

U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE 1.233 REVISION 0



Issue Date: June 2020
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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

A. INTRODUCTION

Purpose

This regulatory guide (RG) provides the U.S. Nuclear Regulatory Commission (NRC) staff's guidance on using a technology-inclusive, risk-informed, and performance-based methodology to inform the licensing basis and content of applications for non-light-water reactors (non-LWRs), including, but not limited to, molten salt reactors, high-temperature gas-cooled reactors, and a variety of fast reactors at different thermal capacities. This RG may be used by non-LWR applicants 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. 1), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 2).

The selection of licensing-basis events (LBEs); classification and special treatments of structures, systems, and components (SSCs); and assessment of defense in depth (DID) are fundamental to the safe design of non-LWRs. These activities also support identifying the appropriate scope and depth of information non-LWR designers and applicants should provide in applications for licenses, certifications, and approvals. This RG endorses Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development," (Ref. 3) as one acceptable method for non-LWR designers to use when carrying out these activities and preparing their applications. The methodology in NEI 18-04 provides a process by which the content of applications will permit understanding of the system designs and their relationship to safety evaluations for a variety of non-LWR designs. The system designs and safety evaluations may also demonstrate compliance with or justify exemptions from specific NRC regulations. Although the technology-inclusive methodology provides a common approach to selecting LBEs, classifying SSCs, and assessing DID, the applicability of

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Electronic copies of this RG, previous versions of RGs, and other recently issued guides are also available through the NRC's public Web site in the NRC Library at <https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/>, under Document Collections, in Regulatory Guides. This RG is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under ADAMS Accession Number (No.) ML20091L698. The regulatory analysis may be found in ADAMS under Accession No. ML18325A214. The associated draft guide DG-1353 may be found in ADAMS under Accession No. ML18312A242, and the staff responses to the public comments on DG-1353 may be found under ADAMS Accession No. ML20091L696.

specific technical requirements in NRC regulations or the need to define additional technical requirements arising from the safety evaluations is made on a case-by-case basis for each non-LWR design.

Applicability

This RG applies to nuclear power reactor designers, applicants, and licensees of advanced non-LWR designs applying for permits, licenses, certifications, and approvals under 10 CFR Part 50 and 10 CFR Part 52. Per the Commission's Policy Statement on the Regulation of Advanced Reactors, advanced designs are expected to provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions.

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

- "Policy Statement on the Regulation of Advanced Reactors" (Volume 73 of the *Federal Register*, page 60612, October 14, 2008) (Ref. 4), 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.
- RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)" (Ref. 5), 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 1.181, “Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)” (Ref. 6), provides methods the NRC staff finds acceptable for complying with the provisions of 10 CFR 50.71(e), requiring periodic development of updates to final safety analysis reports.
- RG 1.201, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance” (Ref. 7), provides guidance for complying with the Commission’s requirements in 10 CFR 50.69, “Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors,” with respect to the categorization of SSCs that are considered in risk-informing special treatment requirements.
- RG 1.206, “Combined License Applications for Nuclear Power Plants (LWR Edition)” (Ref. 8), provides guidance on the format and content of applications for nuclear power plants submitted to the NRC under 10 CFR Part 52, which specifies the information to be included in an application.
- RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light Water Reactors” (Ref. 9), 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,” may be adapted for non-LWR designs. 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).
- NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (Ref. 10), provides guidance to NRC staff in performing safety reviews of construction permit or operating license applications, including requests for amendments under 10 CFR Part 50, and early site permit, DCs, COLs, SDA, or ML applications under 10 CFR Part 52 (including requests for amendments). The principal purpose of the Standard Review Plan is to ensure the quality and uniformity of staff safety reviews. The Plan is also intended to make information about regulatory matters widely available and to improve communication among the NRC, interested members of the public, and the nuclear power industry, thereby increasing understanding of the NRC’s review process.
- “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness,” issued December 2016 (Ref. 11), describes the NRC’s vision and strategy for preparing for non-LWR reviews.
- NUREG-1338, “Draft Preapplication Safety Evaluation Report for the Modular High-Temperature Gas-Cooled Reactor,” issued December 1995 (Ref. 12), provides the NRC staff’s review and insights on the MHTGR design submitted by the U.S. Department of Energy (DOE).
- NUREG-1368, “Preapplication Safety Evaluation Report for the Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor,” issued February 1994 (Ref. 13), provides the NRC staff’s review and insights on the design for the GE-Hitachi PRISM liquid-metal reactor.

- NUREG/BR-0303, “Guidance for Performance-Based Regulation,” issued December 2002 (Ref. 14), provides guidance on a process for developing performance-based alternatives in regulatory decisionmaking.
- SECY-93-092, “Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements,” dated April 8, 1993 (Ref. 15), provides staff insights on issues pertaining to advanced designs and proposes resolutions.
- Staff Requirements Memorandum (SRM)-SECY-93-092, dated July 30, 1993 (Ref. 16), provides the Commission’s direction on topics discussed in SECY-93-092.
- SECY-03-0047, “Policy Issues Related to Licensing Non-Light-Water Reactor Designs,” dated March 28, 2003 (Ref. 17), provides, for Commission consideration, options and recommended positions for resolving the seven policy issues associated with the design and licensing of future non-LWR designs.
- SRM-SECY-03-0047, dated June 26, 2003 (Ref. 18), provides the Commission’s direction on the topics discussed in SECY-03-0047.
- SECY-18-0096, “Functional Containment Performance Criteria for Non-Light-Water Reactors,” dated September 28, 2018 (Ref. 19), provides, for Commission consideration, a recommended methodology for establishing functional containment performance criteria for non-LWRs.
- SRM-SECY-18-0096, dated December 4, 2018 (Ref. 20), provides the Commission’s direction on the topics discussed in SECY-18-0096.
- SECY-19-0117, “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,” dated December 2, 2019 (Ref. 21), provides, for Commission consideration, a recommended methodology to establish key parts of the licensing basis and content of applications for licenses, certifications, and approvals for non-LWRs.
- SRM-SECY-19-0117, dated May 26, 2020 (Ref. 22), provides the Commission’s direction on the topics discussed in SECY-19-0117

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 (T6-A10M), 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: oir_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.

B. DISCUSSION

Reason for Revision

This RG provides guidance for informing the licensing basis and determining an appropriate level of information for parts of preliminary or final safety analysis reports for advanced non-LWRs. The regulations at 10 CFR 50.34(a), 10 CFR 50.34(b), 10 CFR 52.47, 10 CFR 52.79, and 10 CFR 52.157 require that applications for a construction permit, operating license, DC, COL, or ML, respectively, include the level of design information sufficient to enable the Commission to reach a conclusion on safety questions before issuing a license or certification. Applications for an SDA are likewise required by 10 CFR 52.137 to include information needed for NRC staff approval.

Background

This RG endorses the principles and methodology in Nuclear Energy Institute (NEI) 18-04, Revision 1, “Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development,” as one acceptable method for informing the licensing basis and determining the appropriate scope and level of detail for parts of applications for licenses, certifications, and approvals for non-LWRs. The staff takes no significant exceptions to the guidance in NEI 18-04 but does provide clarifications and points of emphasis as detailed in this RG. NEI 18-04 outlines an approach for use by reactor developers to select LBEs, classify SSCs, determine special treatments and programmatic controls, and assess the adequacy of a design in terms of providing layers of DID. The methodology described in NEI 18-04 and this guide also provides a general approach for identifying an appropriate scope and depth of information that applications for licenses, certifications, and approvals should provide. The variety of non-LWR technologies, which use different coolants, fuel forms, and safety system designs, make it necessary to define a methodology as opposed to developing prescriptive guidance on the content of applications, such as that prepared for light-water reactors (LWRs). This methodology also provides a logical and structured approach to identifying the safety or risk significance of SSCs and associated programmatic controls. The methodology’s focus on those measures needed to address risks posed by non-LWR 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. This approach will in turn lead to more effective and efficient NRC reviews.

NEI 18-04 incorporates the resolutions to several past policy issues related to advanced reactors into a consolidated methodology to support the design and licensing of non-LWRs. The methodology is sufficiently developed to provide additional clarity on how past Commission decisions on advanced reactors can be reflected in the design and licensing processes. Per the Commission’s Policy Statement on the Regulation of Advanced Reactors, advanced designs are expected to provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions.

Regulatory Framework

The NRC’s mission is to license and regulate the Nation’s civilian use of radioactive materials to provide reasonable assurance of adequate protection of public health and safety and to promote the common defense and security and to protect the environment. The NRC conducts its reactor licensing activities through a combination of regulatory requirements and guidance. The applicable regulatory requirements are found in 10 CFR Parts 1 through 199. Regulatory guidance is additional detailed information on specific acceptable means to meet the requirements in regulations. Guidance is provided in several forms, such as in RGs, interim staff guidance, standard review plans, NUREGs, review

standards, and Commission policy statements. Much of the NRC guidance has been developed to facilitate the preparation and subsequent NRC review of applications for licenses, certifications, and approvals. However, the majority of the available reactor-related guidance documents address LWRs, with limited applicability to non-LWR technologies.

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,” issued December 2016. The staff developed “NRC Non-Light Water Reactor Near-Term Implementation Action Plans” (Ref. 23), and “NRC Non-Light Water Reactor Mid-Term and Long-Term Implementation Action Plans” (Ref. 24), to identify specific activities that the NRC will conduct in the near-term, mid-term, and long-term timeframes. Strategy 3 within the implementation action plans called for the development of guidance for a flexible non-LWR regulatory review process within the bounds of existing regulations, including the use of conceptual design reviews and staged review processes. The staff interacted with stakeholders to develop the technology-inclusive, risk-informed, and performance-based methodology described in this RG to help non-LWR developers consider regulatory matters during the design process and to support the development of applications for licenses, certifications, and approvals.

Policy on Advanced Reactors

On October 14, 2008, the Commission issued its most recent policy statement on advanced nuclear power reactors, “Policy Statement on the Regulation of Advanced Reactors,” which included items to be considered in the design of non-LWRs and other advanced reactor technologies. The Commission’s 2008 policy statement reinforced and updated the policy statements on advanced reactors previously published in 1986 and 1994. The 2008 policy statement identifies attributes that could assist in establishing the acceptability or “licensability” of a proposed advanced reactor design, including reliable and less-complex shutdown heat removal systems; longer time constants before reaching safety system challenges; simplified safety systems that, where possible, reduce required operator actions; reduced potential for severe accidents; and considerations for safety and security requirements together in the design process. The policy statement goes on to state the following:

If specific advanced reactor designs with some or all of the previously mentioned attributes are brought to the NRC for comment and/or evaluation, the Commission can develop preliminary design safety evaluation and licensing criteria for their safety-related and security-related aspects. Incorporating the above attributes may promote more efficient and effective design reviews. However, the listing of a particular attribute does not necessarily mean that specific licensing criteria will attach to that attribute. Designs with some or all of these attributes are also likely to be more readily understood by the general public. Indeed, the number and nature of the regulatory requirements may depend on the extent to which an individual advanced reactor design incorporates general attributes such as those listed previously.

Guidance on Contents of Applications

The development of applications for NRC licenses, permits, certifications, and approvals is a major undertaking, in that the applicant has to 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, design approval, design certification, operating licenses, combined license, or other action. Efforts to standardize the format and content of applications for LWRs are reflected in RG 1.70, issued in the 1970s, and RG 1.206, issued in 2007 and revised in 2018. Guidance documents,

such as NUREG-0800 and numerous other documents on specific technical areas, address the suggested scope and level of detail for applications.

The NRC's advanced reactor policy statement states the following:

To provide for more timely and effective regulation of advanced reactors, the Commission encourages the earliest possible interaction of applicants, vendors, other government agencies, and the NRC to provide for early identification of regulatory requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of advanced reactor designs. Such licensing interaction and guidance early in the design process will contribute towards minimizing complexity and adding stability and predictability in the licensing and regulation of advanced reactors.

The NRC has interacted with advanced reactor developers, DOE, national laboratories, and other stakeholders to improve the licensing process for non-LWRs. These interactions have resulted in publications such as NUREG-1226, "Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants" (Ref. 25); NUREG-1338; and NUREG-1368. As directed in the Energy Policy Act of 2005, the NRC and DOE prepared and issued the "Next Generation Nuclear Plant Licensing Strategy: A Report to Congress," in August 2008 (Ref. 26). The Next Generation Nuclear Plant Program included numerous interactions, submittals, and NRC staff responses on key licensing issues influencing the design and content of applications for high-temperature, gas-cooled reactors. In 2013, the NRC, in coordination with DOE, began work on the initiative to develop guidance for principal design criteria (PDC) for non-LWRs. The NRC provided such guidance on PDCs following extensive interactions with stakeholders when it issued RG 1.232 in April 2018.

The Licensing Modernization Project (LMP) was a cost-shared initiative led by nuclear utilities and supported by DOE. The LMP developed technology-inclusive, risk-informed, and performance-based non-LWR licensing methods. The LMP refined the Next Generation Nuclear Plant Program methodologies to reflect interactions with the NRC, feedback from industry, and broadening of the scope to ensure applicability to various non-LWR technologies. The LMP activities led to the publication and submittal of NEI 18-04.

Intended Use of This Regulatory Guide

This RG contains the NRC staff's general guidance on using the methodology described in NEI 18-04 to select LBEs, classify SSCs, assess the adequacy of a design in terms of providing layers of DID, identify appropriate programmatic controls, and help determine the appropriate scope and level of detail for information provided in applications for licenses, permits, certifications, and approvals for advanced non-LWR designs. The design and licensing of nuclear reactors are complicated processes that involve many technical and regulatory issues. This complexity is reflected in the hundreds of RGs and other documents issued to support the regulation and oversight of LWRs. Much of the guidance available for LWRs is prescriptive and not readily applicable to other reactor technologies.

The design process and related development of licensing-basis information is iterative, involving assessments and decisions on key SSCs, operating parameters, and programmatic controls to ensure that a reactor can be deployed without posing undue risk to public health and safety. To begin the process of translating design information into a licensing application, a developer needs, at a minimum, a conceptual design that includes a reactor; a primary coolant; and a preliminary assessment of how the design will accomplish fundamental safety functions, such as reactivity and power control, heat removal, and radioactive material retention. When preparing licensing documentation, the applicant typically provides

this information in Chapter 4, “Reactor,” Chapter 5, “Reactor Coolant and Connecting Systems,” and Chapter 6, “Engineered Safety Features” of its safety analysis report.¹ Information within these chapters includes the parameters and values to define when important layers of defense (including physical barriers) to the release of radioactive material would degrade or fail. This type of information is important because it often serves as acceptance criteria for the analyses of LBEs and as an input into the analysis of releases via a mechanistic source-term approach to estimating radiological consequences from potential transients and postulated accidents.

The methodology described in NEI 18-04 and in this RG provides a general framework to support design decisions and decisions related to the scope and level of detail of information to be included in applications. The actual development of an application depends not only on this guidance but also on the design, the safety justifications prepared by the developer, and consideration of the entirety of regulatory requirements the NRC and other agencies have established. The system designs and safety evaluations may demonstrate compliance with or justify exemptions from specific NRC regulations and identify where design-specific regulatory controls are warranted. The guidance in this RG for licensing non-LWR technologies will need to be supplemented by other RGs and documents to help non-LWR developers and the NRC staff prepare and review applications for licenses, certifications, and approvals. An important area to expand upon in other guidance documents is how SSC capabilities and reliabilities will be monitored and maintained during plant operations.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of technical reports, safety guides, and standards constituting a high level of safety for protecting people and the environment. IAEA guides present international good practices and identify best practices to help users striving to achieve high levels of safety. This RG and the NEI technical document endorsed by it contain guidance similar to guidance prepared by IAEA on topics such as the design of nuclear power plants and DID. This RG and the NEI technical document are, with the exception of technology-specific topics, generally consistent with the principles and guidance in the IAEA document series, including the IAEA documents listed below.

- General Safety Requirements (GSR), No. GSR Part 4, “Safety Assessment for Facilities and Activities” (Ref. 27)
- Specific Safety Requirements (SSR), No. SSR- 2/1, “Safety of Nuclear Power Plants: Design” (Ref. 28)
- No. SSR-2/2, “Safety of Nuclear Power Plants: Commissioning and Operation” (Ref. 29)
- Specific Safety Guide (SSG), No. SSG-2, “Deterministic Safety Analysis for Nuclear Power Plants” (Ref. 30)
- No. SSG-3, “Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants” (Ref. 31)
- No. SSG-12, “Licensing Process for Nuclear Installations” (Ref. 32)

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of one or more codes or standards developed by external organizations, and other third party guidance documents. These codes, standards and third party guidance documents may contain references to other codes, standards or third party guidance documents (“secondary references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a

¹ The chapter- and section-level organization of safety analysis reports for LWRs is described in guidance such as RG 1.70, RG 1.206, and NUREG-0800.

requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a RG, then the secondary reference is neither a legally-binding requirement nor a “generic” NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

This RG endorses the methods described in NEI 18-04 for informing the licensing basis and content of applications for permits, licenses, certifications, and approvals for non-LWRs. The staff takes no significant exceptions to the guidance in NEI 18-04 but does provide clarifications and points of emphasis as detailed in this RG. One key distinction between NEI 18-04 and current NRC guidance and regulations developed for LWRs is that the definition of “safety related” SSCs in NEI 18-04 is different from the NRC’s definition of “safety-related” SSCs in 10 CFR 50.2. The NRC staff has determined that the methods described in NEI 18-04 constitute one acceptable means to identify LBEs, classify SSCs, establish special treatments, identify programmatic controls, and assess DID for non-LWRs. As described below, these activities also define a methodology for applicants to identify and provide the appropriate level of information needed to satisfy parts of the regulatory requirements in 10 CFR 50.34, 10 CFR 52.47, 10 CFR 52.79, 10 CFR 52.137, and 10 CFR 52.157. Each section in NEI 18-04 summarized below is part of an integrated methodology that includes defined relationships among LBEs, equipment classification, special treatments, programmatic controls, and assessments of DID. The applicants perform the evaluations in an iterative fashion as they develop the design and licensing strategies.

1. *Selection of Licensing-Basis Events*

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. NEI 18-04 describes a systematic process for identifying and categorizing event sequences as anticipated operational occurrences (AOOs), design-basis events (DBEs), or beyond-design-basis events (BDBEs) for non-LWRs.² The primary determinate for categorizing events is the estimated frequency of the event sequence. Design-basis accidents (DBAs) are derived from DBEs by assuming that only safety-related (SR) SSCs are available to mitigate the events. NEI 18-04 includes definitions and demarcations of the event categories in Table 3.1, “Definitions of Licensing Basis Events,” and Figure 3.1, “Frequency-Consequence [F-C] Target.” The methodology includes plotting event sequence families on the F-C target and assessing margins based on event frequency and estimated 30-day dose at the exclusion area boundary. The mean values of the frequencies are used to classify the LBEs into AOOs, DBEs, and BDBE categories. However, as described in NEI 18-04 Section 3.2.2, “LBE Selection Process,” when the uncertainty bands defined by the 5th percentile and 95th percentile of the frequency estimates straddles a frequency boundary, the LBE is evaluated in both LBE categories. NEI 18-04 acknowledges that the F-C target does not correspond to actual regulatory acceptance criteria but is instead a vehicle to assess a range of events to determine risk significance, support SSC classification, determine special treatment requirements, identify appropriate programmatic controls, and confirm the adequacy of DID.

NEI 18-04 describes an expanded role for probabilistic risk assessment (PRA) for non-LWRs beyond current 10 CFR Part 52 requirements or Commission policy for potential applications under 10 CFR Part 50. Before the first introduction of the design-specific PRA, a designer needs to develop a technically sound understanding of the potential failure modes of the reactor concept, how the reactor plant would respond to such failure modes, and how protective strategies will be incorporated into formulating the safety-design approach. A designer can use safety-analysis methods appropriate to early

2 The definitions of some phrases used in NEI 18-04 are different from the same phrases used in NRC regulations and guidance developed for LWRs. The terms “AOO” and “DBE” are examples of similar terms having different definitions. The methodology in NEI 18-04 also includes a different definition and means to identify SR SSCs from those used in the deterministic approaches for LWRs. NEI 18-04 includes a glossary to help alleviate some of the issues that will arise because of differences in terminology. Applicants referencing this RG are expected to use the terminology in NEI 18-04 and, as needed, identify exceptions to and exemptions needed from NRC regulations.

stages of design, such as failure modes and effects analyses and process hazard analyses. Designers may likewise use the design criteria from RG 1.232 and confirm or refine them throughout the design process to develop the final PDC provided in an application. These techniques provide industry-standardized practices to ensure that such early-stage evaluations are systematic, reproducible, and as complete as the current stage of design permits. The subsequent use of the PRA by the designer is used to develop or confirm the events, safety functions, key SSCs, and adequacy of DID; and provides a structured framework to risk-inform the application for the specific reactor design. The designer's quantification of frequencies and consequences of event sequences in the PRA, and the associated quantification of uncertainties, provides an objective means of comparing the likelihood and consequence of different scenarios in relation to the F-C target. The scope of the PRA, when completed, should cover internal and external hazards and provide an estimate of radiological consequences when the design is completed and site characteristics are defined. Designers seeking certifications or approvals prior to site selection may make assumptions related to site characteristics and external hazards, which would be confirmed or adjusted for licensing an advanced non-LWR at a specific site. Figure 3-2, "Process for Selecting and Evaluating Licensing Basis Events," in NEI 18-04 depicts the iterative process needed to identify and evaluate LBEs and reflects that PRA models are expected to be developed by the designer and refined as the design process progresses and the licensing-basis documents are developed.³

NEI 18-04 acknowledges that reactor designers may propose to address all or parts of the process by assessing layers of defense, including physical barriers, and showing that the facility can contain radioactive materials with a high degree of confidence. Such an approach would still require a designer to obtain some of the information from a PRA, including the identification of challenges to the physical barriers and identification and evaluation of dependencies among the physical barriers. The PRA complexity should reflect the as-designed reactor plant, which, in turn, may incorporate the simple systems, inherent safety characteristics, and limited public health hazard associated with a specific advanced non-LWR design.

The process supports the categorization and evaluation of LBEs in terms of estimated frequencies and consequences of event sequences or event families (groupings of event sequences having similar initiating events, challenges to plant safety functions, plant response, end state, and mechanistic source term). The event sequences and related estimations of frequencies and consequences include equipment malfunctions caused by internal and external hazards. If applicable, the PRA should include event sequences involving two or more reactor modules as well as two or more sources of radioactive material, which could include waste processing and storage systems. NEI 18-04 focuses on safety functions and the identification of SSCs needed to fulfill those functions. The plotting of event sequences, considering frequencies and consequences, with the F-C targets supports defining the SSC capabilities and reliabilities needed to support the design process and inform the content of applications. Uncertainties related to event sequences, plant behavior, assumed reliability of SSCs, and other aspects of the estimation of event frequencies and consequences need to be considered. Uncertainties are addressed, in part, by assessing event sequences on the F-C target based on the uncertainty bands for the event in addition to the mean values of estimated frequencies and consequences. The analyses of event sequences and related uncertainties are inputs into the subsequent processes described in NEI 18-04 for the safety classification of SSCs and assessment of DID.

NEI 18-04 Section 3.2.2, "LBE Selection Process," describes an additional deterministic assessment of selected event sequences to supplement the consideration of AOOs, DBEs, and BDBEs for

³ NEI 18-04 points out that applications made under 10 CFR Part 52 are required to include a description of PRA results. SRM-SECY-15-002, "Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications, dated September 22, 2015 (ADAMS Accession No. ML15266A023) confirmed the Commission's expectations that PRAs would be developed and described in new reactor applications under 10 CFR Part 50.

non-LWRs. A deterministic DBA is associated with each DBE that includes the required safety function challenges, but the DBA analysis is performed with the assumption that the required safety functions are performed by SR SSCs. Applicants typically describe these DBAs in Chapter 15 of a safety analysis report to support the deterministic safety analysis and show that the offsite consequences are below the reference values included in NRC regulations (e.g., 10 CFR 50.34). Although developed for LWRs, NRC RG 1.203, “Transient and Accident Analysis Methods,” provides additional guidance that would be generally applicable for analyzing DBAs for non-LWRs.

NEI 18-04 describes how a set of design-basis external hazard levels (DBEHLs) will be selected to form an important part of the design and licensing bases. This will determine the design-basis seismic events and other external events that the SR SSCs will be required to withstand. When the DBEHLs are determined using traditional NRC-approved methodologies, this approach is generally consistent with current practices used for LWRs to define appropriate protection of SR SSCs against external hazards.

The PRA models used for applications are expected to address the full spectrum of internal events and external hazards that pose challenges to the capabilities of the plant. NEI 18-04 addresses multimodule issues by including guidance that there should be no risk-significant DBEs involving a release from two or more modules, and any BDBEs that involve releases from multiple reactor modules or sources should not be high-consequence BDBEs. NEI 18-04 defines high consequence BDBEs as those with consequences that exceed 10 CFR 50.34 dose criteria. When these objectives related to multimodule issues are achieved, there should be no DBAs with significant releases from two or more modules or radionuclide sources.

The guidance also includes an assessment of the following aggregate risk measures:

- The total frequency of exceeding a site boundary dose of 100 millirem (mrem) from all LBEs shall not exceed 1/plant-year. This metric is introduced to ensure that the application considers the consequences from the entire range of LBEs, from higher frequency, lower consequences to lower frequency, higher consequences. The value of 100 mrem is from the annual exposure limits in 10 CFR Part 20, “Standards for Protection against Radiation.”
- The average individual risk of early fatality within 1 mile of the exclusion area boundary from all LBEs shall not exceed 5×10^{-7} /plant-year to ensure that the plant meets the NRC safety goal quantitative health objective for early fatality risk.
- The average individual risk of latent cancer fatalities within 10 miles of the exclusion area boundary from all LBEs shall not exceed 2×10^{-6} /plant-year to ensure that the plant meets the NRC safety goal quantitative health objective for latent cancer fatality risk.

Important roles for the PRA in NEI 18-04 include the evaluation of the aggregate or plant-level acceptance criteria and identification of risk-significant LBEs. As shown in Figure 3-4, “Use of the F-C Target to Define Risk-Significant LBEs,” NEI 18-04 defines risk-significant LBEs as those with frequencies and consequences within 1 percent of the F-C target, with site boundary doses exceeding 2.5 mrem. To consider the effects of uncertainties, the applicant should use the upper 95th percentile estimates of both frequency and dose. The use of the 1-percent metric is consistent with the approach to defining risk-significant accident sequences in various PRA standards. The 2.5-mrem cutoff is reasonable given it is approximately 10 percent of the dose that an average person at the site boundary would receive in 30 days from background radiation. NEI 18-04 also notes that risk importance measures such as risk reduction worth can be used to gain additional insights into the significance of particular events and SSCs.

C.1 Staff Position: NEI 18-04 provides an acceptable method for identifying and categorizing events, with the following clarifications:

- a. The staff emphasizes the cautions in NEI 18-04 that the F-C target figure does not depict acceptance criteria or actual regulatory limits. The anchor points used for the F-C target figure are expressed in different units, timescales, and distances than those used in NRC regulations to provide common measures for the evaluations included in the methodology.⁴ The F-C target provides a reasonable approach for use within a broader, integrated approach to determine risk significance, support SSC classification, and confirm the adequacy of DID.
- b. The F-C target and related discussions in NEI 18-04 include an upper bound event sequence frequency (i.e., 95th percentile) of 5×10^{-7} /plant-year to define the lower range of BDBEs. Applicants should not consider this demarcation of lowest-event frequencies on the F-C target and category definitions a hard-and-fast cutoff but instead should consider it in the context of other parts of the methodology described in NEI 18-04. These other considerations include the role of the integrated decisionmaking panel described in Section 5 of NEI 18-04, DID assessments, accounting for uncertainties, and assessing for potential “cliff-edge effects,” which involve a dramatic change in plant behavior caused by a small change in a plant parameter.
- c. NEI 18-04 describes a set of DBEHLs that will determine the design-basis seismic events and other external events that the SR SSCs will be required to withstand. When the DBEHLs are determined using NRC-approved methodologies, this approach is generally consistent with current practices and provides acceptable protection of SR SSCs. When supported by available methods, the PRA model is expected to address the full spectrum of internal events and external hazards that pose challenges to the capabilities of the plant, including external hazard levels exceeding the DBEHLs. The inclusion of external events within the BDBE category supports the overall risk-informed approach in NEI 18-04 and the DID assessments described in subsequent sections. The PRA results, including consideration of external hazards, will also validate a designer’s initial selections of DBAs and SR SSCs protected against DBEHLs, and ensure no new DBAs are introduced by external hazards.

NEI 18-04 states the following:

When supported by available methods, data, design and site information, and supporting guides and standards, these DBEHLs will be informed by a probabilistic external hazards analysis and included in the PRA after the design features that are included to withstand these hazards are defined.

If applicants propose methods to identify DBEHLs that the NRC staff has not previously reviewed and approved, the staff would review the proposed methodologies on a case-by-case basis. An applicant may need to reconcile a probabilistic approach to assessing external hazards with the use of applicable consensus standards for the design and construction of safety-significant SSCs

⁴ An example is the anchor point at an event sequence frequency of 5×10^{-7} per plant year and total effective dose equivalent at the EAB of 750 rem for the 30-day period following the onset of a potential release. This anchor point is used to define a sliding F-C target in the region of potential low frequency, high consequence scenarios for use in assessing the importance of SSCs and other measures to provide DID. A traditional measure used to assess risk in the low frequency, high consequence domain is the NRC’s safety goals. However, the anchor point is not intended to directly represent the quantitative health objectives (QHOs) for either early or latent health effects. The methodology described in NEI 18-04 includes a separate assessment of a design against the QHOs for the integrated risks over all the LBEs.

- d. NEI 18-04 describes how the application of a single-failure criterion is not deemed necessary for the designs using the methodology because advanced non-LWRs will employ a diverse combination of inherent, passive, and active design features to perform the required safety functions across layers of defense and will be subjected to an evaluation of DID adequacy. The process described in NEI 18-04 includes assessing event sequences (including reliability and availability of SSCs and combinations of SSCs) over a wide range of frequencies and establishing risk and safety function reliability measures. The approach described in NEI 18-04 is consistent with the Commission's SRM approving the recommendation in SECY-03-0047 to replace the single-failure criterion with a probabilistic (reliability) criterion. The staff finds that the NEI 18-04 methodology, including assessments of event sequences and DID, obviates the need to use the single-failure criterion as it is applied to the deterministic evaluations of AOOs and DBAs for LWRs. The staff notes that the NEI 18-04 methodology is similar to Alternative 3 in SECY-05-0138, "Risk-Informed and Performance-Based Alternatives to the Single-Failure Criterion," dated August 2, 2005 (Ref. 33). The staff's finding is based primarily on the integrated methodology described in NEI 18-04 and to a lesser degree on the design attributes of non-LWRs.

Non-LWR developers that construct a licensing basis for a design using an alternative to the NEI 18-04 methodology would need to maintain or justify not applying the single-failure criterion to those LBEs analyzed in a deterministic or stylized approach, such as DBAs. RG 1.232 describes an approach that maintains the single-failure criterion, but acknowledges the potential future benefits of risk informing the non-LWR design criteria. The NRC provided guidance related to assumptions on passive failures and the application of the single-failure criterion in SECY-94-0084, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems in Passive Plant Designs," dated March 28, 1994 (Ref. 34), and the related SRM dated June 30, 1994 (Ref. 35).

- e. The methodology in NEI 18-04 includes an expanded role for PRA beyond that currently required by 10 CFR Part 52 and policies related to new applications under 10 CFR Part 50. The staff's review of the PRA prepared by a reactor designer could be facilitated by the designer's use of NRC-endorsed consensus codes and standards (e.g., potential NRC endorsement of the American Society of Mechanical Engineers/American Nuclear Society RA-S-1.4, "Probabilistic Risk Assessment Standard for Advanced Non-LWR Nuclear Power Plants"). However, the NRC has not yet endorsed a consensus code or standard for non-LWR PRAs. In the absence of such an endorsed standard, the NRC staff will develop review strategies to address the performance and use of PRAs for specific applications.

2. **Safety Classification and Performance Criteria for Structures, Systems, and Components**

The second major component of the NEI 18-04 methodology involves assessing the risk significance of SSCs and determining if special treatments beyond normal industrial practices are needed to ensure SSC performance of safety functions in the prevention and mitigation of LBEs. This requires that applicants provide the necessary capabilities to perform mitigation functions and ensure the reliability of SSCs to prevent LBEs with more severe consequences. The classification of SSCs is directly related to and performed in an iterative process along with the identification and assessment of LBEs and the assessment of DID described in other sections of NEI 18-04 and this RG.

The relevant SSC capabilities include the ability to prevent an initiating event from progressing to an accident, to mitigate the consequences of an accident, or both. In some cases, the initiating events are failures of SSCs themselves, in which case the reliability of the SSC in question serves to limit the initiating event frequency. In other cases, the initiating events represent challenges to the SSC in question,

in which case the reliability of the SSC to perform a safety function in response to the initiating event needs to be considered. Finally, in some cases the challenge to the SSC in question is defined by the combination of an initiating event and combinations of successes and failures of other SSCs in response to the initiating event. All of these cases are included in the PRA and represent the set of challenges presented to a specific SSC.

Figure 4-1, “SSC Function Safety Classification Process,” and Figure 4-2, “Definition of Risk Significant and Safety Significant SSCs,” in NEI 18-04 depict the SSC safety classification process. The process includes a review of each of the LBEs, including those in the AOO, DBE, and BDBE regions, to determine the function of each SSC in the prevention and mitigation of the LBE. Risk-significant SSCs are those with an important role in controlling the frequencies and consequences of LBEs relative to the F-C target or in meeting the cumulative risk metrics. An SSC that is determined to be important for DID as discussed in Section 5 of NEI 18-04 and the subsequent section of this RG is included within the broader category of safety-significant SSCs, even if the SSC is not otherwise found to be risk significant. A designer would classify a safety function as a “required safety function” if that function is needed to keep the frequency or consequence of a DBE below the F-C target using realistic assumptions, or the consequences of a DBA below the reference values included in NRC regulations using conservative assumptions.

The safety classification categories used in NEI 18-04⁵ for non-LWRs are defined as follows:

- safety related:
 - SSCs selected by the reactor designer from the SSCs that are available to perform the required safety functions to mitigate the consequences of DBEs to within the LBE F-C target and to mitigate DBAs that only rely on the SR SSCs to meet the 10 CFR 50.34 dose limits using conservative assumptions
 - SSCs selected by the reactor designer and relied on to perform required safety functions to prevent the frequency of BDBE with consequences greater than the 10 CFR 50.34 dose limits from increasing into the DBE region and beyond the F-C target
- nonsafety-related with special treatment (NSRST):
 - non-SR SSCs relied on to perform risk significant functions; risk-significant SSCs are those that perform functions that prevent or mitigate any LBE from exceeding the F-C target or that make significant contributions to the cumulative risk metrics selected for evaluating the total risk from all analyzed LBEs
 - non-SR SSCs relied on to perform functions requiring special treatment for DID adequacy
- nonsafety-related with no special treatment:
- all other SSCs (with no special treatment required)

Within the methodology used in NEI 18-04, safety-significant SSCs include all those SSCs classified as SR or NSRST. None of the non-SR with no special treatment SSCs are

⁵ The methodology in NEI 18-04 includes a different definition and means to identify SR SSCs for non-LWRs from those used in the deterministic approaches for LWRs. Additionally, “nonsafety-related” is used in NEI 18-04 but is not a defined term in NRC regulations and has different meanings depending on the context in which it has been used in guidance documents and specific applications. As used in this RG and NEI 18-04, the term “nonsafety-related” means SSCs or an SSC that is not safety-related. NEI 18-04 includes a glossary to help alleviate some of the issues that will arise because of differences in terminology. Applicants referencing this RG are expected to use the terminology in NEI 18-04 and, as needed, identify exceptions to and exemptions needed from NRC regulations.

classified as safety significant, but they may have requirements to ensure that failures following a design-basis internal or external event do not adversely impact SR or NSRST SSCs in their performance of safety-significant functions.

The methodology in NEI 18-04 includes defining performance criteria for the reliability and capability of the SSCs fulfilling safety-significant functions for non-LWRs. Table 4-1, “Summary of Special Treatment Requirements for SR and NSRST SSCs,” in NEI 18-04 gives examples of such requirements. For SSCs classified as SR, required functional design criteria (RFDC) and lower-level design criteria are defined to capture design-specific criteria that may supplement or may not be captured by the principal design criteria for a reactor design developed using the guidance in RG 1.232. These criteria are used within the methodology to frame specific design requirements as well as special treatment requirements for SR SSCs. NEI 18-04 states that NSRST SSCs are not directly associated with RFDC but are subject to special treatment as a result of risk significance or assessments of DID. The RFDC, design requirements, and special-treatment requirements that result from the methodology in NEI 18-04 also define key aspects of the SSCs that will be described in safety analysis reports.

NEI 18-04 describes some non-LWR SSCs as having specific “barrier functions,” in which the SSC serves as a physical or functional barrier to the transport of radionuclides. “Barrier functions” can also include indirect functions, in which an SSC serves to protect one or more other SSCs that may be classified as barriers. The barrier functions are important in the development and assessment of mechanistic source terms that help determine the offsite doses for non-LWR designs for each LBE. Performance criteria for a barrier, or set of barriers taken together, to the transport of radionuclides are discussed in SECY-18-0096, “Functional Containment Performance Criteria for Non-Light-Water-Reactors,” dated September 28, 2018 (Ref. 36), which describes an approach to “functional containment” for non-LWRs that may not rely on traditional containment structures to limit the physical transport and release of radioactive material to the environment. The Commission’s SRM dated December 4, 2018 (Ref. 37), approved the methodology described in SECY-18-0096 for establishing functional containment performance criteria for non-LWRs.

A major objective of the process in NEI 18-04 is to establish a systematic approach to assessing and determining appropriate relationships between the needed capabilities and reliabilities for SSCs and the role of those SSCs in mitigating and preventing LBEs. The safety classification of SSCs is made in the context of how the SSCs perform specific safety functions for each LBE in which they play a role in preventing or mitigating an event. The reliability of the SSC serves to prevent the occurrence of the LBE by lowering its frequency of occurrence. If the SSC function is successfully completed within an event sequence, the SSC and its associated capabilities have helped to mitigate the consequences of the LBE. The safety classification process and the corresponding special treatments to ensure reliabilities and capabilities of SSCs thereby serve to control the frequencies and consequences of the LBEs in relation to the F-C target and ensure that the cumulative risk targets are not exceeded.

SSC safety margins play an important role in the development of SSC design requirements for reliability and performance capability. NEI 18-04 describes how a designer sets acceptance limits on SSC performance with safety margins between the level of performance that is deemed acceptable in the safety analysis and the level of performance that would lead to damage or adverse consequences for all the LBEs in which the SSC performs a preventive or mitigative function. The magnitudes of the safety margins in performance are set considering the uncertainties in performance, the nature of the associated LBEs, and criteria for adequate DID.

The ability to achieve the acceptance criteria, in turn, reflects the design margins that are part of the SSC capability to mitigate the challenges reflected in the LBEs.

C.2 Staff Position: NEI 18-04 provides an acceptable method for assessing and classifying non-LWR SSCs as SR, NSRST, or non-SR with no special treatment. The staff offers the following clarifications:

- a. The SSC classifications and logic outlined in NEI 18-04 are part of an integrated methodology, which includes a defined relationship among LBEs, equipment classification, and assessments of DID for non-LWRs. The classifications and related outcomes may not apply for alternative approaches that do not follow the other parts of the NEI 18-04 methodology. The staff expects that SSCs that provide essential support (including required human actions) for SR or NSRST SSCs will be classified in a manner consistent with the higher-level function, even if the supporting SSC is not explicitly modeled in the PRA.
- b. The SSC classifications outlined in NEI 18-04 include the term “safety-related,” which is defined in NRC regulations in 10 CFR 50.2. Use of the term “safety-related” in NEI 18-04 for non-LWRs is not the same as the definition in 10 CFR 50.2, and the SSCs included in the “safety-related” classification for non-LWRs may not be the same as those considered safety-related for LWRs. Additionally, “nonsafety-related” is used in NEI 18-04 but is not a defined term in NRC regulations and has different meaning depending on the context in which it has been used in guidance documents and specific applications. As used in this RG and NEI 18-04, the term “nonsafety-related” means SSCs or an SSC that is not safety-related. NEI 18-04 includes a glossary to help alleviate some of the issues that will arise because of differences in terminology. Applicants referencing this RG are expected to use the terminology in NEI 18-04 and, as needed, identify exceptions to and exemptions needed from NRC regulations.

3. **Evaluation of Defense-in-Depth Adequacy**

Defense in depth, or the use of multiple independent but complementary methods for protecting the public from potential harm from nuclear reactor operation, is an important part of the design, licensing, and operation of nuclear power plants. According to the NRC glossary, DID is—

...an approach to designing and operating nuclear facilities that prevents and mitigates accidents that release radiation or hazardous materials. The key is creating multiple independent and redundant layers of defense to compensate for potential human and mechanical failures so that no single layer, no matter how robust, is exclusively relied upon. Defense in depth includes the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures.

Figure 5-2, “Framework for Establishing DID Adequacy,” in NEI 18-04 depicts a framework to establish DID for non-LWRs that includes probabilistic and deterministic assessment techniques using a combination of plant capabilities and programmatic controls. Plant capability defense in depth generally relates to hardware and design, and is provided by ensuring that SSCs are able to prevent and mitigate events, defend against common cause failures, include conservative design margins, and provide barriers to the release of radionuclides. Programmatic defense in depth includes measures to increase confidence in SSC performance during operation and throughout the life of a plant (e.g., quality assurance, testing, maintenance, and configuration control), operational procedures and training, and preparedness for emergency plan protective actions.

The methodology in NEI 18-04 calls for non-LWR designers to perform evaluations based on several established approaches to DID to assess a reactor design and determine if additional measures are

appropriate to address an over-reliance on specific SSCs or to address uncertainties. One element of NEI 18-04 related to assessing DID is adapted from a process defined in IAEA standards and guidance, such as IAEA Specific Safety Requirements No. SSR-2/1, “Safety of Nuclear Power Plants: Design.” This approach includes evaluating each LBE to identify the DID attributes incorporated into the design to prevent and mitigate accident sequences and to ensure that the DID attributes reflect adequate SSC reliability and capability. Figure 5-3, “Framework for Evaluating LBEs Using Layers of Defense Concept Adapted from IAEA,” in NEI 18-04, depicts this element of the DID assessment and lists the success criteria for the successive layers as being (1) prevention of abnormal operations, initiating events and AOOs; (2) return to normal [following a possible AOO] and prevention of DBEs; (3) perform required safety functions [in response to possible DBE] and prevent BDBEs; (4) maintain required safety functions for retention of radioactive material; and (5) prevent adverse public health and safety impacts. The five layers of DID reflected in this element are also used in an overall assessment of DID and summarized in Table 5-2, “Guidelines for Establishing the Adequacy of Overall Plant Capability Defense-In-Depth,” in NEI 18-04.

The reactor designer is responsible for ensuring that DID is achieved through the incorporation of DID features and programs in the design phases and, in turn, conducting the evaluation that arrives at the decision of whether adequate DID has been achieved. The process in NEI 18-04 calls for the reactor designer to put in place an integrated decision process (IDP), which supports the overall design effort (including development of plant capability and programmatic DID features), conducts the DID adequacy evaluation of that resulting design, and documents the DID baseline. RG 1.201, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance,” provides a structure for the operation of an IDP, and NEI 00-04, “10 CFR 50.69 SSC Categorization Guide” (Ref. 38), provides the related industry guidance. The guidance in RG 1.201 and NEI 00-04 addresses the importance of a multi-discipline panel of experts and the role of an IDP in assessing limitations of the supporting PRA, modeling SSCs and human actions, and the need to identify and address uncertainties. Figure 5-4, “Integrated Process for Incorporation and Evaluation of Defense-In-Depth,” in NEI 18-04 depicts the overall process and relationships among LBE selection and analyses, SSC classification, and DID assessments. As part of the DID adequacy evaluation, each LBE is evaluated to confirm that risk targets are met without exclusive reliance on a single element of design, single program, or single DID attribute, and this evaluation is confirmed within the IDP.

NEI 18-04 explains that one of the primary motivations of employing DID attributes is to address uncertainties, including those that are reflected in the PRA estimates of frequency and consequence as well as other uncertainties that are not sufficiently characterized for uncertainty quantification nor amenable to sensitivity analyses. NEI 18-4 Section 4.4.5, “Special Treatment Requirements for SSCs,” describes how the plant capability DID attributes include design margins that protect against specific uncertainties. In addition, both the plant capability and programmatic elements of DID incorporate measures to compensate for residual unknowns.

Table 5-1, “Role of Major Elements of TI-RIPB Framework in Establishing DID Adequacy,” in NEI 18-04 summarizes how a designer uses the NEI 18-04 process to establish DID.

Plant Capability Defense in Depth

Table 5-2, “Guidelines for Establishing the Adequacy of Overall Plant Capability Defense-in-Depth,” in NEI 18-04 provides overall guidelines and layer-specific guidelines for non-LWR designers to assess plant capability defense in depth. An important qualitative overall guideline is that two or more independent plant design or operational features be provided to meet the layer-specific guidelines for each LBE. Any SSCs required to meet this guideline, as determined by the IDP, would be regarded as performing a safety function necessary for adequacy of plant capability DID. Such SSCs, if classified as risk significant, would already be classified as safety significant. If one of the plant features used to meet the need for multiple means to ensure DID involves the use of SSCs that are neither SR nor risk significant, the IDP panel (IDPP) would classify the SSC as safety significant and NSRST because it performs a function required for DID adequacy. Special treatment requirements for NSRST SSCs include the setting of performance requirements for SSC reliability, availability, and capability and any other treatments the IDPP responsible for evaluating the adequacy of DID deems necessary.

A non-LWR designer using the methodology described in NEI 18-04 evaluates the adequacy of plant capability DID by focusing on the completeness, resiliency, and robustness of the plant design. The designer assesses the design with respect to all hazards, responding to identified initiating events, and the availability of independent levels of protection in the design for preventing and mitigating the progression of event sequences. The process encourages the use of redundant and diverse means across the collective layers of defense to achieve the needed levels of protection sufficient to address different threats to public health and safety. Additionally, the plant capability DID adequacy evaluation examines whether any single feature is excessively relied on to achieve public safety objectives, and, if so, identifies options to reduce or eliminate such dependency.

A key element of the DID evaluation described in NEI 18-04 is a systematic IDP review of the LBEs for non-LWRs against the layers of defense. This IDP review is necessary to evaluate the plant capabilities for DID and to identify any programmatic DID measures that may be necessary for ensuring DID adequacy. The IDPP performs this review to assess important DID properties such as an appropriate balance between prevention and mitigation of LBEs, identified reliability/availability missions for SSCs serving to prevent or mitigate LBEs, effective physical and functional barriers to retain radionuclides, and ensuring measures exist to address risk-significant sources of uncertainty. Table 5-4, “Event Sequence Model Framework for Evaluating Plant Capabilities for Prevention and Mitigation of LBEs,” in NEI 18-04 provides a generalized model for describing an event sequence in terms of the design features that support prevention and mitigation reflecting the above insights. This information supports the IDP review and also relates to the assessment of layers of defense—including physical barriers—that will need to be addressed within the mechanistic source term for a non-LWR design.

Section 5.7 in NEI 18-04 states that the IDPP’s evaluation of LBEs will determine whether additional compensatory action would be considered, depending on the risk significance of the LBE. Compensatory action can take different forms, including changes to design and operation, refinements to the PRA, revisions to the identified LBEs and safety classification of SSCs, and enhancements to the programmatic elements of DID. NEI 18-04 lists the following broad questions for the IDPP to consider:

- Is the selection of initiating events and event sequences reflected in the LBEs sufficiently complete? Are the uncertainties in the estimation of LBE frequency, plant response to events, mechanistic source terms, and dose well characterized? Are there sources of uncertainty not adequately addressed?
- Have all risk significant LBEs and SSCs been identified?
- Has the PRA evaluation provided an adequate assessment of “cliff-edge effects”?

- Is the technical basis for identifying the required safety functions adequate?
- Is the selection of the SR SSCs to perform the required safety functions appropriate?
- Have protective measures to manage the risks of multimodule and multiradiological source accidents been adequately defined?
- Have protective measures to manage the risks of all risk significant LBEs been identified, especially those with relatively high consequences?
- Have protective measures to manage the risks for all risk-significant common-cause initiating events, such as support system faults, internal plant hazards such as fires and floods, and external hazards, been identified?
- Is the risk benefit of all assigned protective measures well characterized (e.g., via sensitivity analyses)?

The NEI 18-04 methodology for assessing DID includes an assessment of plant risk margins that compares the mean values of each LBE frequency and dose to the F-C target. A more conservative evaluation of margins is also performed that compares the 95th percentile upperbound values of each LBE frequency and dose to the F-C target. The IDPP considers these margins within its deliberations on the adequacy of DID.

Programmatic Defense in Depth

Section 5.8 in NEI 18-04 identifies the following objectives for the IDP assessment to identifying appropriate programmatic controls:

- Assure that adequate margins exist between the assessed LBE risks relative to the F-C target, including quantified uncertainties.
- Assure that adequate margins exist between the assessed total plant risks relative to the cumulative risk targets.
- Assure that design and operational programs reflect appropriate targets for SSC reliability and performance capability for each LBE.
- Provide adequate assurance that the risk, reliability, and performance targets will be met and maintained throughout the life of the plant with adequate consideration of sources of significant uncertainties.

NEI 18-04 acknowledges that, unlike the plant capabilities for DID, which can be described in physical terms and are amenable to quantitative evaluation, the programmatic DID adequacy is more dependent on the IDPP's engineering judgment. Table 5-6, "Evaluation Considerations for Evaluating Programmatic DID Attributes," in NEI 18-04 identifies attributes, such as quality and reliability, compensation for uncertainties, and offsite response, and related focus areas for evaluations, possible implementation strategies, and other evaluation considerations. The guidance provides examples of programmatic controls associated with licensing-basis documents, such as technical specifications, quality assurance programs, plant procedures and guidelines, training, maintenance programs, and testing and surveillance programs.

Risk-Informed and Performance-Based Evaluation of DID Adequacy

Section 5.9 in NEI 18-04 summarizes the role of the IDPP in evaluating the adequacy of DID. Table 5-8, "Risk-Informed and Performance-Based Decision-Making Attributes," in NEI 18-04 provides attributes of the integrated decision-making process and principal focus areas for consideration within the IDP. The attributes include recurring examinations of the risk triplet questions of what can go wrong, how likely it is, and what the consequences are. The IDP should also

consider key attributes such as the level of understanding of the design and plant behavior, the magnitude and sources of uncertainties, and the effectiveness of any compensatory actions included in the design or programmatic controls.

C.3 Staff Position: NEI 18-04 provides an acceptable method for assessing the adequacy of DID to be provided by plant capabilities and programmatic controls, with the following clarification:

- a. Section 5.9.6 in NEI 18-04 discusses change control processes following the issuance of a license, certification, or approval. The staff makes no findings on this topic. The staff may address such change control processes, as well as other aspects of how design assumptions carry into plant operations, in future regulatory actions, including possible rulemakings, licenses conditions, and development of guidance documents.

4. Other Considerations

Emergency Preparedness

The NRC has issued for public comment a proposed rule and related guidance, draft Regulatory Guide (DG)-1350, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities." Appendix A to DG-1350 provides a general methodology for establishing an appropriate emergency planning zone based on analyzing a spectrum of credible accidents for a specific design and site. An emergency planning zone is the area surrounding some nuclear facilities within which special considerations and management practices are preplanned and exercised in case protective actions are needed to protect the public from a release of radioactive material. For non-LWRs, the spectrum of events for evaluating the need for emergency planning zones is expected to be the LBEs as described in NEI 18-04, adjusted as necessary to reflect the specific criteria in the emergency planning decision-making process (e.g., dose calculations over a period of 96 hours from the release of radioactive materials in DG-1350 versus the 30-day period in NEI 18-04 for plotting on the F-C target).

Mechanistic Source Term

An evaluation of events, plant features and programs, and related uncertainties must address the state of knowledge related to the behavior of reactor systems, fuel, and the way in which radionuclides may move within and be released from a facility. The established methods for addressing radiological source terms for LWRs have limited applicability to non-LWR designs, and more mechanistic approaches have been proposed. The NRC will validate analytical tools and computer codes by comparing results to information available from operating experience and experiments. In SRM-SECY-93-092, the Commission approved the NRC staff's recommendation that source terms for non-LWRs be based upon a mechanistic analysis and that the acceptability of the applicant's analysis will rely on the staff's assurance that the following conditions are met:

- The performance of the reactor and fuel under normal and off-normal conditions is sufficiently well understood to permit a mechanistic analysis. Sufficient data should exist on the reactor and fuel performance through the research, development, and testing programs to provide adequate confidence in the mechanistic approach.
- The transport of fission products can be adequately modeled for all barriers and pathways to the environs, including the specific consideration of containment design. The calculations should be as realistic as possible so that the values and limitations of any mechanism or barrier are not obscured.

- The events considered in the analyses to develop the set of source terms for each design are selected to bound severe accidents and design-dependent uncertainties.
- The design-specific source terms for each accident category would constitute one component for evaluating the acceptability of the design.

The above conditions remain valid for the assessment of mechanistic source terms used to estimate radiological consequences within the analyses of event sequences as described in NEI 18-04. Although NEI 18-04 does not address the topic in detail, the development of mechanistic source terms for designs and specific event families is another element of an integrated, risk-informed, performance-based approach to designing and licensing non-LWRs. The NRC staff expects applications or related reports to describe the mechanistic source terms, including the retention of radionuclides by barriers and the transport of radionuclides for all barriers and pathways to the environs. Where applicable, a facility may have multiple mechanistic source terms and specific event sequences to address various systems that contain significant inventories of radioactive material.

Informing the Content of Applications

NEI 18-04 provides useful guidance for non-LWR reactor designers and the NRC staff in the key areas of selecting and evaluating LBEs, identifying safety functions and classifying SSCs, selecting special treatment requirements, identifying appropriate programmatic controls, and assessing DID. Taken together, these activities provide essential insights for the reactor design process, define needed SSC capabilities and programmatic controls, and support documenting the safety arguments supporting applications for licenses, certifications, or approvals. NEI 18-04 thereby defines a methodology for non-LWR applicants to identify and provide the appropriate level of information needed to satisfy parts of the regulatory requirements in 10 CFR 50.34, 10 CFR 52.47, 10 CFR 52.79, 10 CFR 52.137, and 10 CFR 52.157.⁶ The staff finds it more appropriate to define a technology-inclusive methodology for non-LWRs than to develop prescriptive content guidance as was developed for LWRs and documented in RG 1.70 and RG 1.206. The following guidance is acceptable for non-LWR designers in preparing the content of an application; this information is usually documented in preliminary or final safety analysis reports.

For ease of discussion, the following descriptions refer to the traditional chapter-level format of RG 1.206. Non-LWR designers may choose to arrange the information in a safety analysis report in a different format. The general guidance on the methodology to determine the appropriate content and level of detail for safety functions, SSCs, and programmatic controls remains valid no matter how the information is organized within a safety analysis report. NEI 18-04 describes the iterative nature of the design process and how the application reflects changes or additional information gathered as the design evolves through conceptual phases; incorporates various analyses and assessments; and is adapted due to regulatory, business, and policy considerations. Although the staff encourages pre-application discussions with developers, the reactor developer will need to have made design decisions appropriate for the specific license, certification, or approval before submitting an application.

⁶ This guidance focuses on the design features, programmatic controls, and licensing decisions related to limiting the unplanned release of radioactive material resulting from plant transients and postulated accidents. Various NRC regulations and related guidance address radiological effluents from normal operation and the content of applications provided in licensing basis documents other than Final Safety Analysis Reports (e.g., security plans, technical specifications, and environmental reports). RG 1.206 describes various licensing basis documents and a typical organization of those documents within applications for a combined license, early site permit, or design certification. The overall organization of applications described in RG 1.206, including chapter-level organization of a final safety analysis report, is generally applicable to non-LWR applications.

Similar to the processes described in NEI 18-04, the construction of a safety analysis report begins with documenting the basic reactor characteristics, such as non-LWR technology, power level, selection of the materials for the reactor, moderator, coolant, neutron energy spectrum, thermodynamic cycle, parameters of the cycle and energy balance; evaluation of options such as fuel type, indirect versus direct cycle, and passive versus active safety systems; working fluids for secondary cycles; selection of design codes for major SSCs; operations and maintenance philosophy; and other high-level design decisions driven by the top-level requirements and results of the design trade studies. The foundational material for a safety analysis report also includes a comprehensive set of plant-level and system-level functional requirements that have been identified through processes such as those described in NEI 18-04 as serving a role in the prevention or mitigation of events.

Many of the basic reactor characteristics have traditionally been described in Chapters 4, 5, and 6 of safety analysis reports. These chapters address the reactor, including fuel and reactivity control systems, the reactor coolant and connecting systems, backup cooling systems, and functional barriers for retaining radionuclides within the facility. The material in these chapters largely addresses the fundamental safety functions of reactivity and power control, heat removal, and radionuclide retention. The next set of information to be provided describes the fuel or fuel system boundary and primary system in terms of the limits on operation (e.g., values or ranges of values for key parameters) to prevent failures or degradation or to remain within the bounds of testing or qualification of related SSCs. These limits on operation thus establish the safety functions needed to prevent damage to barriers to the release of radionuclides (e.g., functions to maintain integrity of fuel cladding, coatings, or other fuel system boundary). This information is needed to address the NEI 18-04 methodologies and for the development of a mechanistic source term for the specific non-LWR design.

As discussed in the various sections of NEI 18-04 and depicted in Figure 5-2, deterministic evaluations and PRAs inform design decisions and ultimately support the safety arguments presented in applications for licenses, certifications, and approvals for non-LWRs. The interrelationship between the LBEs and the derivation of both plant capabilities and programmatic controls are discussed in NEI 18-04 and non-LWR applicants that reference NEI 18-04 and this RG should reflect this interrelationship in the layout of the safety analysis report. The approach described in NEI 18-04 and this RG involves the assessment of event categories that extend from benign to severe. The analysis of AOOs, DBEs, and BDBEs plays an important role in defining safety functions, classifying SSCs, and assessing DID for non-LWRs. The safety analysis report describes the analysis results for event sequences and related organization into event families. The PRA results are typically described in Chapter 19 of the safety analysis report, which could be expanded; a new section added to Chapter 15; or a new chapter created to include the analysis of AOOs, DBEs, and BDBEs. In addition to plant response information on SSC capabilities typically provided in deterministic evaluations, the description of AOOs, DBEs, and BDBEs needs to include or point to key information identified in NEI 18-04, such as uncertainties and measures to ensure assumed SSC availabilities.

Deterministic evaluations are usually described in Chapter 15 of safety analysis reports, and this remains an option for non-LWR applications developed using the NEI 18-04 methodology. Addressing DBAs in a separate section or chapter from the other LBEs could support maintaining the distinction between the deterministic analyses that assume only SR SSCs and the assessments of the remaining LBEs. A separate chapter might also help with the development of technical specifications and other elements of the licensing-basis documentation that are traditionally focused largely on SR SSCs. Descriptions related to the derivation of DBEHLs and protection of SR SSCs from design-basis external hazards are usually provided in Chapters 2 and 3 of safety analysis reports.

Current guidance for safety analysis report format and content for LWRs (e.g., RG 1.206) does not include a specific section for DID assessments. The importance of DID assessments in the NEI 18-04

methodology and the more systematic approach to performing the assessments lends itself to separate sections or a chapter in safety analysis reports (e.g., the addition of a Chapter 20, “Evaluations of Defense in Depth”). The format and content of the new chapter can follow the assessment methodology in NEI 18-04 and document IDP decisions.

Safety analysis reports for operating LWRs include chapters that contain detailed descriptions of SSCs supporting safety functions. Examples include chapters on instrumentation and control systems, electrical power systems, and cooling water systems. Additional chapters in LWR safety analysis reports are dedicated to power conversion systems and systems needed to handle various forms of radioactive wastes. The various system descriptions for LWRs are appropriate, given the importance of support systems for active safety systems and the potential for support or secondary plant systems to cause a plant transient challenging the fuel cladding or other barrier to the release of radionuclides. NEI 18-04 describes a process to evaluate the risk significance of ancillary SSCs in terms of contributing to initiating events or in the mitigation of event sequences for non-LWRs. The analyses and assessments in NEI 18-04 can provide insights into the appropriate level of detail needed to describe parts of a plant outside the primary systems, which are typically described in Chapters 4, 5, and 6 of a safety analysis report. In some instances, the level of detail for ancillary plant systems in non-LWR designs can be significantly less than that provided for LWRs because of the expected use of passive safety systems and increased thermal capacities of reactor systems, which reduce sensitivities to plant upsets. A description of ancillary plant systems or the interface between the ancillary and primary plant systems should focus on any safety functions being supported and possible contributions to initiating events. Where SSCs do not play a meaningful role in preventing or mitigating LBEs, minimal information on those SSCs should be provided within an application. Other appropriate information on SSCs with a role in preventing or mitigating LBEs includes the safety classification of SSCs and any special treatments identified to address the safety or risk significance of the ancillary SSCs identified via insights from the PRA or DID assessments.

The level of detail for ancillary SSCs can also reflect potential performance-based approaches within applications for licenses, certifications, or approvals. Guidance for NRC staff reviews of advanced reactors encourages the staff to consider performance-based approaches, which can likewise be used to inform the appropriate level of detail in applications. Part 2 to the Introduction to NUREG-0800 for light-water small modular reactors includes the following guidance on the use of performance-based approaches as part of an integrated review for small modular reactors:

Second, the framework incorporates an integrated review approach by using the satisfaction of selected requirements to provide reasonable assurance of some aspects of SSC performance (for example, performance-based acceptance criteria related to SSC capability, reliability, and availability). Examples of requirements that could be applied for this purpose include 10 CFR Part 50, Appendix A (general design criteria, overall requirements, criteria 1 through 5), 10 CFR Part 50, Appendix B (quality assurance program), 10 CFR 50.49 (electric equipment environmental qualification program), 10 CFR 50.55a (code design, inservice testing and inservice inspection programs), 10 CFR 50.65 (maintenance rule), Technical Specifications (TSs), Availability Controls for SSCs subject to Regulatory Treatment of Non-Safety Systems (RTNSS), the Initial Test Program (ITP), and ITAAC. In preparing the safety evaluation for the application, the staff may use the satisfaction of these selected requirements to augment or replace, as appropriate, technical analysis and other evaluation techniques to obtain reasonable assurance that the performance-based acceptance criteria are satisfied. Under the framework, the staff also has the flexibility to use these selected requirements to demonstrate satisfaction of design-based acceptance criteria for the SSCs with low risk significance. The staff will verify the demonstration of the design-basis capabilities of

SSCs that are important to safety as part of the ITAAC completion review prior to plant operation.

The integrated process described in NEI 18-04 and its consideration of plant capabilities and programmatic controls for non-LWRs is well suited to inform the content of applications, including discussions of appropriate performance-based controls of ancillary SSCs, thereby reducing the level of detail in the descriptions of the physical systems. The general guidance on the content of applications provided in this RG will need to be supplemented by other RGs and documents to help non-LWR developers and the NRC staff prepare and review applications for licenses, certifications, and approvals.

D. IMPLEMENTATION

The NRC staff may use this regulatory guide as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this regulatory guide to support NRC staff actions in a manner that would constitute backfitting as that term is defined in 10 CFR 50.109, “Backfitting,” and as described in NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” (Ref. 39) nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in Management Directive 8.4. If a licensee believes that the NRC is using this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

ACRONYMS/ABBREVIATIONS

AOO	anticipated operational occurrence
BDBE	beyond-design-basis event
CFR	<i>Code of Federal Regulations</i>
COL	combined license
DC	design certification
DBA	design-basis accident
DBE	design-basis event
DBEHL	design-basis external 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 process
IDPP	integrated decision process 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.	<i>United States Code</i>

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