to evaluate proposed changes in the scope and requirements of reviews. The development of applications for NRC licenses, permits, certifications, and approvals is a major undertaking, in that an applicant must provide sufficient information to support the agency's safety findings. The needed information and level of detail will vary according to whether an application is for a construction permit, standard design approval, design certification, operating license, combined license, or other action.

The NRC staff has had success with a standard content of application methodology for large-LWRs. The NRC's efforts to standardize the format and content of applications for LWRs are reflected in RG 1.70 (Ref. 9), issued in the 1970s, and RG 1.206, "Applications for Nuclear Power Plants," (Ref. 16) issued in 2007 and revised in 2018. Guidance documents, such as NUREG 0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (Ref. 17), and numerous other documents on specific technical areas, address the suggested scope and level of detail for those applications.

To standardize the development of content within an advanced reactor application, the staff has focused on two activities:

- The Advanced Reactor Content of Application Project (ARCAP), and
- The Technology-Inclusive Content of Application Project (TICAP).

The ARCAP is an NRC-led activity that is intended to provide guidance for a complete advanced reactor application that supports 10 CFR Part 50, 10 CFR Part 52, and the ongoing 10 CFR Part 53 rulemaking effort. As a result, ARCAP is broad and encompasses several industry-led, and NRC-led guidance documents aimed at ensuring a consistent approach to the development of each application document. A complete advanced reactor application is expected to include, among other things, a SAR, a Quality Assurance plan, a Fire Protection program, Emergency and Physical Security plans, etc.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the SAR that describe the fundamental safety functions of the design and details the affirmative safety case for each applicant consistent with the LMP approach. TICAP's focus on those measures needed to address risks posed by non-LWR and SMR technologies will help an applicant provide sufficient information on the design and programmatic controls, while avoiding an excessive level of detail on less important parts of a plant. The specific portions of the SAR applicable to the scope of NEI 21-07 are described below in more detail. Based on the limited scope of the TICAP guidance, TICAP's scope is encompassed by and supplemented by the ARCAP guidance. The ARCAP documents will describe the guidance for the specific areas of the SAR that are outside the scope of the LMP process (i.e., not covered by TICAP) such as site information, and information consistent with use of the American Society of Mechanical Engineers (ASME) Section III, Division 5 construction codes.

As a result of extensive TICAP/ARCAP public interactions with industry and external stakeholders, the proposed development of the SAR for an advanced reactor application is based on a 12-chapter approach. In contrast, the SAR approach for large-LWRs described in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (Ref. 17) is based on a 19-chapter approach. For an advanced reactor application consistent with the ARCAP/TICAP guidance and the methodology described in this RG, the 12 chapters of the SAR are as follows:

- Chapter 1 - General Plant Information, Site Description, and Overview of the Safety Case
- Chapter 2 – Methodologies and Analyses
- Chapter 3 - Licensing Basis Events
- Chapter 4 - Integrated Evaluations
- Chapter 5- Safety Functions, Design Criteria, and SSC Categorization
- Chapter 6 - Safety Related SSC Criteria and Capabilities
- Chapter 7 - NSRST SSC Criteria and Capabilities
- Chapter 8 - Plant Programs
- Chapter 9 - Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste
- Chapter 10 - Control of Occupational Dose
- Chapter 11 – Organization and Human-System Considerations
- Chapter 12 -Post-construction Inspections, Testing and Analysis Programs.

Based on the SAR structure described above, the staff notes that TICAP's scope as described in

NEI 21-07 is only applicable to the LMP-related portions contained in the first 8 chapters[2]. Figure 1 below illustrates the nexus between ARCAP, TICAP, and other guidance in relation to an advanced reactor application.

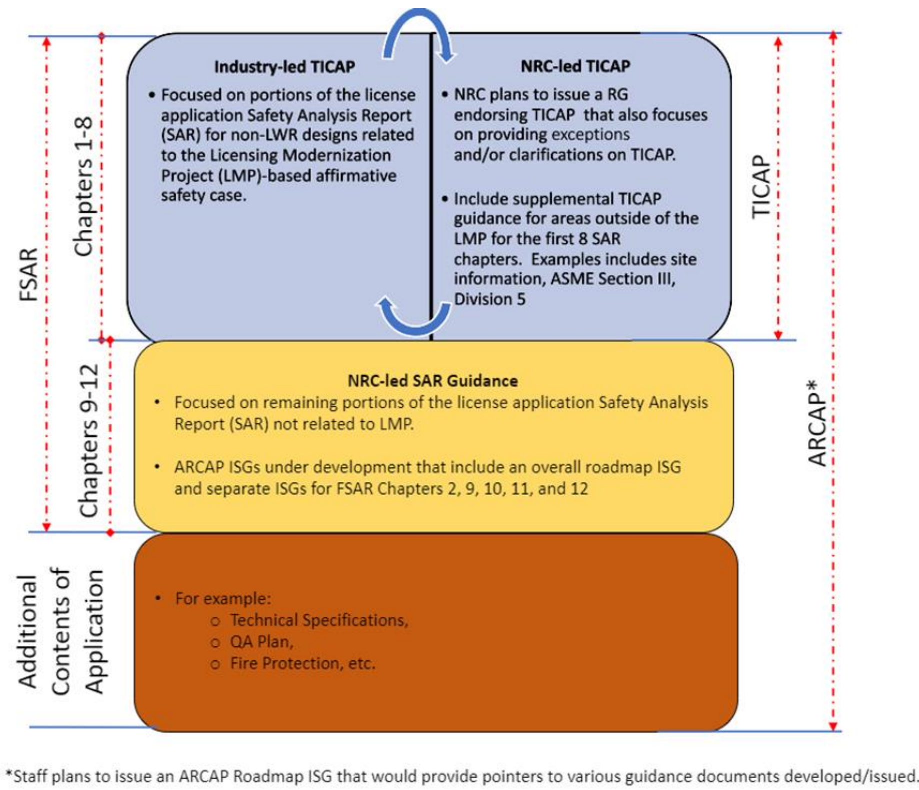

Figure 1: Nexus between ARCAP, TICAP, and the content of an application.

Documents Endorsed in this Guide

Upon completion of the industry-led TICAP efforts, the results of the project were documented as guidance in NEI 21-07, and submitted to NRC for review and endorsement. As a result, the purpose of this RG is twofold:

1. To endorse the sections of NEI 21-07 which describe one acceptable approach for determining the scope and level of detail for the development of structured application content associated with the first 8 chapters of the SAR. The methodology in NEI 21-07 follows the LMP guidance, and systematically describes the selection of licensing-basis events (LBEs); classification and special treatments of structures, systems, and components (SSCs); the assessment of defense in depth (DID) features and supporting information. When applicable, this RG will also describe any additional clarifications,

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[2] Pre-application engagement is highly encouraged for applicants that plan to use the methodology described in NEI-21-07 but rely on a different SAR structure than the 12-chapter approach described in this RG. Similarly, applicants not using the LMP approach described in NEI 21-07 but leveraging the 12-chapter SAR approach should engage the NRC staff early to optimize application reviews. The Commission's advanced reactor policy statement (Ref. 8) highlighted the importance of pre-application activities. Consistent with that policy, guidance on pre-application activities for advanced reactor applications has been provided in Appendix C of the ARCAP Roadmap ISG (Ref. 7).

exceptions, points of emphasis, and/or further details relevant to the specific sections discussed in NEI 21-07 and endorsed by this RG.

2. To describe additional information outside the scope of LMP and NEI 21-07 that NRC staff has determined is also relevant and would expect to be included as part of the application content related to the first 8 chapters.

Based on the above, this RG endorses Sections {x,y, and z}of NEI 21-07 as one acceptable process for use when developing content for portions of the NRC license application SAR for non-LWR and SMR designs in a manner consistent with RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications For Licenses, Certifications, and Approvals for Non-Light-Water Reactors" (Ref. 5). Additional details for each chapter will be described in their corresponding section.

The NRC endorsement of the aforementioned sections does not imply the NRC's endorsement of the references cited in the endorsed sections of NEI 21-07 or to references in the endorsed sections of NEI 21-07 to other (unendorsed) sections of NEI 21-07. The NRC has not necessarily reviewed and approved the guidance provided in these references, except where specifically noted in this regulatory guide.

In summary, the guidance in NEI 21-07 is focused on developing the portions of the SAR containing material addressed in NEI 18-04, and it will help ensure completeness of information submitted to NRC while avoiding unnecessary burden on the applicant and rightsizing the content of application commensurate with the complexity of the design being reviewed. This guidance provides a standardized content development process designed to facilitate efficient preparation by the applicant, review by the regulator, and maintenance by the licensee. The content formulation should optimize the type and level of detail of information provided, based on the complexity of the design's safety case and the nexus between elements of the design and public health and safety.

Harmonization with International Standards

As described in the 2010 IAEA Integrated Regulatory Review Service (IRRS) mission report, the NRC has agreed to review international standards and, when practical, harmonize NRC regulations and guides with the appropriate international standards. During the development of this RG, the NRC staff did not identify any international standards related to this guide.

C. STAFF REGULATORY GUIDANCE

The guidance on the SAR content scope and level of detail described in this RG is based on the appropriate level of design-specific information that should be provided in an application to the NRC to demonstrate that the design's safety case meets the regulatory standards for adequate protection of public health and safety. To accommodate an effective and efficient technology inclusive content guidance while ensuring the underlying intent of the current content requirements is met, this guidance is formulated to describe an LMP-based affirmative safety case. Pre-application engagement between applicants and the NRC is highly encouraged to optimize resources and review schedule, especially for non-LMP based applications.

The following sections describe the NRC's endorsement (with clarifications or exceptions, when applicable) of the corresponding sections described in guidance document NEI 21-07. In general, NEI 21-07 is structured to present the overall safety case first and then provide the specific supporting design and operating details in subsequent chapters. The staff notes that the methods, approaches, or data described in the regulatory position(s) discussed below are not requirements. Appendix B of this document provides supplemental regulatory positions to those described below in Regulatory Positions C.1 through C.8.

1. General Plant and Site Description, And Overview of The Safety Case

The information in this chapter should allow the reviewer to obtain a basic understanding of the overall facility, such as the type of permit, license, certification or approval requested, the number of plant units, a brief description of the proposed plant location, and the type of advanced reactor being proposed. The site description should provide an overview of the actual physical, environmental and demographic features of a site, and how they relate to the affirmative safety case. Examples of information related to site description include geological and demographic, seismological, hydrological, and meteorological characteristics of the site and the surrounding vicinity.

Chapter 1 of NEI 21-07, Rev. 0 (specifically, Sections 1.1 to 1.4) provides an acceptable method for licensees to follow and develop baseline information related to the plant description, site description, the affirmative safety case based on the LMP methodology, and a summary of reference of source materials, respectively.

For reference, the affirmative safety case is defined as a collection of scientific, technical, administrative and managerial evidence which documents the basis that the performance objectives of the technology-inclusive fundamental safety functions (FSFs) are met by a design during design specific Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Beyond Design Basis Events (BDBEs), and Design Basis Accidents (DBAs) by:

- Identifying design specific safety functions that are adequately performed by design specific SSCs and
- Establishing design specific features (programmatic (e.g., inspections) or physical (e.g., redundancy)) to provide reasonable assurance that credited SSC functions are reliably performed.

1st Regulatory Position
NEI 21-07, Chapter 1 provides an acceptable method for developing information related to the plant description, site description, the affirmative safety case based on the LMP methodology, and a summary of reference of source materials. The staff believes that applicants using the LMP methodology to develop an affirmative safety case should include normal operations in addition to AOOs, DBEs, BDBEs, and DBAs. In addition to making an affirmative safety case, the applicant or the licensee is still responsible for making a licensing case by demonstrating compliance with all applicable regulations and may request exemptions as appropriate. The staff has provided guidance on which regulations are applicable to non-LWRs in Appendix D to the ARCAP roadmap ISG (Ref. 7).*(to be provided later)*

2nd Regulatory Position – Construction Permit Information
NEI 21-07, Section xxx provides an acceptable method for developing portions of a construction permit application in accordance with 10 CFR Part 50 requirements. However, for advanced reactor applicants pursuing a construction permit (CP) application under 10 CFR Part 50 and using an alternative risk-informed performance-based approach (such as LMP), additional information not related to the LMP-based affirmative safety case should be provided. Specifically, the additional information is related to the minimum information necessary in a CP application for the staff to issue a CP under 10 CFR 50.35(a) when the applicant has not supplied all of the technical information required to complete the application (i.e., 50.34(a)) and support the issuance of a CP which approves all proposed design features (i.e., obtains finality for the design). The staff notes that the additional CP information described in this RG is consistent with the first 8 Chapters of the SAR. The guidance described in Appendix A of

this RG contains guidance on one acceptable approach in scope and level of detail for applicants to provide the additional relevant CP information for advanced reactor applications related to the first 8 chapters of the SAR.

3rd Regulatory Position – Supplemental Information
In addition to the material identified in NEI 21-07, applicants should also address the following issues in Chapter 1 of the SAR:

a. Identify the applicability of Generic Safety Issues, Unresolved Safety Issues and Three Mile Island action items to the design and their proposed resolution.

b. Identify the RGs applicable to the design and any proposed exceptions.

c. Identify the consensus design codes and standards (ASME, ANSI, IEEE, etc.) used in the design.

2. Methodologies and Analyses

An important part of the design process for reactor designs is the identification of events that could challenge key safety functions and layers of defense against the release of radioactive materials. Therefore, a key part of the review of an advanced reactor application is the selection of licensing basis events (LBEs). The LBEs are described as event sequences such as anticipated operational occurrences (AOOs), design-basis events (DBEs), or beyond-design-basis events (BDBEs). The primary determinate for categorizing events in each of these categories is the estimated frequency of the event sequence. Figure 3-2 of NEI 18-04 provides additional information on the selection and evaluation of LBE's.

Chapter 2 of NEI 21-07, Rev. 0 (specifically, Sections 2.1 to 2.3) provides an acceptable method for licensees to follow and develop baseline information related to the probabilistic risk assessment (overview of the PRA), source-term analysis, and design-basis accidents (DBAs) analytical methods.

4th Regulatory Position
NEI 21-07, Chapter 2 provides an acceptable method for developing information related to the probabilistic risk assessment (overview of the PRA), source-term analysis, and design-basis accidents analytical methods. Applicants should conform to the guidance provided for non-LWR PRAs contained in Trial-Use RG 1.247, "XXXX" , and address the staff exceptions noted in this guidance or provide suitable justification for alternative approaches. In addition, applications should conform to the guidance associated with PRA peer reviews as provided in NEI 20-07, Revision 1, or as endorsed in associated NRC guidance (placeholder).

5th Regulatory Position – Site Information
In addition to the site information described in Chapter 2 of NEI 21-07, additional information not developed using the LMP process should be provided. The purpose of this information is to demonstrate compliance with 10 CFR 100, Subpart B, and the relevant parts of 10 CFR 50 and 52 that discuss site related issues, and to describe the site characteristics used in the design and safety analysis where (i) a design basis external hazard level must be specified for each system, structure, or component (SSCs) designed to withstand this hazard with no adverse impact on their capability to perform their required safety function (RSF) or (ii) an SSC is relied upon to establish the adequacy of defense-in-depth and must be designed with special treatment to withstand a given hazard. The guidance described in draft Interim Staff Guidance (ISG) "Site Information" (ADAMS Accession No. ML21189A031) contains guidance on one acceptable approach in scope and level of detail for applicants to provide relevant site information.

6th Regulatory Position – Methodologies and Analyses
Certain analyses are common to a number of LBE analyses. This chapter of the guidance provides information regarding how to document those analyses in an application. The scope of content, the level of detail, and the structure of the application guidance regarding this topic are acceptable, with the following exceptions and clarifications:

a. Other methodologies and analyses that should be provided include baseline operating parameters; a description of systems, components, and materials performance under normal operating, anticipated transient, and accident conditions.

3. Licensing Basis Events

After the identification of LBEs, the information in this chapter should describe the systematic and reproducible process and methodology used to select the LBEs, and the specific analysis and evaluation of the selected LBEs for the proposed design. The analysis in this section is primarily described in terms of event sequences comprised of an initiating event, the plant response to the initiating event (which includes a sequence of successes and failures of mitigating systems) and a well-defined end state. This chapter should also include information on the process used to group and condense the substantial number of event sequences considered in the PRA into sequence families that are used to define the AOOs, DBEs, and BDBEs. It is important to note that the term "event sequence" is used in lieu of the term "accident sequence" used in LWR PRA standards because the scope of the LBEs includes AOOs and initiating events with no adverse impacts on public safety.

Chapter 3 of NEI 21-07, Rev. 0 (specifically, Sections 3.1 to 3.6) provides an acceptable method for licensees to follow and develop baseline information related to the LBE selection methodology, and summary of LBEs (AOOs, DBEs, BDBEs and DBAs).

7th Regulatory Position
NEI 21-07, Chapter 3 provides an acceptable method for developing information related to the LBE selection methodology, and summary of LBEs (AOOs, DBEs, BDBEs and DBAs).

8th Regulatory Position – Supplemental Information
In addition to the material identified in NEI 21-07, Chapter 3, the SAR should also include a discussion of the following:

1. Aircraft Impact Assessment (10 CFR 50.150) – The objective of the aircraft impact rule is to require nuclear power plant designers to rigorously assess their designs to identify design features and functional capabilities that could provide additional inherent protection to withstand the effects of an aircraft impact. The NRC expects this rule to result in new nuclear power reactor facilities that are inherently more robust with regard to an aircraft impact than if they were designed in the absence of the aircraft impact rule. The rule provides an enhanced level of protection beyond that which is provided by the existing adequate protection requirements applicable to currently operating power reactors. The following Regulatory Guide (RG) provides guidance regarding implementation of this regulation:

    - RG 1.217, "Guidance for The Assessment of Beyond-Design-Basis Aircraft Impacts," describes a method that the NRC staff considers acceptable for use in satisfying the regulations at 10 CFR 50.150, regarding the consideration of aircraft impacts for new nuclear power reactors. This RG endorses the methodologies described in the industry guidance document, Nuclear Energy Institute (NEI) 07-13, "Methodology for Performing Aircraft Impact Assessments for New Plant Designs," Revision 8, dated April 2011.

2. Mitigation of Beyond-Design-Basis External Events from Natural Phenomena (circumstances associated with loss of large areas of the plant due to explosions or fire) (10 CFR 50.155) – One of the primary lessons learned from the accident at the Fukushima Dai-ichi nuclear power plant was the significance of the challenge presented by a loss of multiple safety-related systems following the occurrence of a beyond-design-basis external event (BDBEE). In the case of the Fukushima Dai-ichi accident, the loss of all alternating current power led to loss of core cooling, and ultimately to core damage and a loss of containment integrity. The design basis for U.S. nuclear plants includes bounding analyses with margin for external events expected at each site. Extreme external events (e.g., seismic events, external flooding, etc.) beyond those accounted for in the design basis, while unlikely, could present challenges to nuclear power plants. The following RGs provide guidance regarding implementation of this regulation:

   - RG 1.226, "Flexible Mitigation Strategies for Beyond-Design-Basis Events," identifies methods and procedures the NRC staff considers acceptable for nuclear power reactor applicants and licensees to demonstrate compliance with NRC regulations covering planning and preparedness for beyond-design basis events as required by 10 CFR 50.155, "Mitigation of beyond design-basis events." This RG endorses, with clarifications, the methods and procedures described in technical document NEI 12-06, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide," Revision 4 (NEI 12-06, Revision 4) dated December 2016 as a process the NRC considers acceptable for meeting, in part, the regulations in 10 CFR 50.155. Additionally, this RG provides guidance for meeting the regulations in 10 CFR 50.155 that are in areas not covered in NEI 12-06.

   - RG 1.227, "Wide-Range Spent Fuel Pool Level Instrumentation," identifies methods and procedures the NRC staff considers acceptable for demonstrating compliance with NRC regulations to provide a reliable means to remotely monitor wide-range spent fuel pool levels to support implementation of event mitigation and recovery actions as required by 10 CFR 50.155, "Mitigation of beyond-design-basis events" (10 CFR 50.155). This RG endorses, with exceptions and clarifications, the methods and procedures described NEI 12-02, "Industry Guidance for Compliance with NRC Order EA-12-051, 'To Modify Licenses with Regard to Reliable Spent Fuel Pool Instrumentation'," Revision 1 (NEI 12-02) dated August 2012 as a process the NRC staff considers acceptable for meeting certain regulations in 10 CFR 50.155.

   - Draft Regulatory Guide DG-1319 (Proposed New Regulatory Guide 1.228), "Integrated Response Capabilities for Beyond-Design-Basis Events," identifies methods and procedures the NRC staff considers acceptable for nuclear power reactor applicants and licensees to demonstrate compliance with 10 CFR 50.155, and Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," Section VII, "Communications and Staffing Requirements for the Mitigation of Beyond Design Basis Events." This RG endorses, with clarifications, the methods and procedures described in the following documents as methods the NRC staff considers acceptable for meeting portions of the regulations in 10 CFR 50.155 and 10 CFR Part 50, Appendix E, Section VII:

      - NEI 12-01, "Guidelines for Assessing Beyond-Design-Basis Accident Response Staffing and Communication Capabilities," Revision 0, dated May 2012.

      - NEI 13-06, "Enhancements to Emergency Response Capabilities for Beyond-Design-Basis Events and Severe Accidents," Revision 0, dated September 2014, and NEI 14-01, "Emergency Response Procedures and Guidelines for Beyond-Design-Basis Events and Severe Accidents." Revision 0 dated September 2014.

4. **Integrated Evaluations**

The information in this chapter should describe the integrated risk of all LBEs selected for the proposed design, and evaluated against three cumulative risk targets:

1. The total mean frequency of exceeding a site boundary dose of 100 millirem (mrem) from all LBEs should not exceed 1/plant-year. The value of 100 mrem is selected from the annual cumulative exposure limits in 10 CFR 20.

2. The average individual risk of early fatality within 1 mile of the exclusion area boundary (EAB) from all LBEs based on mean estimates of frequencies and consequences shall not exceed 5×10-7/plant-year to ensure that the NRC safety goal quantitative health objective (QHO) for early fatality risk is met.

3. The average individual risk of latent cancer fatalities within 10 miles of the EAB from all LBEs based on mean estimates of frequencies and consequences shall not exceed 2×10-6/plant-year to ensure that the NRC safety goal QHO for latent cancer fatality risk is met.

Key information in this chapter should be to identify design features that are responsible for preventing and mitigating radiological releases and for meeting the integrated risk criteria, including defense-in-depth (DID). This evaluation leads to performance requirements and design criteria that are developed within the process of the SSC classification. This chapter should also describe information that conveys the evaluated SSC margins against the total mean frequency of exceeding a site boundary dose of 100 mrem in order to establish baseline margins between the frequencies and consequences of individual LBEs against the frequency-consequence curve described in Figure 3-1 of NEI 18-04, Rev. 1

Chapter 4 of NEI 21-07, Rev. 0 (specifically, Sections 4.1 and 4.2) provides an acceptable method for licensees to follow and develop baseline information related to the Integrated Evaluations, which include the overall plant risk performance summary, and identify design features that are responsible for preventing and mitigating radiological releases and for meeting the integrated risk criteria, including defense-in-depth.

9th Regulatory Position
NEI 21-07, Chapter 4 provides an acceptable method for developing information related to the Integrated Evaluations, which include the overall plant risk performance summary, and identify design features that are responsible for preventing and mitigating radiological releases and for meeting the integrated risk criteria, including defense-in-depth.

5. **Safety Functions, Design Criteria, and Systems, Structures, and Components Classification**
Note that the staff will provide an update to this portion of the document in a future revision to reflect the staff's position relative to principal design criteria that is currently under development.

As part of the LMP process, LBEs are generally defined in terms of successes and failures of SSCs that perform safety functions and are modeled in the probabilistic risk-assessment (PRA). Therefore, the PRA safety functions (PSFs) are those functions responsible for the prevention and mitigation of an unplanned radiological release from any source within the plant.

The information in this chapter should describe the approach for designating SSC safety functions and classifications in accordance with the PSFs. For SSCs, information should include a description of the required safety function(s) (RSFs), required functional design criteria (RFDC), principal design criteria

(PDC), safety classification of safety-related, and non-safety related with special treatment (NSRST) SSCs, and the complementary design criteria. Definitions for these terms are described in Section 6 of NEI 18-04, Rev. 1 "Glossary of Terms." The information in this chapter should also identify potential technical concerns related to SSC safety classification, and the derivation of requirements necessary to support PSFs in the prevention and mitigation of LBEs that are modeled in the PRA.

Chapter 5 of NEI 21-07, Rev. 0 (specifically, Sections 5.1 to 5.4) provides an acceptable method for licensees to follow and develop baseline information related to the safety classification of SSCs, which includes information about RSFs, RFDC, PDCs, and NSRST.

10th Regulatory Position

NEI 21-07, Chapter 5 provides an acceptable method for developing information related to the safety classification of SSCs, which includes information about RSFs, RFDC, PDCs, and NSRST.

11th Regulatory Position – Supplemental Information – Fuel Qualification

In addition to the material identified in NEI 21-07, Chapter 5 of the SAR should also address fuel qualification. The reactor core and its fuel are generally identified as safety-related due to the direct involvement in performing fundamental safety functions. The information requirements associated with safety-related SSCs are discussed in Section 6, "Safety-Related SSC Criteria and Capabilities." However, there are regulatory requirements, such as fuel design limits, that are attributed-to or identified with fuel performance and its qualification. One of the characteristics of fuel qualification is the need for irradiation data with associated long-time frames to collect that irradiation data. Accordingly, it is anticipated that advanced reactor designs will use existing data (e.g., Advanced Gas Reactor (AGR) program data, legacy metal fuel data) to support regulatory licensing to some degree. Two NRC documents provide additional guidance in the area of non-LWR fuel qualification: 1) NUREG-2246, Fuel Qualification for Advanced Reactors, Draft Report for Comment (ML21168A063), and 2) NRC staff report "Assessment of White Paper Submittals on Fuel Qualification and Mechanistic Source Terms: Next Generation Nuclear Plant", Revision 1, July 2014 (ML14174A845). The fuel qualification discussion should focus on (1) understanding the role of the fuel in the safety case, and (2) determining the adequacy of the plan to provide the evidentiary basis for fuel performance as assumed in the safety case. Sufficient information should be available to support reasonable assurance findings that:

1) The role of the fuel in the safety case is adequately described. This can be addressed by providing fuel performance requirements during (1) normal operation, including the effects of anticipated operational occurrences, and (2) accident conditions. In support of these findings, sufficient information should be provided such that the safety limits of the fuel and the fuel contribution in the accident source term are clearly identified. Understanding of the safety limits and source term should address uncertainty associated with any limitations on data available and reflected in the analyses discussed in Section 2 "Safety and Accident Analysis Methodologies and Associated Validation" and Section 3 "Discussion of accident source terms" of NEI 21-07.

2) The fuel qualification plan is adequate. The fuel qualification plan should consider the proposed analysis methodologies (e.g., fuel performance codes), the use of existing data, and any ongoing testing or plans to utilize lead test specimens. Where legacy data is used, a justification for the applicability of the data to the current application should be provided (e.g., data was collected for a fuel fabricated consistent with the proposed fuel design and irradiated in an applicable environment).

6. Safety-Related Systems, Structures, and Components Criteria and Capabilities

The information in this chapter should leverage the analysis performed for the safety related SSCs in Chapter 5 of NEI 21-07 and describe further detail into the criteria and capabilities of all safety related SSCs that are part of the affirmative safety case.

For SSCs classified as SR, the information in this chapter should address the design criteria referred to as Safety-Related Design Criteria (SRDC). The SRDC are derived from the RFDC, which in turn are developed from the RSFs determined in the LBE selection process described in Chapters 2 and 3 of NEI 21-07.

Chapter 6 of NEI 21-07, Rev. 0 (specifically, Sections 6.1 to 6.3) provides an acceptable method for licensees to follow and develop baseline information related to the design requirements for SSCs, special treatment requirements for SSCs, and system descriptions for safety-related SSCs.

12th Regulatory Position
NEI 21-07, Chapter 6 provides an acceptable method for developing information related to the design requirements for SSCs, special treatment requirements for SSCs, and system descriptions for safety-related SSCs.

13th Regulatory Position – Supplemental Information
In addition to the material identified in NEI 21-07, Chapter 6 of the SAR should also address the following:

1) If there are instrumentation and control systems that are identified as safety related then Design Review Guide (DRG), “Instrumentation and Controls for Non-Light-Water Reactor (non-LWR) Reviews,” (ADAMS under Accession No. ML21011A140) provides additional guidance for content and review of this material.
2) If there are safety-related equipment and components designed with materials required to withstand high temperature service conditions, reference to ASME B&PV Code Section III, Division 5, "High Temperature Reactors," as appropriate may be provided. Guidance on the use of ASME Section III, Division 5 can be found in the following documents: NUREG-2245, “Technical Review of the 2017 Edition of ASME Code, Section III, Division 5, “High Temperature Reactors” – Draft Report for Comment (ADAMS Accession No. 21223A097), and DG-1380 (proposed Revision 2 to RG 1.87), “Acceptability of ASME Code Section III, Division 5, High Temperature Reactors” (ADAMS Accession No. 2109A276).

7. Non Safety-Related Special Treatment (NSRST) Systems, Structures, and Components Criteria and Capabilities

The information in this chapter should describe the regulatory design and special treatment requirements for those SSCs classified as NSRST in chapter 5 of the SAR. NSRST SSCs are not directly associated with RFDC (i.e.: not SR SCCs), but are relied upon to perform risk-significant functions. Risk-significant SSCs are those that perform functions that prevent or mitigate any LBE from exceeding the frequency-consequence target or make significant contributions to the cumulative risk metrics selected for evaluating the total risk from all analyzed LBEs.

For clarity the term "special treatment" is derived from NRC regulations and Nuclear Energy Institute (NEI) guidelines in the implementation of 10 CFR 50.69. In Regulatory Guide 1.201, the following definition of special treatment is provided:

> "…special treatment refers to those requirements that provide increased assurance beyond normal industrial practices that structures, systems, and components (SSCs) perform their design-basis functions."

Chapter 7 of NEI 21-07, Rev. 0 (specifically, Sections 7.1 and 7.2) provides an acceptable method for licensees to follow and develop baseline information related to the special treatment requirements for NSRST SSCs at the site, and NSRST SSCs descriptions and capabilities. Additional information can be found in Table 4-1 of NEI 18-04.

14th Regulatory Position
NEI 21-07, Chapter 7 provides an acceptable method for developing information related to the special treatment requirements for NSRST SSCs at the site, and NSRST SSCs descriptions and capabilities.

15th Regulatory Position – Supplemental Information
In addition to the material identified in NEI 21-07, Chapter 6 of the SAR should also address the following:

a. If there are instrumentation and control systems that are identified as non-safety related with special treatment, Design Review Guide (DRG), "Instrumentation and Controls for Non-Light-Water Reactor (non-LWR) Reviews," (ADAMS under Accession No. ML21011A140) may provide guidance on appropriate special treatments to include in the application.

8. Plant Programs

The information in this chapter should provide information on those plant programs relied upon to provide special treatment to SR and NSRST SSCs that are part of the affirmative safety case. The information should provide an overview of the special treatment programs, addressing the purpose, scope, and performance objectives as well as applicability to SSCs. The information for the programs should provide reasonable assurance that 1) reliability and performance targets are met, and 2) safety-significant uncertainties are addressed. Program areas could include human factors, quality assurance, startup testing, and equipment qualification, among others.

Chapter 8 of NEI 21-07, Rev. 0 (specifically, Sections X and Y) provides an acceptable method for licensees to follow and develop baseline information related to those plant programs relied upon to provide special treatment to SR and NSRST SSCs that are part of the affirmative safety case.

16th Regulatory Position
NEI 21-07, Chapter 8 provides an acceptable method for developing information related to those plant programs relied upon to provide special treatment to SR and NSRST SSCs that are part of the affirmative safety case.

17th Regulatory Position – Supplemental Information
In addition to the material identified in NEI 21-07, Chapter 8 of the SAR should also address the following:

a. A discussion of SR SSCs and their treatment should be provided in Chapter 8 of the SAR. The term "special treatment" is used in a manner consistent with NRC regulations and Nuclear Energy

Institute (NEI) guidelines in the implementation of 10 CFR 50.69. In Regulatory Guide 1.201, the following definition of special treatment is provided:

> "…special treatment refers to those requirements that provide increased assurance beyond normal industrial practices that structures, systems, and components (SSCs) perform their design-basis functions."

All safety-significant SSCs are subject to special treatment requirements. Chapter 8 of the SAR should describe special treatment requirements applicable to each SR SSC. These requirements should include specific performance requirements to provide adequate assurance that the SSCs will be capable of performing their RSFs with significant margins and with appropriate degrees of reliability. These include numerical targets for SSC reliability and availability, design margins for performance of the RSFs, and monitoring of performance against these targets with appropriate corrective actions when targets are not fully realized. Another consideration in the setting of SSC performance requirements is the need to assure that the results of the plant capability DID evaluation described in Chapter 4 and 5 of the application (in accordance with NEI 21-07) are achieved not just in the design, but in the as-built and as-operated and maintained plant throughout the life of the plant.

b. Associated testing/validation for SR SSCs
Special treatment requirements for SR SSCs may include the performance of routine testing and validation of SSC performance capability. Describe, as applicable, the special treatment requirements from NEI 18-04, Table 4-1, on a case-by-case basis and in the context of the SSC functions in the prevention and mitigation of applicable LBEs. These special treatment items for SR SSC may include the following:

- Equipment qualification - Essentially the same as for existing reactors for SR SSCs, 10 CFR 50.49
- Materials qualification
- Pre-service and risk-informed in-service inspections - See Regulatory Guide 1.178
- Pre-service and in-service testing - In–service testing needs to be integrated with Reliability Assurance Program
- Surveillance testing - Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met (i.e., demonstrate the ability to perform the safety function).

c. All NSRST SSCs are subject to special treatment requirements. This Chapter should describe special treatment requirements applicable to each NSRST SSC. These requirements should include specific performance requirements to provide adequate assurance that the SSCs will be capable of performing their RSFs with significant margins and with appropriate degrees of reliability. These include numerical targets for SSC reliability and availability, design margins for performance of the RSFs, and monitoring of performance against these targets with appropriate corrective actions when targets are not fully realized. Another consideration in the setting of SSC performance requirements is the need to assure that the results of the plant capability DID evaluation described in Chapter 4 and 5 of the application (in accordance with NEI 21-07) are achieved not just in the design, but in the as-built and as-operated and maintained plant throughout the life of the plant.

d. Associated testing/validation for NSRST SSCs
Special treatment requirements for NSRST SSCs may include the performance of routine testing and validation of SSC performance capability. Describe, as applicable, the special treatment requirements

from NEI 18-04, Table 4-1, on a case-by-case basis and in the context of the SSC functions in the prevention and mitigation of applicable LBEs. These special treatment items for NSRST SSCs may include the following:

- Reliability assurance targets
- Seismic qualification
- Pre-service and risk-informed in-service inspections - See Regulatory Guide 1.178
- Pre-service and in-service testing - In–service testing needs to be integrated with Reliability Assurance Program
- Surveillance testing - Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met (i.e., demonstrate the ability to perform the safety function).

D. IMPLEMENTATION

The purpose of this section is to provide information on how advanced reactor applicants and licensees[3] may use this guide and information regarding the NRC's plans for using this RG. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting," and any applicable finality provisions in 10 CFR Part 52.

Use by Applicants and Licensees

Advanced reactor applicants and licensees may voluntarily[4] use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations.

Advanced reactor licensees may use the information in this RG for actions that do not require NRC review and approval such as changes to a facility design under 10 CFR 50.59, "Changes, Tests, and Experiments." Non-LWR licensees may also use the information in this RG or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this RG. Because this guidance applies only to advanced reactors, and not to power reactors that are large LWRs, the NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG. The NRC staff does not expect or plan to request licensees to voluntarily adopt this RG to resolve a

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3 In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Parts 50 and 52; and the term "applicants," refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

4 In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this RG. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the RG, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this RG, generic communication, or promulgation of a rule requiring the use of this RG without further backfit consideration.

During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this RG, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this RG are part of the licensing basis of the facility. However, unless this RG is part of the facility license, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this RG constitutes a violation.

If a licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised RG and (2) the specific subject matter of this RG is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this RG or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52. Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.

If a licensee believes that the NRC is either using this RG or requesting or requiring the licensee to implement the methods or processes in this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 32), and in NUREG-1409, "Backfitting Guidelines," (Ref. 34).

ACRONYMS/ABBREVIATIONS – To Be Updated

AOO	anticipated operational occurrence
ASME	American Society of Mechanical Engineering
BDBE	beyond-design-basis event
CFR	*Code of Federal Regulations*
COL	combined license
DC	design certification
DBA	design-basis accident
DBE	design-basis event
DBEHL	design-basis external hazard level
DBHL	design-basis hazard level
DG	draft regulatory guide
DID	defense-in-depth
DOE	U.S. Department of Energy
F-C	frequency-consequence
IAEA	International Atomic Energy Agency
IDP	integrated decision panel
ITAAC	inspections, tests, analyses, and acceptance criteria
ITP	Initial Test Program
LBE	licensing-basis event
LMP	Licensing Modernization Project
LWR	light-water reactor
MHTGR	modular high-temperature gas-cooled reactor
ML	manufacturing license
mrem	millirem
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NSRST	nonsafety-related with special treatment
OMB	Office of Management and Budget
PRA	probabilistic risk assessment
PRISM	Power Reactor Innovative Small Module
RFDC	required functional design criteria
RG	regulatory guide
RTNSS	regulatory treatment of nonsafety systems
SDA	standard design approval
SR	safety related
SRM	staff requirements memorandum
SSC	structure, system, and component
TS	technical specification
U.S.C.	*United States Code*

REFERENCES[5]

1. Nuclear Energy Institute (NEI) 21-07, "Technology Inclusive Guidance for Non-Light-Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology", Rev. 0

2. Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities"

3. 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"

4. NEI 18-04, Revision 1, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development"

5. RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications For Licenses, Certifications, and Approvals for Non-Light-Water Reactors"

6. SECY 20-0032, "Rulemaking Plan On "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-Ak31; NRC-2019-0062)"

7. ARCAP Roadmap ISG

8. "Policy Statement on the Regulation of Advanced Reactors" (Volume 73 of the Federal Register, page 60612, October 14, 2008)

9. RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)"

10. RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light Water Reactors"

11. NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness

12. NRC Non-Light Water Reactor Near Term Implementation Action Plans

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5 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html. The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

Copies of International Atomic Energy Agency (IAEA) documents may be obtained through their Web site: WWW.IAEA.Org/ or by writing the International Atomic Energy Agency, P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria.

Publications from the Nuclear Energy Institute (NEI) are available at their Web site: http://www.nei.org/ or by contacting the headquarters at Nuclear Energy Institute, 1776 I Street NW, Washington DC 20006-3708, Phone: 202-739-800, Fax 202-785-4019.

13. NRC Non-Light Water Reactor Mid-Term and Long-Term Implementation Action Plans

14. SRM - COMGBJ-10-0004/COMGEA-10-0001, “Use of Risk Insights to Enhance Safety Focus of Small Modular Reactor Reviews”

15. SRM – SECY -11-0024, “Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews”

16. RG 1.206, “Applications for Nuclear Power Plants,” Rev. 1 (October 2018)

17. NUREG 0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition

Appendix A
Construction Permit Application Guidance

Detailed Advanced Reactor Construction Permit Guidance

The staff notes that the Construction Permit (CP) guidance in Appendix A of this document is consistent with the guidance provided in the July 8, 2021, version of this document (ADAMS Accession No. ML21190A014). The staff will be updating the guidance in this Appendix in a future revision to ensure consistency with the latest version of NEI 21-07 and the associated staff positions. Areas where the staff may provide updated guidance (depending on the final version of NEI 21-07) could include the following:

- Section 2.d of the Appendix provides a detailed list of the site information required to be in the CP application and refers to the "Site Information" interim staff guidance for further detail. NEI 21-07, Revision 0 (Chapter 1) requires a high-level summary of site information and refers to Chapter 2 for detailed site information. NEI 21-07 (Chapter 1) does not list the site information required and NEI 21-07 (Chapter 2) does not mention site information at all.

- The source term to be used for the siting determination for non-LWRs is still under consideration by the staff. The outcome for this topic will be addressed in a future revision to this appendix.

- The guidance associated with scope of the PRA information at the CP stage in this Appendix A is broader and more detailed than specified in NEI 21-07, Revision 0.

- Section 2.c of this Appendix provides guidance for a preliminary analysis that is able to support a reasonable assurance finding for 10 CFR 50.34(a)(4) and 50.43(e)(1)(iii). It is not clear if NEI 21-07 covers this item.

- Chapters 1 and 5 of this Appendix describes principal design criteria (PDC) to be included in the CP application but does not mention complimentary design criteria (CDC). Chapter 5 of NEI 21-07 mentions PDCs and CDCs; however, the scope and their role in the safety case are still uncertain. This topic and these chapters will need to be revised as the staff's position on PDC is developed.

- Sections 6 and 7 of this Appendix provides guidance that notes "information should be provided for each safety related (SR) and non-safety related with special treatment (NSRST) structure, system, and component (SSC) to support a determination that the SSC will meet its reliability and performance targets as credited in the PRA". It is not clear if NEI 21-07 requires this information in a CP application.

Draft Proposed Construction Permit Guidance from July 8, 2021 Version of the Document

This guidance is intended for CP applications involving advanced reactors following the licensing modernization project process. The guidance is based on an application using a risk-informed performance-based approach, such as the advanced reactor content of application project (ARCAP) whose purpose is to develop technology-inclusive, risk-informed and performance-based application guidance. The ARCAP, documented in *ISG-XXX, "Advanced Reactor Content of Application Interim Staff Guidance,"* is broad and encompasses the industry-led technology-inclusive content of application project (TICAP). This CP guidance references applicable guidance developed through the ARCAP/TICAP activities as well as guidance derived from separate ongoing regulatory activities (e.g., security and emergency planning rulemaking), as necessary.

The TICAP guidance that is being developed in parallel with the guidance found in this document is based on the Licensing Modernization Project (LMP) described in NEI 18-04, Revision 1, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development," as endorsed by the NRC in Regulatory Guide (RG) 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors." Several vendors have indicated that they plan to implement the LMP to develop the licensing basis for their applications. As such, processes from the LMP and initial guidance referencing TICAP and ARCAP draft documents are referenced throughout this document.

The ARCAP guidance is currently under development and is intended to be used in conjunction with the guidance in this document for the review of a non-LWR CP application. Because ARCAP/TICAP is in its early stages this document italicizes NRC guidance and industry standards that are under development that are not yet formally endorsed. These italics will be removed in future revisions to the document as the ARCAP/TICAP guidance and other NRC guidance and Industry standards to reflect the appropriate endorsed guidance.

However, applicants are not required to utilize the TICAP/LMP approach and may instead use another methodology (e.g., traditional deterministic approach, maximum hypothetical accident[6]) to analyze non-LWR performance and develop a licensing basis. The TICAP/LMP process forms the basis for this guidance although in some areas the guidance provides additional considerations for acceptably addressing a specific topic when a TICAP/LMP approach is not used. As noted above applicants are encouraged to use the preapplication process to optimize reviews, which is especially important if an applicant intends to use a process other than the LMP to develop their licensing basis. Regardless, the review guidance in this document is limited in scope. The NRC staff should continue to consult other established guidance documents, as applicable, to complete reviews of non-LWR applications.

This guidance addresses the minimum information necessary in a CP application for the NRC staff to issue a CP under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.35(a) when the applicant has not supplied all of the technical information required to complete the application (i.e., 10 CFR 50.34(a)) and support the issuance of a CP which approves all proposed design features (i.e., obtains finality for the design). When making its safety finding regarding the issuance of a CP under 10 CFR 50.35(a), the NRC staff should make the determination that the application:

(1) Describes the proposed design of the facility, including, but not limited to,
   a. the principal architectural and engineering criteria for the design, and
   b. the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Describes safety features or components, if any, which require research and development program necessary to resolve any safety questions associated with such features or components.

(3) Provides commitments that such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and

[6] In this context, "maximum hypothetical accident" refers to a conservatively assessed, deterministic accident with consequences that bound the full spectrum of accident conditions for the plant and is not necessarily a credible event.

(4) Describes the site criteria contained in 10 CFR Part 100 and based on that criteria concludes that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Where an applicant desires design finality regarding a specific topic, the NRC staff should review that the application has provided sufficient information about the topic at a level of detail that is expected at the operating license (OL) stage. The guidance that follows is limited to the first 8 chapters of the preliminary safety analysis report (PSAR) consistent with the scope and methodology described in Nuclear Energy Institute (NEI) 21-xx, "XYZ." For CP guidance outside the first 8 chapters of the PSAR, refer to *draft* ARCAP ISG.

Specific Topic Guidance

1. General Plant and Site Description
   The NRC staff should review application content to ensure that the following information is included:
   a. Overview of technology (size of the reactor and planned commercial application of the design—power production, industrial application, etc.), including references to previous experience with similar designs and technology.

   b. General plant and site characteristics including:
      i. The specific number, type, lifetime, and thermal power level of the facilities, or range of possible facilities, for which the site may be used.
      ii. General description of the important plant design and operational features in sufficient detail to allow the reviewer to understand how the plant operates in normal and off-normal conditions, including refueling. The description should include the major plant structures, systems, and components (SSCs) and relied upon to meet the regulations. The important characteristics (coolant, moderator, fuel design, neutron spectra, materials, etc.) of the design. Drawings and other material as necessary to understand the design.
      iii. A description of how the design accomplishes the fundamental safety functions of controlling reactivity, heat removal, and radionuclide retention, including spent fuel storage and cooling, should be provided.
      iv. The Principal Design Criteria (PDCs) applicable to the design (for additional guidance on selecting PDCs, refer to RG 1.232 "Guidance for Developing Principal Design Criteria for Non-Light Water Reactors."
      v. A summary of the approach used in conducting the safety analysis, including Licensing Basis Events (LBEs) including Design Basis Accidents (DBAs), safety classification of SSCs and their performance requirements and special treatments, adequacy of defense-in-depth (DID) and the overall acceptance criteria used.
      vi. Overview of the analytical codes and analysis methods used.
      vii. The location and boundaries of the site.
      viii. The proposed general location of each major structure on the site.

   c. Novel design features – provide a description of novel design features (such as passive systems, inherent safety features, or simplified control features) that may be used in safety-related or safety-significant SSCs. Topics to be considered beyond the reactor system include unique features such as seismic isolators, novel digital instrumentation and control systems, security features, or novel approaches to programs.

d. Identify the applicability of Generic Safety Issues, Unresolved Safety Issues and Three Mile Island action items to the design and their proposed resolution.

e. Identify the RGs applicable to the design and any proposed exceptions.

f. Identify the consensus design codes and standards (ASME, ANSI, IEEE, etc.) used in the design along with what SSCs they apply to.

2. Methodologies and Analyses
   a. Source Terms
   The NRC staff should review the source term methodology used by the applicant to include the validation and verification of the associated engineering computer programs. The source term development needs to include radiological source terms for accident analysis, routine effluents, radwaste system design, shielding design and equipment qualification. The NRC staff should consider the guidance and references found in SECY-16-0072, "Accident Source terms and Siting for Small Modular Reactors and Non-Light Water Reactors" (ML15309A319) for additional information regarding expected CP application content in this area.

   b. PRA
   The NRC staff should review the description and results of the applicant's PRA described in a CP application. The plant design and the associated PRA at the CP application stage are less mature relative to the Operating License and, accordingly, are considered to be preliminary. Therefore, the description of the PRA is a high-level overview or summary that covers topics such as the methodology, scope, and acceptability of the PRA. When assessing the acceptability of the PRA, the NRC staff should consider any self-assessment, use of the non-LWR PRA standard (ASME/ANS RA-S-1.4-2021) including any exceptions, and/or peer review performed by the applicant commensurate with the plant design and PRA development stage. The description of PRA should also discuss how insights gained from the PRA have been, and will be, used during the design and construction of the plant. The NRC staff should examine the methods used or to be used to conduct a thorough and systematic search for initiating events (such as the use of master logic diagrams, heat balance fault trees, process hazards analysis, failure modes and effects analysis, operating experience reviews, etc.). The results of PRA should summarize the key outputs of the PRA including risk-significant LBEs, SSCs and human actions as well as other risk insights such as those on defense-in-depth. The results should also discuss the uncertainty analysis and sensitivity analysis performed. The NRC staff reviews the planned further development of the PRA and the use of its results to help resolve any safety questions associated with the major features or components identified in a CP application.

   In order for the NRC staff to conclude that the PRA is of sufficient scope and technical adequacy to support a CP application, the staff needs to be assured that:

   - The PRA description addresses the methodology used, includes a discussion regarding initiating events, includes key outputs and risk insights, and describes further plans for PRA development and use.
   - The methodology is generally consistent with either consensus industry standards or good industry practices.
   - The search for initiating events was complete given the level of design completeness.

- The PRA results were properly derived.
- Insights identified were incorporated into preliminary designs.

The reviewer should first understand the context in which the PRA is being used, which includes the description and results of the PRA. The description of PRA should include the key PRA assumptions. To assess the quality of the PRA for the decision-making in support of the application, it is expected that the applicants conform with the guidance provided in Section 2.1, "Probabilistic Risk Assessment," of NEI 21-xxx regarding the content of a SAR related to PRA.

In addition, the frequencies and probabilities should be appropriately estimated; and the engineering analyses, assumptions, and approximations used in developing the PRA model be appropriate and should demonstrate the robustness with respect to the uncertainties in the assessment.

The NRC staff should make evaluation findings that the PRA has been performed in such a way that the PRA results are reasonable based on the level of maturity of the design, and information provided in the SAR is reasonable and sufficient to support the findings.

c. Safety and Accident Analysis
The staff should review the safety and accident analysis used by the applicant to support findings associated with 10 CFR 50.34(a)(4). This review should consider that the requirement under 10 CFR 50.43(e)(1)(iii), that sufficient data exist on the safety-features of the design to assess the analytical tools used for safety analysis, is not applicable to a CP. Accordingly, evaluation of the safety margins using approved evaluation models is not required to support a CP. However, preliminary analyses should be available to support reasonable assurance findings that:

1. The design will be able to provide sufficient margins of safety during normal operations and transient conditions.
2. The applicant has identified the structures, systems, and components necessary for the prevention of accidents and the mitigation of the consequences of accidents.
3. The applicant has demonstrated an understanding of the uncertainty associated with the performance of structures, systems, and components necessary for the prevention of accidents and the mitigation of the consequences of accidents.

It is noted that items above are closely related (e.g., an understanding of the uncertainties under item 3 is essential to an understanding of the margin under item 1). Additionally, items 2 and 3 support staff findings associated with 10 CFR 50.35(a)(3) that safety features or components which require research and development have been described and that there will be conducted a research and development program reasonably designed to resolve any safety questions associated with such features or components (see Section 17 on Research & Development). Additionally, the review of the safety analysis should consider the identification of licensing basis events (see Section 3 on licensing basis events).

d. Site Information
The NRC staff should review the site information in the application. Guidance regarding specific information content for this section can be found in draft *ARCAP ISG, "Site Information*," (for applications using the LMP approach) *and [forthcoming] Staff Requirements Memorandum (SRM) to SECY-20-0045, "Population-Related Siting*

Considerations for Advanced Reactors," for guidance regarding population distribution. The relevant topics areas are:

i. Site Characteristics and Site Parameters (Overview)
ii. Geography and Demography
    (1) Site Location and Description
    (2) Exclusion Area Authority and Control
    (3) Population Distribution
iii. Nearby Industrial, Transportation, and Military Facilities
iv. Regional Climatology, Local Meteorology, and Atmospheric Dispersion
v. Hydrological Description
    (1) Floods
    (2) Flooding Protection
    (3) Groundwater
vi. Geology, Seismology, and Geotechnical Engineering
    (1) Geologic Hazards
    (2) Vibratory Ground Motion
    (3) Surface Deformation
    (4) Stability of Subsurface Materials and Foundations
    (5) Stability of Slopes
vii. Summary of Design Basis External Hazards

3. Licensing Basis Events

The NRC staff should review the process described in the application for selection of LBEs and classification and treatment of SSCs. One acceptable approach is described in RG 1.233, which classifies LBEs as either Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Beyond Design Basis Events (BDBEs), or DBAs. DBAs are selected from the set of DBEs. Other risk-informed approaches will need to be reviewed, evaluated, and determined acceptable by the staff. Regardless of the approach described for addressing LBEs and classification and treatment of SSCs, the staff review should ensure that the application adequately describes the analysis of the radiological consequences of accidents to show compliance with 10 CFR 50.34(a)(1), to include the following:

a. Discussion of selected DBAs. The NRC staff should ensure that the spectrum of DBAs includes those DBAs that present the greatest challenge with respect to calculated fission product releases.

b. Discussion of accident source terms. The NRC staff should consider the following:
    i. The identification of radionuclide release mechanisms from fuel, the associated limits, and the contribution to source term are or will be supported by experimental data that cover the needed range of applicability.
    ii. The performance of fission product barriers credited to prevent and/or inhibit the release of radionuclides are or will be supported by existing or planned experimental data that cover the needed range of applicability.

The NRC staff should evaluate the applicant's use of bounding assumptions and conservative modeling to account for the uncertainty in final design details. For review of mechanistic source terms (if provided), additional information on development of accident source terms can be found in [INL paper] "Technology-Inclusive Determination of Mechanistic Source

Terms for Offsite Dose-Related Assessments for Advanced Nuclear Reactor Facilities," (ML20192A250). The staff should consider SECY-16-0012, "Accident Source Terms and Siting for Small Modular Reactors and Non-Light Water Reactors," for guidance on mechanistic source terms.

c. Discussion of the major SSCs of the facility that are intended to mitigate the radiological consequences of a DBA with a description of how the three fundamental safety functions are accomplished for each DBA. Major SSCs of the facility include those that may affect the performance of barriers that restrict or limit the transport of radioactive materials from the fuel to the public (i.e., that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in 10 CFR 50.34(a)(1)). The staff's review should include identification of the design basis for the SSCs (e.g., codes and standards to be followed, seismic categories, etc.) as well as the SSC fission product removal mechanisms. This includes natural fission product removal processes or for unique features of the design that may require additional information from the applicant to fully explain the process being credited, the amount of removal being credited (specifically decontamination factors or coefficients and timing), basis for the proposed values and inputs to the dose analysis calculation, and the justification for assuming the removal process is applicable to the design of the plant for the duration of the event

d. Discussion of the characteristics of fission product releases from the proposed site to the environment including the rates of fission product release, the isotopic quantities and the chemical forms of fission products released to the environment.

e. Discussion of the meteorological characteristics of the proposed site used in the accident analysis including the site-specific short-term atmospheric dispersion (χ/Q) values determined by the applicant.

f. Discussion of the analysis methods, assumptions and results for the total calculated radiological consequence dose at the exclusion area boundary (EAB), the outer boundary of the low population zone (LPZ) and control room (if required, e.g., operator actions are relied upon for safety-significant functions) from the DBAs. The uncertainty analyses in the mechanistic source terms and radiological doses should be reviewed as part of the evaluation of conservative assumptions used in this analysis. The plant design features intended to mitigate the radiological consequences of accidents, site atmospheric dispersion characteristics and the distances to the EAB and to the LPZ outer boundary are acceptable if the total calculated radiological consequences for the postulated fission product release (calculated at the upper 95th percentile of consequences) fall within the following exposure acceptance criteria specified in 10 CFR 50.34(a)(1)(ii)(D):

    i. An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE), and
    ii. An individual located at any point on the outer boundary of the LPZ, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage), would not receive a radiation dose in excess of 25 rem TEDE.

The NRC staff should consider performing an independent confirmatory radiological consequence analysis using pertinent information in the application to assess whether the proposed site meets the radiological consequence evaluation factors identified in 10 CFR 50.34(a)(1).

4. Integrated Evaluations
   a. Evaluation of Integrated Plant Risk
      Integrated individual risks of site boundary dose and early and latent health effects should be reviewed over the range of LBEs analyzed. The analysis method and assumptions should be reviewed for consistency with NRC practice. Considerations could include:

      - was off-site evacuation in accordance with the facility's EP plan assumed?
      - was medical treatment for those members of the public exposed assumed?
      - what latent fatality risk coefficient was used
      - what segment of the population [average healthy individual or something else] does the risk coefficient represent, etc.?

      The integrated risk evaluation should be reviewed against three cumulative risk targets:
      i. The total mean value frequency of exceeding a site boundary dose of 100 mrem from all LBEs should not exceed 1/plant-year. The value of 100 mrem is selected from the annual exposure limits in 10 CFR Part 20.
      ii. The average individual risk of early fatality within 1 mile of the EAB shall not exceed a mean value of 5×10^{-7}/plant-year to ensure that the NRC safety goal Quantitative Health Objective (QHO) for early fatality risk is met.
      iii. The average individual risk of latent cancer fatalities within 10 miles of the EAB shall not exceed a mean value of 2×10^{-6}/plant-year to ensure that the NRC safety goal QHO for latent cancer fatality risk is met.

   b. Defense-in-Depth
      DID is a design approach to account for uncertainties in equipment and human performance. It can result in redundant, diverse and independent measures to accomplish safety functions and ensure that safety is not dependent upon a single SSC or human action. For applications that use a risk-informed performance-based approach, the staff should expect the DID information to address the systematic assessment methodology endorsed by RG 1.233 and document preliminary integrated decision-making process panel (IDPP) decisions according to NEI 18-04, Revision 1.

      The staff should ensure that the applicant has provided necessary commitments to establish DID adequacy. Commitments to implement the DID evaluation processes in RG 1.233 should be adequate. Alternately, the staff should ensure that the applicant's DID process involves incorporating DID into design features, operating and emergency procedures, and other programmatic elements to ensure performance requirements are maintained throughout the life of the plant. For applicants that choose not to use the RG 1.233 endorsed approach, the applicant will need to explain its approach to DID and include in the application a description regarding how DID is addressed.

5. Safety Functions, Design Criteria, and SSC Categorization
   a. Principal Design Criteria

The NRC staff should review the PDCs proposed in the application. The NRC staff expects prospective non-LWR applicants will review the general design criteria (GDCs) pertaining to LWRs provided in Appendix A to 10 CFR Part 50 and the guidance in RG 1.232 to develop their PDCs and ensure that necessary safety functions and SSCs are covered under the selected PDCs. The staff should determine that the PDCs were appropriately developed. As part of this process, the staff should evaluate the acceptability the safety functions (referred to as the required safety functions (RSFs) in the LMP process) that must be fulfilled to keep the DBEs within the dose and integrated risk targets. Required Functional Design Criteria (RFDC) are then derived from the RSFs. The staff should ensure that the RFDCs are defined to capture design-specific criteria that may be used to supplement or modify the applicable GDCs or Advanced Reactor Design Criteria in the formulation of PDCs.

b. Safety-Related (SR) SSCs
The NRC staff should review the list of the SR SSCs identified through the LBE analysis. The staff should ensure that for each SR SSC, the basis for such classification is indicated in a traceable manner.

c. Complementary Design Criteria
The NRC staff should review the complementary design criteria (CDCs) proposed in the application. The staff should determine that the CDCs were appropriately developed. As part of this process, the staff should evaluate the acceptability the risk significant functions that must be fulfilled to address DID adequacy. The NRC staff should ensure that necessary risk significant safety functions and other safety functions for adequate DID are covered under the selected CDC.

d. Non-Safety-Related with Special Treatment (NSRST) SSCs
The NRC staff should review the list of the NSRST SSCs identified through the LBE analysis. The staff should ensure that for each NSRST SSC, the basis for such classification is indicated in a traceable manner.

e. SSC Categorization Process
The NRC staff should review the SSC categorization process described in the application. NRC accepted guidance for SSC categorization includes RG 1.233 which endorses the methodology in NEI 18-04, RG 1.201, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance,” and NEI-00-04, “10 CFR 50.69 SSC Categorization Guideline.”

6. Safety-Related SSC Criteria and Capabilities
Refer to NEI 18-04 for a definition of SR SSCs. The NRC staff should review the SR design criteria and special treatment requirements for each SR SSC described in the application. Information should be provided for each SR SSC to support a determination that the SSC will meet its reliability and performance targets as credited in the PRA. [Specifically, the staff should review information for each SR SSC including:
    - Design requirements and applicable codes and standards used in the design of the SSC.
    - The RSF of the SSC, its RFDCs and its relationship to the PDCs.

The NRC staff should ensure that the application describes how the SR SSCs that are credited in the fulfillment of RSFs are capable to perform their RSFs with a high degree of confidence in response to any Design Basis External Hazard Levels (DBEHLs).

The NRC staff should ensure that commitments are provided to describe SR SSC reliability and capability performance requirements, performance of testing and validation of SSC performance capability, operability/availability requirements, special treatment requirements, and any required support functions at the operating license stage.

7. Non-Safety Related with Special Treatment (NSRST) SSC Criteria and Capabilities
   Refer to NEI 18-04 for a definition of NSRST SSCs. The NRC staff should review the design criteria and special treatment requirements for each NSTST SSC described in the application. Information should be provided for each NSRST SSC to support a determination that the SSC will meet its reliability and performance targets as credited in the PRA. Specifically, the staff should review information for each NSRST SSC including:

   - Design requirements and applicable codes and standards used in the design.
   - The risk significant functions and functions required for defense-in-depth of the SSC, and its relation to the PDCs (In TICAP these PDCs are called CDCs).

   The staff should ensure that the application describes how the NSRST SSCs are capable of performing their risk-significant functions or functions that are necessary for defense-in-depth adequacy with a high degree of confidence in response to any internal hazard (e.g., internal floods, internal fires, pipe whip, spatial placement, etc.) or DBEHLs.

   The staff should ensure that commitments are provided to describe NSRST SSC reliability and capability performance requirements, performance of testing and validation of SSC performance capability, availability requirements, special treatment requirements, and any required support functions at the OL stage.

8. Plant Programs
   The NRC staff should review the application for commitments to develop programs needed to implement the special treatments and meet reliability and performance targets for SR SSCs and NSRST SSCs. Such program areas may include in-service testing, maintenance, human factors, training, and reliability assurance.

APPENDIX B
NRC REGULATORY POSITION ON NEI 21-07, REVISION 0, "TECHNOLOGY INCLUSIVE GUIDANCE FOR NON-LIGHT WATER REACTORS SAFETY ANALYSIS REPORT CONTENT FOR APPLICANTS USING THE NEI 18-04 METHODOLOGY"

Introduction

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed Nuclear Energy Institute (NEI) 21-07, Revision 0, "Technology Inclusive Guidance for Non-Light Water Reactors Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology." The purpose of this appendix is to supplement the Regulatory Positions discussed in Regulatory Positions C.1 through C.8 of this RG. The staff's detailed position on the applicable portions of NEI 21-07, Revision 0 are found in the following table. The table notes areas where the staff has identified an "exception," "clarification," "addition," or "comment/suggested edit." The definition of these terms is as follows:

- **Exception** – feedback labeled as an NRC Exception is used to highlight statements, or portions thereof, in NEI 21-07 that are factually incorrect or guidance that would result in the need for an NRC Request for Additional Information (RAI) if followed by an applicant in developing a safety analysis report (SAR).

- **Clarification** – feedback labeled as an NRC Clarification is used to indicate statements or guidance in NEI 21-07 that are ambiguous and would require clarification by the NRC to limit the possible interpretations by an applicant or other stakeholder consulting NEI 21-07. An applicant relying on NEI 21-07 to develop an application in the absence of the Clarification would likely be subject to RAIs if the guidance was improperly interpreted. Similarly, stakeholders consulting NEI 21-07 in the absence of the Clarification could conclude that publicly available application information is inadequate to the extent that it could form the basis for a contention.

- **Addition** – feedback labeled as an NRC Addition is used to indicate staff regulatory guidance that should be followed by an applicant in addition to the guidance in NEI 21-07 in order to develop a SAR that addresses their safety case. Additions not related to the LMP-based affirmative safety case will be included in the ARCAP guidance.

The information described in this Appendix is preliminary and will be updated as appropriate based on continuing discussions with stakeholders regarding NEI 21-07. The purpose of providing the draft proposed information is to aid in the discussion and development of technology-inclusive, risk-informed, and performance-based application guidance.

NRC Draft NEI 21-07, Revision 0 Exceptions, Clarifications, Additions, and Comment/Suggested Edit

<table>
<tr><th>NEI 21-07 Section Number ID</th><th>Topic</th><th>Discussion</th><th>Type</th><th>Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)</th></tr>
<tr><td>A.2</td><td>Background</td><td>Page 3 (last paragraph) - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that in addition to making a safety case, an applicant should also make a licensing case that focuses on compliance with applicable regulations and includes any exemptions, as necessary.</td><td>Clarification</td><td>Clarification provided in TICAP DG (pgs. 2 and 11)</td></tr>
<tr><td>A.3a</td><td>Supplemental information affecting first 8 chapters of the SAR outside the scope of Industry TICAP guidance</td><td>Page 3 Clarification and addition. The staff will continue to reference in its TICAP RG the guidance that is relevant to the first 8 chapters of the SAR (e.g., siting, fuel qualification, instrumentation and control design review guide, ASME Section III Division 5). See supplemental information found in 7/8 version of TICAP RG draft white paper https://www.nrc.gov/docs/ML2119/ML21190A014.pdf</td><td>Clarification and Addition</td><td></td></tr>
<tr><td>A.3b</td><td>Scope</td><td>Page 4 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that that an affirmative safety case should include normal operation and that applicants should also make a licensing case with respect to compliance with regulations and include exemptions, as necessary. That is, the applicant must make the case for and claim compliance with or exemptions from specific regulations. The NRC will not just review the safety case and derive from it those regulations that are met in order to makes its findings.</td><td>Clarification</td><td>Clarification provided in TICAP DG (pg. 11)</td></tr>
<tr><td>B.2</td><td>SAR Outline</td><td>Page 7 (bottom) - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that an affirmative safety case should include normal operation as well as LBEs.</td><td>Clarification</td><td>Clarification provided in TICAP DG (pg. 11)</td></tr>
<tr><td>B.3</td><td>Explanation and Use of text that is in italics</td><td>Page 9 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper clarifying the meaning of the use of the regular text and text in italics throughout the SAR content guidance in Section C of NEI 21-07. Examples of text that the staff believes should be in regular font vice in italics include:
<table>
<tr><th>NEI 21-07 Section Number</th><th>Topic</th><th>Issue</th></tr>
<tr><td>1a</td><td>Guidance in Introduction Section should be regular font.</td><td>The fourth, fifth, and sixth paragraphs of this section should be regular text since they provide instructions for the applicant regarding information to be included, formatting, and level of detail.</td></tr>
<tr><td>2b</td><td>Discussion of topical reports</td><td>Page 21 – topical reports approved by the NRC during pre-application engagement activities should be incorporated by reference into the SAR and not</td></tr>
</table></td><td>Clarification</td><td></td></tr>
</table>

<table>
<tr><th>NEI 21-07 Section Number ID</th><th>Topic</th><th>Discussion</th><th>Type</th><th>Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td></td><td></td><td>simply be listed as general references. Applicants should specifically identify documents IBR’d into the SAR. The staff also believes the sentence should be in regular text.</td></tr>
<tr><td>3</td><td>Guidance regarding licensing basis events should be regular font</td><td>Page 27 - The third paragraph should be in regular font because it provides guidance regarding LBEs.</td></tr>
<tr><td>3.6</td><td>DBA guidance should be regular font.</td><td>Page 35 – The fourth paragraph in this section should be regular font because it provides guidance regarding the documentation of conservative deterministic DBA analyses that is generally modeled after accident analysis descriptions found in Chapter 15 of SARs for current LWRs.</td></tr>
<tr><td>4.2a</td><td>Guidance regarding DID should be regular font.</td><td>Page 38- the final sentence in the first paragraph of Section 4.2 should be in regular font because it provides guidance.</td></tr>
<tr><td>4.2b</td><td>Defense in depth discussion and clarification that some of the guidance should be in regular text</td><td>Page 39 – the second paragraph of Section 4.2 and the bulleted list immediately below it should be in regular font and not in italics since it provides guidance.

The sixth bullet of this list should be modified to read, “Evaluation of single features that are risk significant to assure no overdependence on that feature …."

The first sentence of the paragraph following these bullets in Section 4.2 should be revised to state: “Note that the information responsive to this bulleted list should be provided in either this chapter or in Chapters 3, 5, 6, 7, and 8.”</td></tr>
<tr><td>4.2.1</td><td>DID plant capability summary</td><td>Page 40 – portion of second paragraph should be in regular font because it provides guidance</td></tr>
<tr><td>4.2.1.2</td><td>DID guidance should be regular font.</td><td>Page 41 – The first paragraph in this section should be regular font because it provides guidance regarding the DID evaluation.</td></tr>
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NEI 21-07 Section Number ID	Topic	Discussion			Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
		4.2.2a	Defense in Depth Summary discussion in the SAR	Page 42 and 43, the second paragraph in Section 4.2.2, which starts with "Programmatic DID should be used ..." should be in regular font and not in italics since it provides guidance.		
		4.2.3b	Integrated defense in depth discussion in the SAR	Page 44, the following text should be in regular font and not in italics since it provides guidance: The baseline DID evaluation results in the SAR reflect the finalization of all DID adequacy evaluations. The evaluation in this section determines that incremental evaluations of DID outlined in NEI 1804 Section 5.9.3 for plant capability are collectively complete, programmatic actions are appropriate to sustain identified safety significant performance requirements and residual risks are very low."		
		4.2.2.1	Evaluation of Significant Uncertainties	Page 44 – Further discussion in needed in either NEI 21-07, Revision 1 or the TICAP draft RG white paper to document that "The consideration of uncertainties may also identify some sources of uncertainty that may be safety significant and lead to specific actions for DID purposes. A summary of the sources of significant uncertainty should be describe in the SAR. The details of these analyses should be documented in plant records." This text should be in regular font		
		4.2.3	Integrated DID evaluation	Page 45 - the following text should be in regular font and not in italics since it provides guidance: The baseline DID evaluation results in the SAR reflect the finalization of all DID adequacy evaluations. The evaluation in this section determines that incremental evaluations of DID outlined in NEI 18--04 Section 5.9.3 for plant capability are collectively complete, programmatic actions are appropriate to sustain identified safety significant performance requirements and residual risks are very low.		
		5.4	Safety Related Structures, Systems, and Components (SSC) description in the SAR	Page 49 - Section 5.4 first paragraph text should be in regular font vice in italics since it provides guidance. The staff will also revise the following text in the TICAP RG regarding Safety-related SSC discussion in the SAR: "The information reflected in Table 5-2, which describes combinations of SSCs that are provided in the design to fulfill each RSF and identifying whether each set of SSCs is available or not on each of the DBEs, should be included in the application."		

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<tr><th>NEI 21-07 Section Number ID</th><th>Topic</th><th>Discussion</th><th>Type</th><th>Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)</th></tr>
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<tr><td>6.1.1a</td><td>Design Basis Hazard Level discussion in the SAR</td><td>Page 55 - The following text should be in regular font vice in italics since it provides guidance: “Note that this guidance document uses the nomenclature of DBHL instead of the DBEHL term from NEI 18-04. While not discussed comprehensively in NEI 18-04, there is a need to consider not only hazards external to the plant (traditional external events) but also hazards external to the SSCs performing PRA Safety Functions – i.e., internal plant hazards such as internal fires, floods, turbine missiles, and high energy line breaks. To clarify the original intent of NEI 18-04 to address both categories of hazards, this guidance document uses the DBHL term instead of DBEHL.”

This appears to be a deviation from NEI 18-04 and if it is a deviation then it should be noted as such.</td></tr>
<tr><td>6.1.2</td><td>Guidance regarding SRDC description should be regular font</td><td>Page 57 - In the second paragraph, the following text should be regular font because it provides guidance: “For each of the RFDC, this section should identify a set of SRDC appropriate to the SR SSCs selected to perform the RSFs. These SRDC exclude Special Treatment Requirements, which are separately covered in Section 6.2. The RFDC, which are expressed in the form of functions and involve collections of SSCs and intrinsic capabilities of the plant, may be viewed as a bridge between the RSFs and the SRDC. The SRDC is more detailed requirements for specific SR SSCs in the performance of the RSF functions in specific DBAs. Examples of SRDC that were developed for the MHTGR are found in Appendix A of the LMP SSC report.”

It would be more helpful to a user of this guidance document to include some SRDC examples rather than just provide a reference to an external document.</td></tr>
<tr><td>7.1</td><td>Reliability and Capability Targets for NSRST SSCs</td><td>Page 63 – Text in first paragraph should be in regular text since it provides guidance</td></tr>
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NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
B.5	Two-Step Licensing (CP/OL)	Page 10 - Clarification of several items should be made: (1) the requirement under 50.34(a)(4) for demonstration of an affirmative safety case that includes normal operation reflecting that LMP does not address normal operation; (2) a licensing case also needs to be made by the applicant with respect to claims of compliance with or requests for exemption from regulations; and (3) the COL application scope includes ITAAC whereas the CP/OL scope does not. Clarification proposed that the LMP-based safety case shifts from compliance with prescriptive regulatory requirements to an approach that focuses on identification and performance of fundamental safety functions to address and satisfy associated regulatory requirements and provide reasonable assurance of adequate protection of public health and safety.	Clarification and Addition	
B.6	Design Certification	Page 11 – Further discussion is needed in either NEI 21-07, Revision 1, or in the TICAP draft RG white paper to clarify that the SAR content developed through use of LMP is similar in scope only to the Tier 2 information required for a DC application. Guidance for Tier 1 information, including ITAAC, required for a DC application is neither contemplated by NEI 18-04 nor discussed in the TICAP guidance document. Also included a proposed change to page 11 (last paragraph) to reference Tier 2 Information	Clarification and Addition	Public meeting discussion on wording change from “only” to “primarily” being acceptable – pending receipt of 21-07 markup.
1b	Licensing Basis Information	Page 16 – Clarify what language in Chapter 1 of a SAR will be included and maintained as part of the licensing basis, and what parts of the regulation those parts seek to fulfill.	Clarification	
1.1.2	Intended Use of the Reactor	Page 17 – The NEI proposed text does not seem to fully address 10 CFR 50.34(a)(1)(ii)(A) regarding use of the reactor. Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to address the radioactive materials inventory portion of the regulation.	Addition	
1.3.3	Defense in Depth	Page 21 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that DID adequacy is based on 3-elements; plant capability DID, programmatic DID, and RIPB DID. Applicants should address risk-informed, performance-based DID also and cite key examples for this DID element	Clarification and Addition	
2a	Pre-licensing engagement	Page 21 – The highlighted sentence gives the incorrect perception that pre-licensing interactions affect the level of detail that should be provided within the docketed license application and related submittals (e.g., topical reports)	Clarification	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
2.1	PRA discussion to be included in the SAR	Page 22– The fourth and fifth sentences in the first paragraph of Section 2.1 provide guidance and should therefore be in regular text. In order to reflect the Commission's affirmation in SRM-SECY-2015-002 regarding the need for PRA information for CP/OL applications for new reactors, they should be modified to read, "The PRA information included in the SAR should be at a summary level only as described below. It should include a description of the design-specific or plant-specific PRA, as appropriate, and its results."	Clarification	
2.1.1a	Conformance (with any deviations) with the advanced non-LWR PRA standard, ASME/ANS RA-S-1.4-2021 NEI 20-09, Rev. 0 PRA peer review	Page 22 and 23 - Trial-use RG 1.247 to endorse the std is under development. NRC staff positions in RG 1.247, once issued, should be addressed along with the Std. NEI 20-09, Revision 1, has been submitted to the NRC for endorsement. Revision 1 should be cited instead of Revision 0.	Clarification	
2.1.1b	Discussion of PRA information to be included in the SAR	Page 23 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to cover the level of detail for the PRA information to be included in the SAR as follows: "This section should describe PRA assumptions, the identification of PRA-based insights, and an overview of the results and insights from importance, sensitivity, and uncertainty analyses. A pointer should be provided if the information is described in other Chapters (e.g., Chapter 3). Detailed information used in the PRA will not be included in the SAR but will be available for NRC audit."	Clarification and Addition	
2.1.1c	Discussion of PRA info in SAR – Two-step licensing (CP application)	Page 24 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG with paper to clarify the basis for omitting peer review for PRA for a CP application as follows (italics are used to set off the clarification – final text should be in regular font): To be clear, consistent with the baseline for this guidance, to the extent that an applicant does not request any design finality as part of its CP application, no PRA peer review should be required at the CP application stage.	Clarification and Addition	
2.1.2	Summary of Key PRA Results	Page 24 – The last bullet in this section states that SAR Chapters 6 and 7 are to address reliability and capability targets for SR and NSRST SSCs. Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to address SR and NSRST human actions.	Clarification and Addition	
3.3	Anticipated operational occurrences (AOOs) –	Page 31 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that non-DBA LBE as analyzed in the PRA should be summarized in the SAR.	Clarification	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
	clarification of discussion of AOOs in the SAR			
3.3.1	AOOs – key information regarding AOOs should be captured in the SAR	Page 31 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that a description of the models, site characteristics, and supporting data associated with the calculation of the mechanistic source terms and radiological consequences (to the extent such information is not provided in Section 2.2) should be included in the discussion of AOOs with a release in Section 3.3.1 of the SAR. The text stating that this information is only in plant records should be removed from NEI 21-07, Revision 1 or addressed by an exception in the TICAP draft RG white paper. The word “additional” is suggested as a modifier to the “information that should be provided for any AOO with a release” in the sentence preceding the bulleted list to clarify that it is in addition to the narrative that should be provided for each AOO as listed in the same section. The exception to the statement regarding omission of the information and retention in plant records is appropriate because the safety case for the reactor is tied to appropriately identifying licensing basis events, including Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Design Basis Accidents (DBAs), and Beyond Design Basis Events (BDBEs). This type of information should be captured in the SAR to ensure that changes to the plant are appropriately assessed under the applicable change process (e.g., 10 CFR 50.59) reflecting their status as methods of evaluation used in establishing the design bases or in safety analyses.	Clarification and Exception	Staff considering revision to guidance in this area. See attachment to this appendix.
3.4.1	Design Basis Events (DBEs) - key information regarding DBEs should be captured in the SAR	Page 32 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document the need for a description of the models, site characteristics, and supporting data associated with the calculation of the mechanistic source terms and radiological consequences for DBEs with a release (to the extent such information is not provided in Section 2.2). The text stating that this information is only in plant records should be removed from NEI 21-07, Revision 1 or addressed by an exception in the TICAP draft RG white paper. The word “additional” is suggested as a modifier to the information that should be provided for the most limiting DBE that was used to map into each DBA to clarify that it is in addition to the narrative that should be provided for each DBE as listed in the same section. The exception to the statement regarding omission of the information and retention in plant records appropriate because the safety case for the reactor is tied to appropriately identifying licensing basis events, including Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Design Basis Accidents (DBAs), and Beyond Design Basis Events (BDBEs). This type of information should be captured in the SAR to ensure that changes to the plant are appropriately assessed under the applicable change process (e.g., 10 CFR 50.59) reflecting their status as methods of evaluation used in establishing the design bases or in safety analyses.	Clarification and Exception	Staff considering revision to guidance in this area. See attachment to this appendix

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
3.5.1	Beyond Design Basis Events (BDBEs) – key information regarding BDBEs should be captured in the SAR	Page 33 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document the need for a description of the models, site characteristics, and supporting data associated with the calculation of the mechanistic source terms and radiological consequences for BDBEs with a release (to the extent such information is not provided in Section 2.2). The text stating that this information is only in plant records should be removed from NEI 21-07, Revision 1 or addressed by an exception in the TICAP draft RG white paper. The word "additional" is suggested as a modifier to the information that should be provided for information provided for BDBEs with a release to clarify that it is in addition to the narrative that should be provided for each BDBE. The exception to the statement regarding omission of the information and retention in plant records appropriate because the safety case for the reactor is tied to appropriately identifying licensing basis events, including Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Design Basis Accidents (DBAs), and Beyond Design Basis Events (BDBEs). This type of information should be captured in the SAR to ensure that changes to the plant are appropriately assessed under the applicable change process (e.g., 10 CFR 50.59) reflecting their status as methods of evaluation used in establishing the design bases or in safety analyses.	Clarification and Exception	Staff considering revision to guidance in this area. See attachment to this appendix
4.1	Discussion of overall plant risk information found in the SAR	Page 37 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document the need for a discussion of the following items where different from the analysis performed under Chapter 3: • The site parameters (e.g. meteorology, off-site population distribution, EAB size) used in the analysis, • Assumptions on location of individual members of the public, • Source of dose (cloud shine, inhalation, ground shine) • The analysis method used, • Key assumptions (e.g., emergency preparedness measures, source terms, timing and duration of release, credit for medical treatment, early and latent fatality risk coefficients) used in the analysis, • Modes of operation (full power, low power & shutdown, refueling) considered in the analysis. • How multiple units on the site were considered, • Uncertainty/sensitivity analysis performed.	Addition	
4.2.1	Guidance for DID evaluation	Page 40– Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that "For SSCs that are relied upon to perform DID prevention and mitigation functions for risk-significant LBEs, and	Clarification	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
		where not described elsewhere in the SAR, this section should describe the set of requirements related to the performance, reliability, and availability of the SSC functions that are relied upon to ensure the accomplishment of their tasks, as defined by the PRA or deterministic analysis. This description should include how that capability is ensured through testing, maintenance, inspection and performance monitoring. "		
4.2.1.4	Prevention-Mitigation Balance	Page 43 – ADAMS ML numbers or hyperlinks to referenced documents and reports should be added to promote efficient user interface with this guidance document.	Clarification	
4.2.2b	Guidance for programmatic DID added	Page 44 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that "The applicant should provide the justification for where the design does not incorporate the programmatic capability attributes provided in NEI 18-04 Table 5-6." This text should be regular font.	Clarification	Upon re-review, staff determined that this comment can be deleted
4.2.2.2	Human Factors Considerations – SR SSC performance Monitoring	Page 44, Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to state that an applicant should include the description of programs to assure human performance for risk-significant functions should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, procedures, training and V&V, human performance monitoring (where not described in Chapter 6).	Addition	
4.2.2.3	Human Factors Considerations – NSRST SSC performance monitoring	Page 45, Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to state that an applicant should include the description of programs to assure human performance for safety-significant functions should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, procedures, training and V&V, human performance monitoring (where not described in Chapter 7).	Addition	
4.2.3b	Integrated defense in depth discussion in the SAR	Page 45 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that an applicant should address the following to describe how the integrated DID analysis meets the standards in NEI 18-04: "The applicant should summarize how the integrated DID process was applied in evaluating the overall adequacy of DID. The description should address how each of the decision guidelines listed in NEI 18-04, Section 5.9.3, was evaluated and the basis for an affirmative response. The criteria used in making the decisions (e.g., risk margins are sufficient, prevention/mitigation balance is sufficient, etc.) should be provided. If quantitative measures were used as part of the criteria, they should be provided. A description of how the results of the integrated DID process are documented and available for future DID decision-making and operations support should also be provided."	Addition	
4.2.3c	Added guidance to include a description of the change	Page 46 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that an applicant should include a discussion of the change process associated with defense in depth analysis described in Section 4.2.3 of the NEI guidance document: "The change control process should be described addressing	Clarification and Addition	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
	process to defense in depth discussion found in the SAR	how the baseline DID evaluation will be re-evaluated, based on proposed changes, to determine which programmatic or plant capability attributes have been affected for each layer of defense. Changes that impact the definition and evaluation of LBEs, safety classification of SSCs, or risk significance of LBEs or SSCs should be assessed.		
5.3	Principal Design Criteria (PDC)	Page 47 and 48- considering whether following proposed addition is appropriate related to PDC guidance: "These LMP derived requirements may be considered together with generic applicable Advanced Reactor Design Criteria (ARDC) in formulating the principal design criteria for the license application. When considering the use of generic ARDC for this purpose, the LMP methodology does not include the application of the Single Failure Criterion (SFC) that is included in the ARDC language. In the LMP approach to formulating design requirements for SSCs, reliability and capability targets are used to inform the selection of special treatment requirements. This obviates the need to applying the SFC. Hence when ARDCs are considered in developing the principal design criteria, the SFC language should be removed." Last sentence, third paragraph proposed edits to be more consistent with stated NRC positions: However, the General Design Criteria and Advanced Reactor Design Criteria are intended to provide guidance in establishing the principal design criteria for non-LWR designs. Fourth paragraph proposed edits to be more consistent with stated NRC positions. Proposed revised paragraph	Note – staff still developing position and path forward regarding PDC guidance. It is unclear at this point as to whether an exception, clarification or addition (or a combination of these) will be included in the staff TICAP RG	
5.5.1	Non Safety Related SSCs performing risk significant functions discussion in the SAR	Page 51 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that information similar to that found in Tables 5-1 and 5-2 for safety related SSCs should be provided for non-safety related SSCs performing a risk-significant function.	Addition	Upon re-review, staff determined that this comment can be deleted

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
5.6a	Complimentary Design Criteria (CDC) discussion in the SAR	Page 53 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper regarding CDC information that should be provided in the SAR, similar to the comments provided in an August 13, 2021, email that was discussed during an August 17, 2021, public meeting (see: https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML21225A565) This could include (a) the CDC are considered part of the affirmative safety case, since they specify safety criteria, (b) when they are defined at the functional level, they are considered equivalent to PDCs and (c) when they are defined at the PRA Safety Function level, they are considered subparts of a higher level PDC. In addition, the TICAP Guidance Document text should provide examples of both types of defined CDCs. The staff notes that the expectations regarding discussion of the CDC information in the SAR could be influenced by the outcome of the staff's position regarding PDC.	Clarification and Addition	
5.6b	CDC discussion in the SAR	Page 53 - Language should be added to clarify that NSRST SSCs may be included within the PDC rather than being limited to inclusion in the CDCs.	Clarification	
5.6c	CDC discussion in SAR	Page 53 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that the importance and contribution of engineering criteria for the design will be considered under 10 CFR 50.35(a), as necessary, in the finding of reasonable assurance regardless of whether the NSRST SSCs are addressed by CDCs. The focus is on the engineering criteria for the design rather than inclusion of SSCs as part of CDCs or PDCs. It is clear from the LMP process that NSRST SSCs are necessary for either PRA Safety Functions or DID. Inclusion of CDCs may also bridge the gap between the NRC's expectation for an affirmative safety case and an LMP-based affirmative safety case which does not include normal operations (see comment in earlier Section A.3)	Clarification	
6.1.1b	Design Basis Hazard Level discussion in the SAR	Page 56 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that the SAR Should include discussion regarding the calculation methodology for DBHLS loads on the SSCs Calculation methodology has traditionally been part of the licensing basis. For example, where the methodology for combining loads is either ABSUM (absolute summation) or SRSS (square root of sum of the squares) can make a big difference for the design	Clarification	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
		loads on SSCs. Also, there is a 50.59 question that specifically focuses on evaluation methodology. Not sure if this question will carry over to Part 53 but Part 50 and Part 52 applicants will need to consider it.		
6.1.1c	Design Basis Hazard Level discussion in the SAR	Page 56 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to clarify that an applicant should summarize the basis for the DBHLs in the SAR.	Clarification and Addition	
6.1.1d	Editorial correction to Table 6-1	Page 56 – verify that the table title and the second column heading should exclude the term "external."	Clarification	
6.3/7.2	FOAK SR SSCs and NSRST SSCs	Page 60 and 63 – Text suggests incomplete Validation and Verification tests can be covered under special treatment at the submittal of a license application. Staff suggests an addition / revision to the text to include the timing of the NRC SER and the possibility of license conditions, consistent with 50.43(e).	Clarification and Addition	
6.4.1a	Human Factors Considerations – SR SSCs	Page 62 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that where human actions perform required safety functions, the description of controls and displays should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, and V&V.	Addition	
7.3.1a	Human Factors Considerations – NSRST SSCs	Page 65 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that where human actions perform PRA safety functions, the description of controls and displays should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, and V&V.	Addition	
6.4.1b and 7.3.1b	Human Reliability and Capability	Pages 61 and 65 - These sections list the design aspects of the various SR and NSRST SSCs, including human actions. Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that the applicant should describe the measures to be taken to ensure that the human actions meet their reliability and capability targets assumed in the PRA. For the reliability and capability of equipment, these measures are called Special Treatment.	Addition	
Appendix B	Example LBE Descriptions	The staff does not plan to endorse Appendix B "Example Descriptions" of NEI 21-07 because the agency does not endorse examples provided in guidance documents due to the need for technical review and approval.	Clarification	Staff considering revision to this clarification

<u>Specific Chapter 3 Comment</u>:

A comment was made to NEI 21-07 regarding application content describing LBE analysis in Chapter 3 sections addressing AOOs, DBEs, and BDBEs (with releases). An example comment is shown below:

> **"3.3.1 AOO-1[7]**
>
> For each AOO, the following information should be provided:
>
> …
>
> The following additional information should be provided for any AOO with a release. The applicant may elect to provide some or all of the following information for other AOOs:
>
> - Description of the models, site characteristics, and supporting data associated with the calculation of the mechanistic source terms and radiological consequences (to the extent such information is not provided in Section 2.2). "

<u>Explanation</u>:

Understanding LBE analyses for events that have releases, other than DBAs, is important because the output of these analyses are evaluated against the F-C curve criteria (e.g., 100 mrem for AOOs, QHOs) and are used to evaluate the risk-significance of SSCs and defense-in-depth.

The Chapter 3-related comment is consistent with NEI 21-07, Chapter 2 text that states following (italic text):

- *"Certain analyses and analytical tools (methodologies) are used in the identification of licensing basis events, the evaluation of the consequences of such events, or assessing the performance of SR and NSRST SSCs. This chapter of the SAR presents information on some of those analyses and analytical tools. It is intended primarily for cross-cutting information or evaluations that support multiple LBEs or SSCs. Providing that information or evaluation upfront in one place is intended to make the documentation that follows in subsequent chapters more efficient and concise*."

(and in regular text) Section 2.1.1, "Overview of the PRA":

- "Identification of the software and analytical tools that were used to perform the event sequence modeling and quantification, determine the mechanistic source terms, and perform radiological consequence evaluations…"

The Chapter 3 comment asks to have the model, site characteristics and supporting data used in the radiological consequence analysis of AOOS, DBEs and BDBEs (with releases) be described in Chapter 3 only if it is not provided in, or is different from, the information in Chapter 2 functional or system descriptions in Chapters 5-7, or other sections of the SAR. The comment is not asking that all of the relevant parameters be documented in the SAR for every LBE evaluated (e.g., not asking for all parameters necessary to perform an independent calculation). Since the models, site characteristics, and supporting data would typically be generic for all or most of the LBE analysis, this information could be described in the Chapter 2 information, as specified in the referenced text above, or alternatively in a separate referenceable topical report. The inclusion of this information in such a document in the application either as a referenced topical report or SAR chapter appendix would address this comment provided

[7] Note that the NEI 21-07 comment markup shows one of the bullets in Chapter 3 "Discussion of significant factors that influence any degradation of layers of defense" as a comment addition. However, this text is included in the baseline NEI 21-07 document.

that the AOO, DBE and BDBE analysis does not deviate from the document or utilize some unique event specific parameters.

It's noted that recent combined license and design certification applications have typically included a topical report or generic evaluation document that addresses the evaluation models and parameters for analysis of radiological consequences of accidents. The concept of including some of this information in Chapter 2 and some of this information in a topical report was also described in the recently completed Xe-100 Tabletop Exercise Report that stated the following:

> **"4.1 Observations and Lessons Learned**
>
> ***…***
>
> ***Safety Analysis Details***
>
> The descriptions of many general analysis methodologies and approaches were developed at a preliminary level of detail during the tabletop exercise, but it was recognized that Regulatory Guide 1.203 elements would be best placed in Chapter 2, including phenomena uncertainties, evaluation model development, and sensitivity analyses and risk-significance discussion. Some of this content could be placed in subsequent chapters (i.e., LBE evaluations) as an alternative.
>
> **Quantitative Data**
>
> The description of mechanistic source term development has the potential to include a significant amount of quantitative data in the form of release fractions, uncertainties, leak path factors, etc. The team dialogue around whether to place such detailed content in the SAR, and the necessary context for a reader to understand its basis, should be weighed against the placement of such details in technical or topical reports that naturally provide such context."

<u>Proposed Comment Revision</u>

In order to better characterize the intent of the comment above, the staff is revising the previously provided comment to read as follows:

> Description of the models, site characteristics, and important supporting data associated with the calculation of the mechanistic source terms and radiological consequences (to the extent such information is not provided in methodologies and analyses discussions in Chapter 2, functional or system descriptions in Chapters 5-7, or other sections of the SAR). Important supporting data is data that is significant to the development of the [AOO] analysis conclusions regarding risk significance, meeting F-C curve targets or QHOs, developing SSC classification, or evaluating defense-in-depth.