# AdaPTIVENESS OF THE US NRC RegulatoRY FRAMEWORK TO REVIEW RISK-INFORMED Small Modular Reactor DESIGNS

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**Abstract**

## The new generation of Small Modular Reactors (SMRs) has proposed safety strategies, which have used Probabilistic Safety Assessment (PSA) inputs, i.e., quantified values generated by PSA models in various ways with regards to supporting the design and licensing processes for SMRs. The applicants have used PSA insights to develop safer designs, as well as to propose different innovative approaches to use PSA inputs to develop designs that may be more economical. For instance, NEI 18-04, entitled, “Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light-Water Reactor Licensing Basis Development” [1], which is generally referred to as the Licensing Modernization Project (LMP) uses PSA inputs to classify systems as safety-related versus non-safety-related, define the licensing basis events (LBE), and support the determination of the adequacy of defence in depth of the design. LMP has been endorsed by the US Nuclear Regulatory Commission (NRC) via Regulatory Guide 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors” [2]. Other approaches such as those proposed in ANSI/ANS-30.3-2022, “Light-Water Reactor Risk-Informed, Performance-Based Design,” prepared by the American Nuclear Society, has a lower reliance on PSA inputs [3]. The BWRX-300 (a new-light water reactor design) Safety Strategy prepared by GE Hitachi [4], has some similarities to the LMP approach, as well as with the ANSI/ANS-30.3-2022, Light Water Reactor Risk-Informed, Performance Based Design standard and uses PSA inputs in the licensing process in a manner different from the LMP process consistent with the International Atomic Energy Authority (IAEA) framework SSR 2/1 [5] framework. Applicants have used these risk-informed design approaches to attempt to comport with the NRC’s regulatory framework, while at the same time, also meeting with some key components of other international frameworks, to the extent practical. Even though there are significant variations among the LMP, ANS 30.3 and the BWRX-300 approaches in how systems are classified, all three of these approaches use the five levels of defence in depth, as described in SSR 2/1. Innovation on the part of the industry has prompted the NRC to be adaptive and ready to enable safe use of nuclear power, a critical component of its mission, in a proactive as opposed to a reactive manner. The NRC has been adaptive in accommodating these various innovative approaches of using PSA inputs under its two existing licensing pathways, Section 10 of Part 50 of the Code of Regulations (10 CFR 50) [6] and 10 CFR Part 52 [7]. To that extent, the current licensing pathways and associated guidance documents that the NRC has endorsed has enabled the NRC to reach a state of readiness to receive and review advanced reactor designs which use PSA insights to different degrees in the licensing processes. The NRC, however, continues to optimize its regulatory licensing pathways using lessons learned from the various ongoing advanced reactor licensing reviews. This proposed paper summarizes how the NRC has reached a state of readiness to receive and review advanced reactor designs that use PSA insights to different degrees, as well as how the NRC continues to enhance its existing regulatory framework to gain additional efficiencies.

## InTRODUCTION

The Nuclear Energy Innovation and Modernization Act [8] requires the NRC to (1) establish stages within the licensing process; (2) increase the use of risk-informed, performance-based licensing evaluation techniques and guidance; and (3) establish by the end of 2027, a technology-inclusive regulatory framework that encourages greater technological innovation for commercial nuclear reactors. Designers of new light-water and non-light-water reactors have responded to the challenge by proposing different ways to leverage the strength of the PSA technology to propose designs that are safer. These designers are also proposing innovative ways to use PSA insights to improve the economic viability of the designs as well which poses unique challenges to NRC as a safety regulator to encourage innovation while ensuring safety. Number of proactive measures that the NRC has accomplished during the last several years such as timely review and endorsement of key consensus standards has enabled NRC to achieve its readiness posture with respect to receive and review advanced reactors designs and continue to learn from ongoing reviews to further enhance its readiness posture. The NRC has already taken steps to adapt its framework to review applications for advanced reactor designs using its two existing licensing pathways (10 CFR Part 50, and 10 CFR Part 52). To that extent, Section 2 of this paper summarizes the characteristics of the two existing licensing pathways that encourage the innovative uses of PSA to enhance the safety and economic aspects of the design and provides the status of the third licensing pathway, in the proposed 10 CFR Part 53 rulemaking [9]. Section 3 of this paper summarizes three different approaches used by applicants to leverage PSA inputs in the design and licensing processes. Section 3 highlights some similarities and differences in the way these three approaches use PSA inputs to create components of the licensing basis of the nuclear power plant such as the (1) subset of design basis events (DBE), (2) subset of licensing basis events (LBE), (3) subset of safety-related systems, and (4) the subset of non-safety significant systems that require regulatory treatments as well other related components such as defence in depth and treatment of single failure. Section 4 then highlights how the NRC’s current licensing pathways offer the agility to review these different approaches, by in part, leveraging the exemption process afforded by Part 50.12 of the NRC’s regulations, entitled, “Exemptions,” in 10 CFR 50 [6]. In Section 5, the author summarizes a few initiatives that further enhance NRC’s readiness posture to review advanced reactor applications and provides the author’s concluding remarks.

## Use OF PSA DURING THE DESIGN PROCESS FOR 10 CFR pART 50 and 10 CFR pART 52

**2.1 Use of PSA during the Design Process under 10 CFR Part 50 Licensing Pathway**

The PSA technology was not used when 10 CFR Part 50 was promulgated. Publication of WASH-1400 [10], and lessons learned from the accident at the Three Mile Island provided the impetus to the US NRC to motivate operating plants to perform PSAs and use insights from those PSAs to improve plant safety. The Commission’s Severe Accident Policy [11], issuance of the Generic Letter 88-20, entitled, “Individual Plant Examinations,” and its supplements [12], and inclusion of a new section in 10 CFR 50.36(f)(1), entitled, “Additional TMI Related Items,” [6] adequately addressed that gap in that it motivated all operating reactor licensees to develop plant specific-PSAs, identify them to modify plant designs and operating procedures using PSA insights. Number of other Commission policies published since the promulgation of 10 CFR Part 50 such as SRM-SECY-93-087 [13], entitled, “Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactors,” SECY 94-084 [14], entitled, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems,” have also provided ample information to the designer of advanced light-water reactors about the Commission’s expectations with respect to using PSA inputs during the design and licensing processes, when the designers use 10 CFR Part 50.

* 1. **Use of PSA during the Design Process under 10 CFR Part 52 Licensing Pathway**

The US NRC codified the use of PSAs during the design process when it issued 10 CFR Part 52. The following excerpt from the code of federal regulations is illustrative of the Commission’s initiative to elevate the Commissions expectations regarding use of PSA from guidance to the staff and applicants to a regulatory mandate:

10 CFR 52.47(a)(27), 10 CFR 52.79(a)(45), CFR 52.137(a)(25) requires that an application must include “[a] description of the design-specific probabilistic risk assessment and its results.”

“10 CFR 50.71(h)(1): No later than the scheduled date for initial loading of fuel, each holder of a combined license under subpart C of 10 CFR part 52 shall develop a level 1 and a level 2 probabilistic risk assessment (PRA). The PRA must cover those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel.”

It is important to note here that whereas 10 CFR Part 52 requires applicants to develop PSAs and use them to enhance safety of the design and identify a subset of systems that may require regulatory treatment albeit being safety-related, it did not require licensees to use PSA inputs to develop key components such as the DBE, the LBE, and the safety-related systems.

## DifferenT APPROACHES IN USING PSA INSIGHTS IN DESIGN

International guidance also emphasizes the significance of using PSA insights in the design process. For example, Section 12, Rev. 1 of IAEA SSG-3 [15], entitled, “Development and Application of Level 1 PSA for Nuclear Plants,” provides high-level guidance on how PSA insights can be used to enhance plant designs. IAEA SSR 2/1 [16], entitled, “Safety of Nuclear Plants: Design,” describes important concepts on the application of defence in depth and single failure criteria during plant design. In addition to making the designs safer, applicants use inputs from PSA to modify how they plan to develop important components of its licensing basis. For example, designers use PSA insights to develop the DBEs, LBE and to select the subset of safety-related structures, systems, and components (SSCs). When the applicants use PSA insights to develop components in the licensing basis, the applicant must demonstrate how the proposed design meet the NRC’s regulatory requirements or request exemptions from the regulations or justify deviations from the NRC staff’s guidance, as provided in the NRC’s standard review plan (SRP) [17]. The NRC’s regulatory framework is adaptable to address such situations, e.g., such as departures from meeting specific criteria in the SRP or regulatory guidance or leveraging the exemption process if existing regulations cannot be met. For example, Section 50.36(h), entitled, “Conformance with the Standard Review Plan (SRP)” in 10 CFR 50 [6] identifies the need to justify deviations from the SRP. That section then goes on to state that the SRP was issued to establish criteria that the NRC staff intends to use in evaluating whether an applicant/licensee meets the Commission's regulations, that the SRP is not a substitute for the regulations, and that compliance is not a requirement. It notes that the applicants shall identify differences from the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP criteria provide an acceptable method of complying with the Commission's regulations. Section 50.12, entitled, “specific exemptions,” in 10 CFR 50 [6] delineates criteria under which the Commission may grant exemptions from the regulatory requirements. For instance, 10 CFR 50.12 states that the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations under special circumstances and articulates six specific circumstances under which exemptions from the regulations may be granted. These attributes of 10 CFR Part 50 make it adaptable to receive and review advanced reactor designs that use PSA insights to develop the licensing basis.

The subsections below summarize three different approaches of how applicants have proposed using PSA in the design process and how the NRC has either completed or initiated the review of those proposed approaches.

**3.1 Use of PSA Inputs to Define LBEs and Select Safety-Related SSCs – The LMP Approach**

 The LMP approach documented in NEI 18-04 [1], entitled, “Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light-Water Reactor Licensing Basis Development has been endorsed by the NRC using its Regulatory Guide 1.233 [2], “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.” It relies significantly on results of a Level 3 PSA to classify systems, and identify the LBEs, and support the determination of the adequacy of defence in depth. The defence in depth concept used in NEI 18-04 has been derived from IAEA SSR 2/1 [16]. Within the LMP construct, a designer who uses the LMP approach will leverage a risk-informed approach to meet the regulatory requirements associated with the single failure criterion. LMP’s reliance on PSA inputs in the licensing basis is significantly more than the two frameworks described below. This is because, whereas those two approaches use PSA inputs only to identify the DBEs and LBEs, the LMP approaches use PSA inputs to identify safety-related SSCs using a Frequency-Consequence curve. This approach necessitates the use of a Level 3 PSA of acceptable quality to the staff to implement the LMP approach.

**3.2 Use of PSA Insights to Define LBEs and Select SR SSCs – The ANSI/ANS-30.3-2022 Standard**

The American Nuclear Society (ANS) submitted ANSI/ANS 30.3 [3], entitled, “Light-Water Reactor Risk-Informed, Performance-Based Design.” to the NRC for review and endorsement in 2022. In comparison to the LMP process, ANS 30.3 relies to a lesser degree on PSA inputs to determine the design basis events (DBEs), the LBEs, which includes the DBEs such as the Abnormal Operating Occurrences (AOOs) and Postulated Accidents (PAs) as well as special events (SEs). The ANS 30.3 methodology also uses event sequence frequencies derived from a PSA to address single failure related requirements in a risk-informed manner. The approach that ANS has offered appears to be similar to the staff’s proposed Option 1 of SECY 19-0036 [18] entitled, “Application of the Single Failure Criterion to NUSCALE Power LLC’s Inadvertent Actuation Block Valves,” in that it proposes to use event sequence frequencies to address single failure requirements. The ANS 30.3 methodology, like LMP, also uses the defence in depth approach concept provided in IAEA SSR 2/1 [16]. It is not clear whether ANS 30.3 uses event sequence frequencies or initiating event frequencies to identify AOOs, which could significantly influence the subset of systems that must be classified as safety-related. Once the DBEs are selected using deterministic methods augmented by the design-specific PSA, unlike the LMP, the designer does not use other PSA inputs to select the safety-related SSCs. Consequently, a designer who uses the ANS/ANS 30.3 standard does not have to develop a full scope Level 3 PSA that covers all operating modes and all initiators. Rather, only a Level 2 PSA is required to use the ANSI/ANS 30.3 standard. Section 5 (LBE Identification), Section 6 (Design-Basis Safety Analysis), and Section 7 (Probabilistic Risk Assessment) of ANSI/ANS 30.3 provide details on how an applicant who chooses to use the standard should use PSA insights to develop and maintain its licensing basis.

**3.3 Use of PSA Insights to Define LBEs and Select SR SSCs – BWRX-300 Safety Strategy**

In 2024, the NRC staff accepted the safety strategy paper that GE Hitachi submitted to the NRC [4] for a detailed technical review. In comparison to the LMP process, the BWRX-300 Safety Strategy has a less reliance on PSA. It uses PSA inputs to distinguish between the design basis and beyond design basis events (BDBE). To that extent, the BWRX-300 Safety Strategy relies heavily on the applicant to estimate event sequence frequencies accurately and evaluate the robustness of those frequencies in light of uncertainties and key assumptions. Similar to both the ANS 30.3 and the LMP approaches, the BWRX-300 Safety Strategy also uses the defence in depth strategy in IAEA SSR 2/1 [16]. Unlike the LMP approach, however, the BWRX-300 Safety Strategy approach relies heavily on the defence in depth approach proposed by the IAEA guidance as opposed to numerical values generated by the PSA models to determine the safety classes of systems. As part of the BWRX-300 Safety Strategy, including the use of PSA insights, the PSA importance (sensitivity) studies are performed for the BWRX-300 Safety Strategy to evaluate whether Safety Class 1 (synonym for Safety-Related) system(s) alone are adequate to meet: (1) NRC safety goals of CDF less than 1.0 E-4 per reactor-year and large release frequency (LRF) less than 1.0 E-6 per reactor-year, and (2) Canadian Nuclear Safety Commission (CNSC)’s safety goals of CDF less than 1.0 E-05 per reactor-year and LRF sum of frequencies of all fault sequences that can lead to a release to the environment of more than 1014 becquerels of cesium-137 less than 1.0 E-06 per reactor-year. Implementation of BWRX-300 does not require a Level 3 PRA. Rather, ability to estimate CDFs and LRFs, which can be generated via Level 2 PSAs is sufficient.

## quality requirements for psa to enAble readiness of reviews

Consensus standards developed by the Joint Committee on Nuclear Risk Management (JCNRM), a joint committee between the ANS and American Society of Mechanical Engineers (ASME) have been instrumental in the NRC’s ability to establish an agile framework, which can accommodate the needs of nuclear plant designers who rely on PSA insights to different degrees, and then, use those insights from the PSAs to influence the key components of the licensing basis to varying degrees. The NRC’s initiatives to recognize the pending needs, including the prioritization of its resources to review a subset of these PSA standards in an expeditious basis, have been instrumental in supporting the NRC readiness to receive and review new reactor licensing applications.

Section 3 above summarized three variations in how applicants have used PSA insights to different degrees. In the case of the LMP, to enable the review process, an applicant must have access to PSA Standards that are acceptable to the NRC. Furthermore, in the event that the use of these innovative approaches results in situations where the applicant cannot meet the regulatory requirements, the regulatory framework must be amenable to accommodate those situations. In 2020, the NRC issued Revision 3 to Regulatory Guide 1.200 [19], entitled, “Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities,” which continued to endorse ASME/ANS RA-Sa-2009 [20] entitled “Standard for Level 1/Large Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications,” DC/COL-ISG-028 [21] entitled “Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification and Combined License Application,” with some modifications, “Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License, and endorsed ASME/ANS RA-S Case 1 [22],“Case for ASME/ANS RA-Sb-2013 Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment of Nuclear Power Plant Applications.” This action enables NRC to review applications such as BWRX-300 Safety Strategy and provide sufficient clarity and predictability with respect to use of PSA. Conversely, the NRC’s initiative to review and endorse ASME/ANS RA-S-1.4-2021 [23], entitled, “Probabilistic Risk Assessment Standard for Advanced Non-Light-Water Reactor Nuclear Power Plants” in 2022 using Regulatory Guide 1.247 [24], entitled, “Acceptability of Probabilistic Risk Assessment Results for non-Light-Water Reactor Risk-Informed Activities,” on an expedited basis, provides applicants with clarity and reliability on quality expectations for advanced non-light-water reactor licensing (ANLWR), which chooses to use the LMP. Availability of these Standards and NRC’s endorsement of them, are necessary but insufficient to achieve the readiness that is needed. However, these in combination of other characteristics of NRC regulatory framework discussed earlier (presence of sections 50.12 and 50.34(h)) provided the agility that NRC needs to receive and review applications that use PSA to different degrees.

5. ADDITIONAL IMPROVEMENTS TO THE READINESS CAPABILITY AND CONCLUDING REMARKS

With the issuance of critical documents such as RG 1.247 and RG 1.233 and revisions to RG 1.200, the NRC is well-positioned to receive and review advanced reactor applications that use PSA inputs to different degrees to design and license nuclear power plants. In leveraging these guidance documents, the NRC staff has been successful in completing the reviews of some designs and is in the process of reviewing various other designs. Even though the NRC’s current licensing pathways and the associated regulatory guidance enable the NRC staff’s review of new and advanced reactor licensing applications, which use PSA insights to different degrees, the staff is working on other significant initiatives to further strengthen that framework by leveraging lessons learned from the reviews of light-water reactors (LWRs) and advanced non-light-water reactors (ANLWRs). The NRC’s initiative to promulgate a new rule, entitled, “Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors” [9] will be codified in 10 CFR Part 53 and will provide a third licensing pathway for advanced reactors. That rulemaking, when finalized, would revise the US NRC’s regulations by adding a risk-informed, technology-inclusive regulatory framework for commercial advanced nuclear reactors in response to the Nuclear Energy Innovation and Modernization Act. Issuance of other key documents such as Regulatory Guide 1.253 [25] entitled “Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” is symbolic of another major advancement of NRC’s regulatory structure that enables licensing of ANLWRs. A presentation made at the NRC [26] provides a summary of significant progresses that NRC has made to achieve its readiness posture with respect to ANLWRs by pointing to facts such as addressing more than 35 Commission policy issues, 10 NRC and Department of Energy collaborations, review of more than 90 topical reports, and completion of 10 advanced reactor design computer models. On the new light-water reactor front, the NRC staff has also undertaken initiatives to use lessons learned from its ongoing reviews of advanced light-water reactor designs such as the NUSCALE US460 Standard Design Approval Application for small modular reactors [27], the BWRX-300 Safety Strategy, and the ANSI/ANS-30.3-2022 standard to identify and develop innovative solutions to reduce staff review burdens and encourage innovation on the part of the designers. More specifically, NRC has undertaken an initiative entitled “Reactor Accident Analysis Modernization Effort” to identify 11 issues such as the ability to credit non-safety-related systems in accident analysis and enabling the use of risk-informed approaches to disposition the requirements for single active failure, which when dispositioned on a priority basis could expedite the review of future ALWR designs [28]. When completed, these initiatives will further strengthen the NRC’s readiness posture with respect to ALWR reviews.

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