Contributing activities within the NRC's implementation action plan for improving its regulatory readiness for non-light water reactor (non-LWR) designs includes developing guidance for a flexible non-LWR regulatory review process (Strategy 3). The staff is preparing a draft regulatory guide to inform the content of non-LWR applications for licenses, certifications, and approvals. This working draft white paper has been prepared and is being released to support ongoing public discussions on the draft regulatory guide. This working draft paper has not been subject to NRC management and legal reviews and approvals, and its contents should not be interpreted as official agency positions. Following the public discussions (including a public meeting scheduled for August 21, 2018), the staff plans to continue working on this paper as well as other activities defined in the agency's vision and strategies document. This white paper and related interactions with stakeholders will be considered in the preparation of the draft regulatory guide and future interactions with the Advisory Committee on Reactor Safeguards (tentatively scheduled for October 30, 2018).

GUIDANCE FOR A TECHNOLOGY-INCLUSIVE, RISK-INFORMED, AND PERFORMANCE-BASED APPROACH TO INFORM THE CONTENT OF APPLICATIONS FOR LICENSES, CERTIFICATIONS, AND APPROVALS FOR NON-LIGHT-WATER REACTORS

A. INTRODUCTION

Purpose

This [draft] regulatory guide (RG) describes the Nuclear Regulatory Commission's (NRC's) proposed guidance on using a technology-inclusive, risk-informed and performance-based methodology to inform the content of applications for licenses, certifications, and approvals for non-light water reactors (non-LWRs). The selection of licensing basis events; classification and special treatments of structures, systems, and components (SSCs); and assessment of defense in depth are fundamental to the safe design of non-LWRs. These activities also support identifying the appropriate scope and depth of information provided in applications for licenses, certifications, and approvals required by U.S. *Code of Federal Regulations*, Title 10, "Energy," Part 50, "Domestic Licensing of Production and Utilization Facilities," (10 CFR 50) (Ref. 1) and Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," (10 CFR Part 52) (Ref. 2).

Applicability

This RG applies to nuclear power reactor designers, applicants, and licensees of non-LWR designs subject to 10 CFR Part 50 and 10 CFR Part 52.

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, combined licenses, standard design approvals, and manufacturing licenses for nuclear power facilities.
    - o 10 CFR 52.47, “Contents of applications; technical information,” describes the information to be included at an appropriate level in final safety analysis reports supporting applications for standard design certifications (DCs).
    - o 10 CFR 52.79, “Contents of applications; technical information in final safety analysis report,” describes the information to be included at an appropriate level in final safety analysis reports supporting combined licenses (COLs).
    - o 10 CFR 52.137, “Contents of applications; technical information,” describes the information to be included at an appropriate level in final safety analysis reports supporting standard design approvals (SDAs).
    - o 10 CFR 52.157, “Contents of applications; technical information in final safety analysis report,” describes the information to be included at an appropriate level in final safety analysis reports supporting manufacturing licenses (MLs).

Related Guidance, Communications, and Policy Statements

- NRC, “Policy Statement on the Regulation of Advanced Reactors” (73 FR 60612, October 14, 2008), 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
- NRC, RG 1.70, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition),”
- NRC, RG 1.181,” Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)
- NRC, RG 1.186,” Guidance and Examples for Identifying 10 CFR 50.2 Design Bases”
- NRC, RG 1.206, “Combined License Applications for Nuclear Power Plants (LWR Edition),”
- NRC, RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light Water Reactors,”
- NRC, NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,”
- NRC, “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness,” December 2016
- NRC,

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 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), under control numbers 3150-0011 and 3150-0151. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0011, 3150-0151) Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

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

TABLE OF CONTENTS

To be developed

B. DISCUSSION

Reason for Issuance

This revision (Revision 0) provides guidance for determining an appropriate level of information for parts of preliminary or final safety analysis reports for non-LWRs. Applications for a construction permit, operating license, design certification, combined license, or manufacturing license are required by 10 CFR 50.34(a), 10 CFR 50.34(b), 10 CFR 52.47, 10 CFR 52.79, and 10 CFR 52.157, respectively, to include the needed level of information to enable the Commission to reach a conclusion on safety questions before issuing a license or certification. Applications for a standard design approval are likewise required by 10 CFR 52.137 to include information needed for NRC staff approval.

This RG endorses, with clarifications as detailed in this RG, the principles and methodology in NEI 18-04, Rev. 0, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development," as one acceptable method for determining the appropriate scope and level of detail for parts of applications for licenses, certifications, and approvals for non-LWRs. NEI 18-04, Rev. 0 outlines an approach for use by reactor developers to select licensing basis events, classify SSCs, determine special treatments and programmatic controls, and assess the adequacy of a design in terms of providing layers of defense in depth.

The methodology described in NEI 18-04, Rev. 0, and this guide also provide a general methodology for identifying an appropriate scope and depth of information to be provided in applications for licenses, certifications, and approvals. The NRC finds it appropriate and necessary to define a methodology versus the prescriptive nature of current LWR-centric guidance on content of applications in order for this guidance to be applicable to a variety of non-LWR technologies. This methodology also provides a logical and structured approach to identify the safety or risk significance of SSCs and associated programmatic controls; thereby ensuring needed information is provided in the application while avoiding an excessive level of detail of information in applications. This approach will in turn lead to more effective and efficient NRC reviews.

Background

The NRC Regulatory Framework

In accordance with its mission, the NRC protects public health and safety and the environment by regulating the design, siting, construction, and operation of commercial nuclear power facilities. 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 regulation. 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 applications for licenses, certifications, and approvals. However, the vast majority of the available guidance addresses 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 (ADAMS Accession No. ML16356A670). The staff developed implementation action plans (IAPs) to identify specific activities that the NRC will conduct in the near-term, mid-term, and long-term timeframes (ADAMS Accession Nos. ML17165A069 and ML17164A173). Strategy 3 within the IAPs was to develop 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 developers consider regulatory matters during the design process and to support the development of applications for licenses, certifications, and approvals.

NRC 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," (Ref. 12) which included items to be considered in their designs. The Commission's 2008 policy statement reinforced and updated the policy statements on advanced reactors previously published in 1986 and 1994. The policy statement identifies attributes that could assist in establishing the acceptability or listenability 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:

> 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, certifications, and approvals is a major undertaking in that sufficient information must be provided to support the agency's safety findings. Efforts to standardize the format and content of applications for LWRs are reflected in RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)," issued in the 1970s, and RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," issued in 2007. The scope and level of detail within applications are also informed by guidance documents such as NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," and numerous other guidance documents addressing specific technical areas.

The NRC's Advanced Reactor Policy Statement states:

> 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 had interactions with advanced reactor developers, DOE, national laboratories, and other stakeholders regarding means to improve the licensing process of 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," issued in June 1988, NUREG-1338, "Preapplication Safety Evaluation Report for the Modular High-Temperature Gas-Cooled Reactor (MHGTR) – Draft Copy of the Final Report," issued in December 1995, and NUREG-1368, "Preapplication safety evaluation report for the Power Reactor Innovative Small Module (PRISM) liquid-metal reactor. Final report," issued in February 1994. 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. The Next Generation Nuclear Plant (NGNP) 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. The NRC issued RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors,” in April 2018 following extensive interactions with stakeholders.

The Licensing Modernization Project (LMP) is led by nuclear utilities and cost-shared by DOE. The project developed technical non-LWR licensing methods that are technology-inclusive, risk-informed, and performance-based. The LMP involved a refinement of the NGNP methodologies to reflect interactions with the NRC, feedback from industry, and broadening to ensure applicability to various non-LWR technologies. The LMP activities led to the publication and submittal of NEI 18-04.

External Documents Endorsed in This Guide

This RG endorses, in part, the use of one or more codes, standards, or guidance documents developed by external organizations. 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 requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in an RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated into NRC regulations nor endorsed in an RG, 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.

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 the IAEA on topics such as the design of nuclear power plants and defense in depth.

C. STAFF REGULATORY GUIDANCE

This section contains information on the intended use of the RG. It also contains NRC staff's general guidance on using the framework described in NEI 18-04, Rev 0, to select licensing basis events, to classify SSCs, to assess the adequacy of a design in terms of providing layers of defense-in-depth, to identify appropriate programmatic controls, and to help determine the appropriate scope and level of detail for information provided in applications for licenses, certifications, and approvals. 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 regulatory guides and other documents issued to support the regulation and oversight of LWRs. Much of the guidance available for light-water reactors is prescriptive and not readily applied to other reactor technologies. This guidance supporting the licensing of non-LWR technologies will need to be supplemented by other regulatory guides and other documents to help developers and the NRC staff prepare and review applications for licenses, certifications, and approvals.

The design process and related development of licensing basis information is an iterative process involving assessments and decisions on key SSCs, operating parameters, and programmatic controls to ensure a reactor can be deployed without posing undue risk to public health and safety. In terms of beginning the process of translating design information into a licensing application, a developer would need at least a conceptual design that includes a reactor, a primary coolant, and a preliminary assessment of how fundamental safety functions of reactivity control, heat removal, and retention of radioactive materials would be accomplished. In terms of licensing documentation, this information is typically found in safety analysis report Chapter 4, "Reactor," Chapter 5, "Reactor Coolant and Connecting Systems," and Chapter 6, "Engineered Safety Features." 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 licensing basis events 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, Rev. 0, and this guide provides a general framework to support design decisions and for deciding on the needed information to be included in applications. The actual development of an application will depend not only on this guidance but also on the design, the safety case prepared by the developer, and consideration of the entirety of regulatory requirements established by the NRC and other agencies.

Intended Use of This Regulatory Guide

This RG endorses, with clarifications, the methods described in NEI 18-04, Rev. 0, dated September 2018. The NRC staff has determined that the methods described in the NEI 18-04, Rev. 0, constitute one acceptable means to identify licensing basis events, classify SCCs, establish special treatments, identify programmatic controls, and assess defense in depth. 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 is part of an integrated methodology, which includes defined relationships between licensing basis events, equipment classification, special treatments, programmatic controls, and assessments of defense in depth. The evaluations are performed in an iterative fashion as the design and licensing strategies are developed.

1. ***<u>Selection of Licensing Basis Events</u>***

An important part of the design process and formulation of a safety case 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). 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 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 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. NEI 18-04 acknowledges that the F/C target does not correspond to actual regulatory 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 defense in depth.

Figure 3-2, "Process for Selecting and Evaluating Licensing Basis Events," in NEI 18-04 provides a depiction of the iterative process needed to identify and evaluate licensing basis events. An initial list of LBEs to be used in the design process are likely to be based on engineering judgment and analysis techniques such as FMEAs and HAZOPs. PRA models are expected to be developed and refined as the design process progresses and the licensing basis documents are developed. The process supports the categorization and evaluation of LBEs in terms of estimated frequencies and consequences of event sequences or event families, which are 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. The assessments described in NEI 18-04 focus on safety functions and the identification of SSCs needed to fulfill those functions. The frequency-consequence targets support defining needed SSC capabilities and reliabilities to support the design process and to inform the content of applications. A key consideration is the uncertainties related to event sequences, plant behavior, assumed reliability of SSCs, and other aspects of the estimation of event frequencies and consequences. Uncertainties are addressed, in part, by assessing event sequences on the F/C target based on the uncertainty bands for the event and not only on the mean values of estimated frequencies and consequences. The analyses of event sequences are an input into the subsequent processes described in NEI 18-04 for the safety classification of SSCs and assessment of defense in depth.

NEI 18-04 describes assessments of event sequences in addition to the consideration of AOOs, DBEs, and BDBEs. A deterministic DBA is associated with each DBE that includes the required safety function challenges but assumes that the required safety functions are performed by safety-related SSCs. These DBAs are described in of the portion of the license application typically in Chapter 15 of safety analysis reports 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). NRC Regulatory Guide 1.203, “Transient and Accident Analysis Methods,” provides additional guidance for analyzing DBAs. A set of Design Basis External Hazard Levels (DBEHLs) will be selected to form an important part of the design and licensing basis. This will determine the design basis seismic events and other external events that the safety related SSCs will be required to withstand. In addition, the PRA model 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 multi-module 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 would not be high consequence BDBEs. When this objective is achieved, there should be no DBAs with significant releases from two or more modules or radionuclide sources. The guidance also includes as assessment of the following aggregate risk measures:

- The total frequency of exceeding a site boundary dose of 100 mrem from all LBEs shall not exceed 1/plant-year. This metric is introduced to ensure that the consequences from the entire range of LBEs from higher frequency, lower consequences to lower frequency, higher consequences are considered. The value of 100 millirem is selected from the annual exposure limits in 10 CFR Part 20.
- The average individual risk of early fatality within 1 mile of the Exclusion Area Boundary (EAB) from all LBEs shall not exceed 5×10^{-7}/plant-year to ensure that the NRC Safety Goal QHO for early fatality risk is met.
- The average individual risk of latent cancer fatalities within 10 miles of the EAB from all LBEs shall not exceed 2×10^{-6}/plant-year to ensure that the NRC safety goal QHO for latent cancer fatality risk is met.

NEI 18-04 describes a potentially expanded role for PRA beyond current requirements in CFR Part 52 or Commission policy for potential applications under 10 CFR Part 50. Prior to first introduction of the design-specific PRA, it is necessary 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. The incorporation of safety analysis methods appropriate to early stages of design, such as FMEA and PHA, 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 to develop or confirm the events, safety functions, key SSCs, and adequacy of defense in depth provides a structured framework to risk-inform the application for the specific reactor design. The PRA’s quantification of frequencies and consequences of event sequences, 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. NEI 18-04 acknowledges that designers may propose to address all or parts of the process by assessing layers of defense, including physical barriers, and showing that radioactive materials are retained within the facility with a high degree of confidence. Such an approach would still require some of the information provided by 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 simple systems, inherent characteristics, and limited public health hazard expected of some non-LWR designs.

Important roles for the PRA included 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 in NEI 18-04, "Use of the F-C Target to Define Risk-Significant LBEs," the methodology defines risk significant LBEs as those with frequencies and consequences within 1% of the F-C Target with site boundary doses exceeding 2.5 mrem. To consider the effects of uncertainties, the upper 95th percentile estimates of both frequency and dose should be used. The use of the 1% metric is consistent with the approach to defining risk significant accident sequences in the PRA standards. The 2.5 mrem cut-off is selected as this is approximately 10% of the dose that an average person at the site boundary would receive in 30 days due to background radiation. NEI 18-04 also notes that various risk importance measures can be used to gain additional insights into the significance of particular events and SSCs.

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 figure are surrogates for other measures that may be expressed in different units, time scales, or distances. The F-C target provides a reasonable approach to be used within a broader, integrated approach to determine risk significance and support SSC classification and confirm the adequacy of defense in depth.

b) The F-C target and related discussions in NEI 18-04 include a frequency of 5×10^{-7} per plant-year to define the lower range of beyond design basis events. This demarcation of lowest event frequencies on the F-C target and category definitions should not be considered a hard and fast cutoff but should instead be considered in the context of other parts of the methodology described in NEI 18-04. These other considerations include the role of the integrated decision-making panel, defense-in-depth assessments, accounting for uncertainties, and assessing for potential for cliff-edge effects.

c) NEI 18-04 describes a set of DBEHLs that will determine the design basis seismic events and other external events that the safety related 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 safety-related 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 defense-in-depth assessments described in subsequent sections. NEI 18-04 states:

"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." [LPM clarify – NRC position likely that alternate methods to identify DBEHLs, if not addressed within NRC endorsed codes or NRC guidance documents will be reviewed on a case-by-case basis.]

d) NEI 18-04 states: "In view of the fact that advanced non-LWRs will employ a diverse combination of inherent, passive, and active design features to perform the RSFs [required safety functions] across layers of defense and taking into account the fact that the reactor safety design approach will be subjected to an evaluation of defense-in-depth adequacy, the application of a single failure criterion is not deemed to be necessary. The process described in NEI 18-04 includes assessing event sequences (including unavailability of SSCs and combinations of SSCs) over a wide range of frequencies and establishing risk and safety function reliability measures. The staff finds that methodology in NEI 18-04, including assessments of event sequences and defense in depth, obviates the need to use the single failure criterion 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. 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 advanced reactors. Advanced reactor 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 being analyzed in a deterministic or stylized approach such as DBAs. An approach that maintains the single failure criterion is described in RG 1.232, which also recognized 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, and the related staff requirements memorandum dated June 30, 1994.

e) The methodology in NEI 18-04 includes a potentially expanded role for PRA beyond that currently required by 10 CFR Part 52. The staff's review of the PRA prepared by a designer could be facilitated by the NRC endorsement of consensus codes and standards (e.g., ASME/ANS RA-S-1.4, "Probabilistic Risk Assessment Standard for Advanced Non-LWR Nuclear Power Plants) and the use of that approved standard by the designer.

2. <u>Safety Classification and Performance Criteria for SSCs</u>

The second major component of the methodology described in NEI 18-04 involves assessing the risk significance of SSCs, and determining special treatments if needed to ensure SSC performance of safety functions in the prevention and mitigation of LBEs. Such requirements include those to provide the necessary capabilities to perform their mitigation functions and those to meet their reliability requirements 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 defense in depth described in the subsequent sections of NEI 18-04 and this guide.

The SSC safety classification process in NEI 18-04 is depicted in Figure 4-1, "SSC Function Safety Classification Process," and Figure 4-2, "Definition of Risk Significant and Safety Significant SSCs." 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 location of LBEs relative to the F-C target or in meeting the cumulative risk metrics. The assessments of each LBE also consider criteria relative the adequacy of DID as discussed in Section 5 of NEI 18-04. An SSC that is important for DID but that was not otherwise found to be risk significant is included within the broader category of safety-significant SSCs. Safety functions classified as "required safety functions" must be fulfilled to meet the F-C Target for the DBEs using realistic assumptions and dose requirements for the DBAs using conservative assumptions.

The evaluations of LBEs, DID, and classification of safety functions is used to design and categorize specific SSCs. The safety classification categories used in NEI 18-04 are defined as follows:

- Safety-Related (SR):
    - SSCs selected by the 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 dose limits of 10 CFR 50.34 using conservative assumptions
    - SSCs selected by the 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
- Non-Safety-Related with Special Treatment (NSRST):
    - Non-safety-related 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 make significant contributions to the cumulative risk metrics selected for evaluating the total risk from all analyzed LBEs.
    - Non-safety-related SSCs relied on to perform functions requiring special treatment for DID adequacy
- Non-Safety-Related with No Special Treatment (NST):
    - All other SSCs (with no special treatment required)

Safety significant SSCs include all those SSCs classified as SR or NSRST. None of the NST SSCs are classified as safety significant but they may have requirements to ensure failures following a design basis internal or external event do not adversely impact SR or NSRST SSCs in their performance of safety significant functions.

Performance criteria for reliabilities and capabilities are established for the SSCs fulfilling safety significant functions. Examples of such requirements are provided in Table 4-1, "Summary of Special Treatment Requirements for SR and NSRST SSCs," in NEI 18-04. 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 guidance such as RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors.” These criteria are used to frame specific design requirements as well as special treatment requirements for SR SSCs. NSRST SSCs are not directly associated with FDC but are subject to special treatment as determined by the integrated decision-making process for evaluation of defense-in-depth. The FDC, design requirements, and special treatment requirements define key aspects of the descriptions of SSCs that will be included in safety analysis reports. NEI 18-04 describes a specific role for some SSCs as “barrier functions” in which the SSC serves as a physical or functional barrier to the transport of radionuclides and indirect functions in which performance of an SSC function 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. As discussed in SECY-18-xyz, “Functional Containment Performance Criteria for Non-Light-Water-Reactor Designs,” establishing performance criteria for a barrier, or set of barriers taken together, that serve as a “functional containment” to effectively limit the physical transport and release of radioactive material to the environment is a policy issue requiring Commission approval.

A major objective of the process described 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 appear. The reliability of the SSC serves to prevent the occurrence of the LBE by lowering its frequency of occurrence. If the SSC function is successful along the event sequence, the SSC helps to mitigate the consequences of the LBE. The safety classification process and the corresponding special treatments 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. The LBE frequencies are a function of the frequencies of initiating events from internal events, internal and external hazards, and the reliabilities and capabilities of the SSCs (including the operator) to prevent and mitigate the LBE. The 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, there are other cases in which 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.

SSC safety margins play an important role in the development of SSC design requirements for reliability and performance capability. Acceptance limits on SSC performance are set 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 prevention or mitigation 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 defense-in-depth. 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.

Staff Position: NEI 18-04 provides an acceptable method for assessing and classifying SSCs as safety related, nonsafety related with special treatment, or nonsafety related. The staff offers the following clarification:

a) The SSC classifications and logic outlined in NEI 18-04 are part of an integrated methodology, which includes a defined relationship between licensing basis events, equipment classification, and assessments of defense in depth. The classifications and related outcomes may not be applicable for alternative approaches that do not follow the other parts of the methodology described in NEI 18-04.

3. Evaluation of Defense-in-Depth Adequacy

The philosophy of defense-in-depth, multiple independent but complimentary 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, defense-in-depth 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 in NEI 18-04 depicts a framework that includes probabilistic and deterministic assessment techniques to establish defense in depth using a combination of plant capabilities and programmatic controls. Evaluations are performed based on several established approaches to defense in depth 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 defense in depth 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 that have been incorporated into the design to prevent and mitigate accident sequences and to ensure that they reflect adequate SSC reliability and capability. The 5 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."

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 form an Integrated Decision Panel (IDP) which guides 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. The process and outcome in terms of assessments and demonstration that a reasonable level of defense in depth has been incorporated into the design will be described in an application for a license, certification, or approval. A structure for the operation of an IDP is provided in RG 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," and the related industry guidance in NEI 00-04, "10 CFR 50.69 Categorization Guide." Figure 5-4, "Integrated Process for

Incorporation and Evaluation of Defense-In-Depth," in NEI 18-04 depicts the overall process and relationships between LBE selection and analyses, SSC Classification, and 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.

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 which are not sufficiently characterized for uncertainty quantification nor amenable to sensitivity analyses. The plant capability DID include design margins that protect against certain uncertainties, and measures to compensate for residual unknowns are incorporated into both plant capability and programmatic elements of DID. A summary of how a designer and the process described in NEI 18-04 establish DID is provided in Table 5-1, "Role of Major Elements of TI-RIPB Framework in Establishing DID Adequacy."

Plant Capability Defense in Depth

The plant capability DID adequacy guidelines in Table 5-2 of NEI 18-04 require that two or more independent plant design or operational features be provided to meet the 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 safety-related nor risk significant, the IDP 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 deemed necessary by the IDP responsible for evaluating the adequacy of DID.

The evaluation of plant capability DID adequacy focuses on the completeness, resiliency, and robustness of the plant design with respect to addressing all hazards, responding to identified initiating events, the availability of independent levels of protection in the design for preventing and mitigating the progression of event sequences, and 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 evaluation of DID described in NEI 18-04 is a systematic review of the LBEs against the layers of defense. This review by the IDP is necessary to evaluate the plant capabilities for DID and to identify any programmatic DID measures that may be necessary for ensuring DID adequacy. This review is performed 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. A generalized model for describing an event sequence in terms of the design features that support prevention and mitigation reflecting the above insights is provided in Table 5-4 of NEI 18-04. This information 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.

The methodology for assessing DID described in NEI 18-04 includes an assessment of plant risk margins that includes a comparison of the mean values of each LBE frequency and dose to the F-C target and a comparison of the 95th percentile upper bound values of each LBE frequency and dose to the F-C target.

Programmatic Defense in Depth

Section 5.7 in NEI 18-04 states that the evaluation of LBEs by the IDP will focus on the DID assessment when determining if additional compensatory action would be considered, depending on the risk significance of the LBE. Compensatory action can take on different forms including changes to design and operation, refinements to the PRA, revisions to the identified LBEs and safety classification of SSCs, as well as enhancements to the programmatic elements of DID. The broad questions listed in NEI 18-04 for the IDP to consider are:

- 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 require safety functions appropriate?
- Have protective measures to manage the risks of multi-module and multi-radiological 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?

Section 5.8 in NEI 18-04 also notes the importance of programmatic DID and identifies the following objectives for the assessment and IDP process for identifying appropriate programmatic controls:

- Assuring adequate margins exist between the assessed LBE risks relative to the F-C Target including quantified uncertainties
- Assuring adequate margins exist between the assessed total plant risks relative to the Cumulative Risk Targets
- Assuring appropriate targets for SSC reliability and performance capability are reflected in design and operational programs for each LBE

- Providing 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 are more dependent on engineering judgment by the IDP. 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 technical specifications, quality assurance programs, plant procedures and guidelines, training, maintenance programs, and testing and surveillance programs.

Section 5.9 in NEI 18-04 summarizes the role of the IDP in evaluating the adequacy of DID. Table 5.8, "Risk-Informed and Performance-Based Decision-Making Attributes," provides attributes of the integrated decision-making process and principal focus areas for consideration by the IDP. The attributes include recurring examinations of the risk triplet questions of what can go wrong, how like is it, and what are the consequences. Additional key attributes for consideration by the IDP include 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.

Staff Findings: NEI 18-04 provides an acceptable method for assessing the adequacy of defense in depth to be provided by plant capabilities and programmatic controls, with the following clarifications:

a) Section 5.9.6, "Considerations in Documenting Evaluation of Plant Capability and Programmatic DID," discusses change control processes following the issuance of a license, certification, or approval. The staff plans to address such change control processes in future guidance documents and therefore makes no findings on this section of NEI 18-04.

Other Considerations

Emergency Preparedness

Add discussion on the relationship between NEI 18-04 and Emergency Planning Zone Proposed Rulemaking and DG-1350, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production and Utilization Facilities"

Mechanistic source term.

Add discussion on mechanistic source term

$$R_j = Q * F_{IE,j} * P_{ASSC,j} * P_{PSSC,j} * r_{fuel,j} * r_{PB,j} * r_{cont,j}$$

or similar SNL/NRC representation:

$$ST(S_i, RN_j, t) = I(RN_j) \cdot F(S_i,\ t) \cdot MR(S_i, RN_j, t) \cdot PSR(S_i, RN_j, t)\ \cdot LPF(S_i, RN_j, t)$$

Where the source term (ST) is characterized by a product of factors that modify the initial inventory (I). Each factor is dependent on radionuclide group (RN), event sequence (S), and time (t). A generic set of factors representing releases past barriers can be defined as a damage ratio or release from fuel (F), releases from fuel matrix (M), releases from primary system (PSR), and releases via a leak path from structures (LPF).

Expand the discussion to (1) connect the representation of MST with the methodology – e.g., the notion that ST is determined for event sequences versus the traditional LWR approach with a maximum hypothetical accident for assessment of containment, and (2) introduce the eventual construct of the licensing basis which will interweave the release factors, safety functions, and the SSCs and programmatic controls needed to define capabilities/availabilities using the F-C target to inform decisions. Example can be relationship between release factors from fuel and fuel matrix with transients involving increasing temperatures – with successful heat removal, these release factors remain low and prevent release. Failure of heat removal systems or other low frequency events may introduce reliance on LPF.

Informing content of applications

NEI 18-04 provides useful guidance for reactor designers and the NRC staff in the key areas of selecting and evaluating licensing basis events, identifying safety functions and classifying SSCs, selecting special treatment requirements, identifying appropriate programmatic controls, and assessing defense in depth. Taken together, these activities provide essential insights for the reactor design process, define needed SSC capabilities and programmatic controls, and support documenting the safety case supporting applications for licenses, certifications, or approvals. NEI 18-04 thereby defines 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. 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 content of an application usually located in certain sections of preliminary or final safety analysis reports.

For ease of discussion, the following descriptions use the traditional chapter-level format of RG 1.206. Designers may choose to arrange the information in an FSAR in a different format. The general guidance regarding 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 changes will be made or additional information gathered as a design evolves through conceptual phases, various analyses and assessments, and the designer makes decisions related to regulatory, business, and policy issues. Although the staff encourages preapplication discussions with developers, the developer will need to have made design decisions appropriate for the specific license, certification, or approval prior to making an application.

As in 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, and coolant, neutron energy spectrum, thermodynamic cycle, parameters of the cycle and energy balance, and evaluation of options such as fuel type, indirect versus direct cycle, passive versus active safety systems, working fluids for secondary cycles, selection of design codes for major SSCs, Operations and Maintenance (O&M) 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 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 address the fundamental safety functions of controlling reactivity and power, heat removal, and the 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, degradation, or to remain within the bounds of testing or qualification of related SSCs. These limits on operation will in turn establish the needed safety functions to prevent damage to barriers to the release of radionuclides (e.g., functions maintain integrity of fuel cladding, coatings, or other fuel system boundary). This information is required for the methodologies outlined in NEI 18-04 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, “Framework for Establishing DID Adequacy,” deterministic evaluations and probabilistic risk assessments inform design decisions and ultimately support the safety case presented in applications for licenses, certifications, and approvals. The interrelationship between the licensing basis events and the derivation of both plant capabilities and programmatic controls are defined in NEI 18-04 and need to be reflected in layout of the safety analysis report. The approach described in NEI 18-04 and this guide 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 defense in depth. The analysis results for event sequences and related organization into event families will be described in the safety analysis report. The PRA results are typically described in Chapter 19 and this chapter could be expanded 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 will need 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 applications developed using NEI 18-04. Addressing DBAs in a separate chapter from the other LBEs could support maintaining the distinction between the deterministic analyses assuming only safety-related 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 related to safety-related SSCs. Descriptions related to the derivation of DBEHLs and protection of safety-related 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 defense in depth assessments. The importance of the DID assessments in the NEI 18-04 methodology and the more systematic approach to performing the assessments lends itself to specific 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 chapter can follow the assessment methodology and be used to document decisions by the integrated decision-making panel.

Safety analysis reports for operating LWRs 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. The analyses and assessments in NEI 18-04 can provide insights into the appropriate level of detail needed to describe parts of plant outside the primary systems typically described in Chapters 4, 5, and 6. In many instances, the level of detail in the information for ancillary plant systems in advanced reactor 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. Other appropriate information 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 assessments of defense in depth.

The level of detail for ancillary SSCs can also reflect potential performance-based approaches within applications for licenses, certifications, or approvals. Consideration of performance-based approaches is encouraged in the guidance for NRC staff reviews of advanced reactors and can likewise be used to inform the appropriate level of detail in applications. The introduction to NUREG 0800 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 is well suited to inform the content of applications and including discussions of appropriate performance-based controls of ancillary SSCs and thereby reducing the level of detail in the descriptions of the physical systems.

The staff expects to continue to refine the above guidance and develop additional guidance related to the scope and level of detail of information needed to support non-LWR applications for licenses, certifications, and approvals. Revisions to this regulatory guide and development of additional regulatory guides are likely as the staff interacts with stakeholders and gathers additional insights into the designs and attributes of various non-LWR technologies.

IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees[1] may use this guide and information regarding the NRC's plans for using this RG. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting," and any applicable finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

Use by Applicants and Licensees

Applicants and licensees may voluntarily[2] use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be deemed acceptable if the applicant or licensee provides sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations.

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

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this RG. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this RG to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this RG without further backfit consideration. Examples of such unplanned NRC regulatory actions include: issuance of an order requiring the use of the RG, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this RG, or generic communication, or promulgation of a rule requiring the use of this RG.

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

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

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

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

Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.

If a licensee believes that the NRC is either using this RG or requesting or requiring the licensee to implement the methods or processes in this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines" (Ref. 27), and the NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 28).

ACRONYMS/ABBREVIATIONS

To be developed

REFERENCES[3]

1. *To be developed*

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