SMR, LLC. A Holtec International Company
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Telephone (856) 797-0900
Fax (856) 797-0909

February 20, 2025

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: SMR, LLC Submittal of Approved Version of Licensing Topical Report, "Holtec PSA Risk Significance Determination Methodology Licensing Topical Report," (Project No. 99902049)

SMR, LLC is pleased to submit the approved version of licensing topical report, "Holtec PSA Risk Significance Determination Methodology Licensing Topical Report," HI-2230875-A Revision 1.

SMR, LLC submitted Revision 0 of the subject topical report for NRC review on June 11, 2024 (ML24163A398). Revision 1 of the topical report was submitted on October 18, 2024 (ML24292A046). The NRC issued their final safety evaluation (SE) of the subject topical report on February 6, 2025 (Letter ML25034A099; SE ML24345A006).

If you have any questions or require any additional information, please contact Andrew Brenner, Director of Licensing, SMR, at a.brenner@holtec.com, (O) 856-957-2011, or (C) 215-704-8387.

Respectfully,

Andrew Brenner

Digitally signed by Andrew Brenner
DN: cn=Andrew Brenner, o=Holtec, ou=SMR, email=A.Brenner@holtec.com

Andrew Brenner
Director of Licensing, SMR, LLC

Enclosures:

1. "Holtec PSA Risk Significance Determination Methodology Licensing Topical Report," HI-2230875-A Revision 1, Nonproprietary

CC:
K. Trice (Holtec International, President)
J. Fleming (Holtec International, LLC, VP of Licensing & Regulatory Affairs)
J. Hawkins (SMR, LLC, Executive Director of SMR)
M. Hayes (USNRC, DNRL, NLIB, Branch Chief)
V. Huckabay (USNRC, DNRL, NLIB, Senior Project Manager)
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I. Banks (USNRC, DNRL, NLIB, Project Manager)

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Enclosure 1

Holtec PSA Risk Significance Determination Methodology Licensing Topical Report
HI-2230875-A, Revision 1

SMR, LLC. A Holtec International Company
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Contents

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Section A

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 6, 2025

Mr. Andrew Brenner
SMR, LLC, A Holtec International Company
Krishna P. Singh Technology Campus,
1 Holtec Blvd.
Camden, NJ 08104

SUBJECT: FINAL SAFETY EVALUATION FOR THE TOPICAL REPORT ON THE SMR (HOLTEC) PSA RISK SIGNIFICANCE DETERMINATION METHODOLOGY LICENSING TOPICAL REPORT (DOCKET NO. 99902049)

Dear Mr. Brenner:

By letter dated June 11, 2024, SMR, LLC, a Holtec International Company (SMR (Holtec)), submitted Licensing Topical Report (TR) HI-2230875, Revision 0, "Holtec PSA Risk Significance Determination Methodology Licensing Topical Report ."[1] The U.S. Nuclear Regulatory Commission (NRC) accepted the TR for review on July 10, 2024.[2]

The NRC staff provided an audit plan[3] requesting information and other material necessary for the regulatory audit. An audit entrance meeting was held with Holtec on August 15, 2024 to discuss the NRC staff's audit process and information needs. The audit formally concluded on November 7, 2024, with all audit information needs resolved. The staff will issue an audit report to summarize the information needs and their resolution. By letter dated October 18, 2024[4], Holtec submitted Revision 1 of its Risk Significance Determination Methodology TR for NRC staff's review.

The NRC staff completed its review of the Holtec PSA Risk Significance Determination Methodology TR, Revision 1, and the staff's Final Safety Evaluation is provided in the Enclosure to this letter.

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1 Letter from A. Brenner to NRC, "SMR, LLC, Submittal of Holtec PSA Risk Significance Determination Methodology Licensing Topical Report," June 11, 2024, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML24163A398, part of package ML24163A397).
2 U.S. NRC, "SMR-Holtec Risk Significance Methodology Topical Report Acceptance Review," July 10, 2024," (ML24192A233).
3 U.S. NRC, "SMR Holtec Risk Significance Methodology Topical Report - Audit Plan," August 6, 2024 (ML24211A226).
4 Letter from A. Brenner to NRC, "SMR, LLC, Submittal of Holtec PSA Risk Significance Determination Methodology Licensing Topical Report, Revision 1," October 18, 2024 (ML24292A046, part of package ML24292A045).

The enclosed SE is being provided to Holtec, because the NRC staff has found the Holtec Risk Significance Determination Methodology TR, Revision 1, acceptable for referencing in licensing actions to the extent specified and under limitations and conditions delineated in the TR. The final SE defines the basis for the NRC staff's acceptance of the TR.

The NRC staff requests that Holtec publish an approved version of this TR within 3 months of receipt of this letter. The approved version should incorporate this letter and the enclosed SE after the title page. The approved version should include a "-A" (designating approved) following the TR identification symbol.

If you have any questions or comments concerning this matter, I can be reached via email at Emmanuel.Sayoc@nrc.goc

Sincerely,

Signed by Sayoc, Emmanuel
on 02/06/25

Emmanuel C. Sayoc, Project Manager
New Reactor Licensing and Infrastructure Branch
Division of New and Renewed Licenses
Office of Nuclear Reactor Regulation

Docket No.: 99902049

Enclosure:
Final Safety Evaluation

SUBJECT: FINAL SAFETY EVALUATION FOR THE TOPICAL REPORT ON THE SMR (HOLTEC) PSA RISK SIGNIFICANCE DETERMINATION METHODOLOGY LICENSING TOPICAL REPORT (DOCKET NO. 99902049)
DATED: FEBRUARY 6, 2025

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PKG: ML25034A092
LTR: ML25034A099
SE: ML24345A006 ***via email** **NRR-106**

OFFICE	DNRL/NLIB: PM	DNRL/NLIB: LA	DNRL/NLIB: BC	NRR/APLC: BC
NAME	ESayoc	SGreen	VHuckabay	ANeuhausen
DATE	12/4/2024	12/10/2024	12/11/2024	12/10/2024
OFFICE	OGC (NLO)	DNRL/NLIB: BC	DNRL/NLIB: PM	
NAME	MCarpenter	MHayes	ESayoc	
DATE	1/13/2025	12/12/2024	2/6/25	

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Safety Evaluation by the Office of Nuclear Reactor Regulation Related to

SMR, LLC Licensing Topical Report HI-2230875, Revision 1,

"Holtec PSA Risk Significance Determination Methodology Licensing Topical Report"

1.0 Introduction

By letter dated October 18, 2024 (Ref. 1), SMR, LLC (A Holtec International Company, hereafter referred to as Holtec) submitted licensing topical report (TR) HI-2230875, Revision 1, "Holtec PSA Risk Significance Determination Methodology Licensing Topical Report," (Ref. 2), to the U.S. Nuclear Regulatory Commission (NRC) staff for review and approval. This TR describes Holtec's proposed methodology for identifying candidate risk-significant structures, systems, and components (SSCs) using the SMR-300 probabilistic risk assessment (PRA) and the basis for the risk significance criteria used. This methodology is specific to the SMR-300 design and uses alternative risk significance criteria that deviate from Regulatory Guide (RG) 1.200, Revision 3, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," (Ref. 3).

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (SRP), Section 19.0, Revision 3, "Probabilistic Risk Assessment and Severe Accident Evaluations for New Reactors," (Ref. 4), states that the term *significant* is intended to be consistent with the definition provided in RG 1.200, and any other definition shall be subject to additional NRC staff review and approval. This safety evaluation (SE) describes the NRC staff's review and approval of the TR and the limitations and conditions on its use.

2.0 Regulatory Criteria

The NRC staff considered the following regulatory guidance during its review of the TR:

- RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," (Ref. 5), describes an approach that is acceptable to the NRC staff for developing risk-informed applications for a licensing basis change that considers engineering issues and applies risk insights.

- RG 1.200, Revision 3, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," describes an approach that is acceptable to the NRC staff for determining whether a base PRA, in total or in the portions that are used to support an application, is sufficient to provide confidence in the results, such that the PRA can be used in regulatory decision-making for light-water reactors.

- RG 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," (Ref. 6), endorses NEI 00-04, "10 CFR 50.69 Categorization Guideline," (Ref. 7), and describes an approach that is acceptable to the NRC staff for complying with the Commission's requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," with respect to the categorization of SSCs that are considered in risk-informing special treatment requirements.

- SRP Section 17.4, Revision 1, "Reliability Assurance Program," (Ref. 8), provides the NRC staff review guidance for the reliability assurance program description in design certification and combined license applications.

- SRP Section 19.0, Revision 3, "Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors," provides the NRC staff review guidance for the design-specific PRA for a design certification and the plant-specific PRA for a combined license application.

- SRP Section 19.2, "Review of Risk Information Used to Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance," dated June 2007 (Ref. 9), provides the NRC staff review guidance for risk-informed reviews of licensees' proposals for changes to the licensing basis of nuclear power plants.

3.0 Summary of Technical Information

Licensing TR HI-2230875 describes Holtec's proposed methodology for identifying candidate risk-significant SSCs for the SMR-300 design using the SMR-300 PRA. Holtec stated that this methodology is specific to the SMR-300 design, and it can only be used with a PRA and analysis of core damage frequency (CDF) and either large release frequency (LRF) or large early release frequency (LERF), as applicable, that is technically adequate.

In the TR, Holtec stated that RG 1.200 discusses the term *significant* as it relates to the relative risk criteria and defines basic events that have a Fussell-Vesely (FV) importance greater than 0.005 or a risk achievement worth (RAW) greater than 2 as *significant*. Holtec described that the relative risk criteria used in RG 1.200 for FV and RAW are based on the relative risk associated with the operating fleet of reactors and, therefore, do not account for the lower risk profile of the passive SMR-300 design. Holtec stated that applying the relative risk criteria in RG 1.200, which are determined as a ratio to the total CDF of LRF/LERF, to the SMR-300 design would artificially elevate the significance of SSCs that do not have commensurate contribution to risk and that this artificially inflated significance of SSCs would not be risk-informed because it would result in unnecessary resource allocation for both the licensee and regulatory staff.

Holtec proposed a methodology for identifying candidate risk-significant SSCs for the SMR-300 design that adjusts the thresholds for RAW and FV based on the baseline CDF and LRF to ensure that measurable contributors to risk are identified regardless of the risk profile. Holtec stated that this methodology is based on the approach in RG 1.174 for acceptable increases in risk based on the baseline risk. Holtec's proposed methodology is summarized in the following sections.

3.1 Risk Achievement Worth Criteria

The proposed methodology applies the following RAW criteria at a single-unit level for CDF and LRF. The RAW criteria are applicable to all initiating events collectively and aggregated across all hazards and operating modes (i.e., internal events, low-power and shutdown conditions, internal flooding, internal fires, and external hazards).

The proposed methodology considers the RAW for basic events representing equipment unavailability and human failure. The proposed methodology does not consider the RAW for internal initiator basic events or external initiator basic events.

3.1.1 Core Damage Frequency

Holtec proposed the following RAW criteria for identifying component-level basic events as candidate risk significant using CDF:

- When the baseline CDF is greater than or equal to 1×10^{-7} and less than 1×10^{-6} per year, a component-level basic event with a RAW greater than 5 is identified as candidate risk significant.

- When the baseline CDF is less than 1×10^{-7} per year, a component-level basic event with a RAW greater than 30 is identified as candidate risk significant.

The proposed methodology implements a tailored approach that increases the component-level RAW criteria from the current criterion in RG 1.200 and is consistent with the criterion approved for the NuScale design (Ref. 10) based on the baseline CDF. Holtec stated that the proposed component-level RAW criteria meet the intent of RG 1.200 and RG 1.174.

For system-level basic events (i.e., basic events that represent a common-cause failure (CCF) of the system), Holtec stated that it considered the criterion that a CCF event is risk significant if it has a RAW greater than 20, which is contained in NEI 00-04, Revision 0, “10 CFR 50.69 SSC Categorization Guideline,” and endorsed by RG 1.201, Revision 1, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance”. Holtec stated that most systems expected to provide or assist safety missions in the SMR-300 design typically include some inter- and intra-system redundancy, which was the rationale for using an order of magnitude increase (i.e., a multiplication factor of 10) for the system-level criterion compared to the component-level criterion. To ensure conservatism, Holtec reduced the multiplication factor as the baseline CDF decreases:

- When the baseline CDF is greater than or equal to 1×10^{-7} and less than 1×10^{-6} per year, a multiplication factor of 7 is used, so a system-level basic event with a RAW greater than 35 is identified as candidate risk significant.

- When the baseline CDF is less than 1×10^{-7} per year, a multiplication factor of 2 is used, so a system-level basic event with a RAW greater than 60 is identified as candidate risk significant.

Holtec stated that the proposed system-level RAW criteria are similar to the criteria approved for the economic simplified boiling water reactor (ESBWR) design (Ref. 11) and the criteria approved for the NuScale design (Ref. 10). In the approved ESBWR methodology, a system-level basic event with a RAW greater than 50 is identified as risk significant. In the approved NuScale methodology, a system-level basic event with a CDF conditional on the failure of the basic event greater than 1×10^{-5} per year is identified as candidate risk significant, and the conditions and limitations require the core damage frequency to be “very low” (i.e., approximately 1×10^{-7} per year or less). When the baseline CDF is 1×10^{-7} per year, a conditional CDF of 1×10^{-5} per year is equivalent to a RAW greater than 100. Holtec stated that the proposed system-level RAW criteria meet the intent of RG 1.200 and RG 1.174.

3.1.2 Large Release Frequency

The proposed methodology uses the same approach for LRF as it does for CDF, except the baseline LRF values are reduced by an order of magnitude from the baseline CDF values. This is consistent with the Commission's conditional containment failure probability (CCFP) goal of less than 0.1 for new reactors (Ref. 12) and the approach in RG 1.174.

Holtec proposed the following RAW criteria for identifying component-level basic events as candidate risk significant using LRF:

- When the baseline LRF is greater than or equal to 1×10^{-8} and less than 1×10^{-7} per year, a component-level basic event with a RAW greater than 5 is identified as candidate risk significant.

- When the baseline LRF is less than 1×10^{-8} per year, a component-level basic event with a RAW greater than 30 is identified as candidate risk significant.

Holtec proposed the following RAW criteria for identifying system-level basic events as candidate risk significant using LRF:

- When the baseline LRF is greater than or equal to 1×10^{-8} and less than 1×10^{-7} per year, a system-level basic event with a RAW greater than 35 is identified as candidate risk significant.

- When the baseline LRF is less than 1×10^{-8} per year, a system-level basic event with a RAW greater than 60 is identified as candidate risk significant.

Holtec stated that the proposed methodology is based on LRF since LRF and CCFP are used during modern application reviews. Since the Commission approved the NRC staff's recommendation to transition from LRF to LERF at or before initial fuel load and discontinue regulatory use of LRF and CCFP thereafter in SRM-SECY-12-0081, "Staff Requirements – SECY-12-0081 – Risk-Informed Regulatory Framework for New Reactors," (Ref. 13), the proposed methodology uses the same criteria for LERF as it does for LRF. Holtec stated that this is conservative based on the LRF goal of less than 10^{-6} per year being more restrictive than the LERF goal of 10^{-5} per year.

3.2 Fussell-Vesely Criteria

To supplement the RAW criteria, the proposed methodology uses the FV importance to identify those SSCs that have the largest fractional contribution to risk. Holtec stated that the focus of these criteria is on identifying SSCs for which reliability and availability have the greatest influence on the risk profile.

The proposed methodology applies the following FV criteria at a single-unit level for CDF and LRF. The FV criteria are applied individually to each hazard group and mode of plant operation.

The proposed methodology considers the FV for basic events representing equipment unavailability and human failure and for internal initiator basic events because they represent failures of plant components. The proposed methodology does not consider the FV for external initiator basic events because they do not represent failures of plant components.

The proposed methodology sums the FV for each basic event (failure mode) of an SSC (contributor) to calculate the total FV for the SSC. An SSC is identified as candidate risk significant if the total FV for the SSC exceeds the FV criteria.

3.2.1 Core Damage Frequency

Holtec proposed the following FV criteria for identifying SSCs as candidate risk significant using CDF:

- When the baseline CDF is greater than or equal to 1×10^{-7} and less than 1×10^{-6} per year, a basic event with a FV greater than 0.02 is identified as candidate risk significant.

- When the baseline CDF is less than 1×10^{-7} per year, a basic event with a FV greater than 0.2 is identified as candidate risk significant.

The proposed methodology implements a tailored approach that increases the FV criteria from the criterion in RG 1.200 to a criterion consistent with that approved for the NuScale design based on the baseline CDF. Holtec stated that the proposed component-level RAW criteria meet the intent of RG 1.200 and RG 1.174.

3.2.2 Large Release Frequency

The proposed methodology uses the same approach for LRF as it does for CDF, except the baseline LRF values are reduced by an order of magnitude from the baseline CDF values. This is consistent with the Commission's CCFP goal of less than 0.1 for new reactors and the approach in RG 1.174.

Holtec proposed the following FV criteria for identifying SSCs as candidate risk significant using LRF:

- When the baseline LRF is greater than or equal to 1×10^{-8} and less than 1×10^{-7} per year, a basic event with a FV greater than 0.02 is identified as candidate risk significant.

- When the baseline LRF is less than 1×10^{-8} per year, a basic event with a FV greater than 0.2 is identified as candidate risk significant.

3.3 Summary of Risk Significance Criteria

The proposed methodology for identifying candidate risk-significant SSCs is summarized in Table **1** and Table **2**.

Table 1. Risk significance criteria using CDF

Baseline CDF (per year)	RAW		FV
	Component Level	System Level	
$1\times10^{-7} \leq CDF < 1\times10^{-6}$	5	35	0.02
$CDF < 1\times10^{-7}$	30	60	0.2

Table 2. Risk significance criteria using LRF

Baseline LRF (per year)	RAW		FV
	Component Level	System Level	
$1\times10^{-8} \leq LRF < 1\times10^{-7}$	5	35	0.02
$LRF < 1\times10^{-8}$	30	60	0.2

4.0 Technical Evaluation

In the absence of specific review procedures for evaluating methods for assessing risk significance, the NRC staff identified the following three key areas of review for this TR:

- selection of the risk metrics for assessing risk significance
- selection of the risk metric thresholds
- application of the risk metrics

4.1 Selection of the Risk Metrics for Assessing Risk Significance

The proposed methodology for identifying candidate risk-significant SSCs for the SMR-300 design uses the relative risk metrics RAW and FV. The NRC staff finds the use of RAW and FV acceptable because it is consistent with the guidance in RG 1.200.

4.2 Selection of the Risk Achievement Worth Thresholds

The proposed methodology for identifying candidate risk-significant SSCs for the SMR-300 design adjusts the thresholds for RAW based on the baseline CDF and LRF to ensure that measurable contributors to risk are identified regardless of the risk profile. Holtec stated that this methodology is based on the approach in RG 1.174 for acceptable increases in risk based on the baseline risk. The basis for the proposed thresholds for RAW is summarized in the following sections.

4.2.1 Core Damage Frequency

Holtec provided the following basis for the proposed RAW criteria for identifying component-level basic events as candidate risk significant using CDF:

- When the baseline CDF is greater than or equal to 1×10^{-6} per year, a component-level basic event with a RAW greater than 2 is identified as candidate risk significant. The basis for this criterion is RG 1.200, which utilizes the same RAW criterion for CDF.

- When the baseline CDF is greater than or equal to 1×10^{-7} and less than 1×10^{-6} per year, a component-level basic event with a RAW greater than 5 is identified as candidate risk significant. The basis for this criterion is that the current RAW criterion for CDF in RG 1.200 corresponds to an increased risk of 2×10^{-5} per year when the basic event is assumed to fail, based on an operating reactor with a nominal CDF of 1×10^{-5} per year. When the baseline CDF is 1×10^{-6} per year, using (1) an absolute risk criterion of an increased risk of 2×10^{-5} per year when the basic event is assumed to fail would result in very few basic events identified as candidate risk significant and (2) a relative risk criterion of RAW greater than 2 would not represent a significant loss in safety margin with respect to the 1×10^{-4} per year safety goal for CDF. To account for the lower baseline CDF of the SMR-300 design, and still identify basic events that drive the risk, Holtec adjusted the threshold for RAW and proposed that a component-level basic event with a RAW greater than 5 is identified as candidate risk significant.

- When the baseline CDF is less than 1×10^{-7} per year, a component-level basic event with a RAW greater than 30 is identified as candidate risk significant. The basis for the selection of this criterion is that it is equivalent to the risk criterion approved for the NuScale design. In the approved NuScale methodology, a component-level basic event with a CDF conditional on the failure of the basic event greater than 3×10^{-6} per year is identified as candidate risk significant. When the baseline CDF is 1×10^{-7} per year, a conditional CDF of 3×10^{-6} per year is equivalent to a RAW greater than 30.

Holtec stated that the proposed component-level RAW criteria provide sufficient margin to the NRC safety goal for CDF to account for PRA uncertainties. In the approval for the NuScale methodology, the NRC staff stated that the ratio of the 95th percentile to mean value for CDF was less than 10 for the nuclear power plants documented in NUREG-1150, “Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants,” (Ref. 14), and the PRA results for two nuclear power plant designs certified by the NRC that include passive safety systems. Holtec stated that the SMR-300 design is also expected to have a ratio of the 95th percentile to mean value for CDF that is less than 10 for the following reasons:

- The SMR-300 design uses proven light-water reactor technology similar to the nuclear power plants analyzed in NUREG-1150.

- The SMR-300 design relies on automatic actuation of passive safety systems to accomplish its safety functions.

- PRA modeling practices used to evaluate the SMR-300 design are consistent with industry standard practices described in RG 1.200.

Holtec combined the proposed component-level RAW criteria with the expected uncertainty ratio of 10 to demonstrate sufficient margin to the NRC safety goal for CDF as follows.

- When the baseline CDF is greater than or equal to 1×10^{-7} and less than 1×10^{-6} per year, a RAW of 5 combined with an uncertainty ratio of 10 provides a factor of 2 margin to the NRC safety goal for CDF. Holtec described that using a larger threshold for RAW would reduce or eliminate the margin and using a smaller threshold for RAW would be inconsistent with the intent to reduce the number of SSCs identified as candidate risk significant compared to the number of SSCs that would be identified as candidate risk significant using the current RAW criterion for CDF in RG 1.200.

- When the baseline CDF is less than 1×10^{-7} per year, a RAW of 30 combined with an uncertainty ratio of 10 provides a factor of 3.33 margin to the NRC safety goal for CDF, which is consistent with the approved NuScale methodology.

The NRC staff finds that, as the baseline CDF decreases, the proposed criteria result in a decreasing absolute risk threshold for an SSC to be identified as candidate risk significant. This decreasing absolute risk threshold accounts for uncertainty, which is expected to increase as the baseline risk decreases. The NRC staff finds that this basis adequately addresses uncertainty considerations associated with the proposed component-level RAW criteria.

Holtec provided the following basis for the proposed RAW criteria for identifying system-level basic events as candidate risk significant using CDF:

- When the baseline CDF is greater than or equal to 1×10^{-7} and less than 1×10^{-6} per year, a multiplication factor of 7 is used, so a system-level basic event with a RAW greater than 35 is identified as candidate risk significant. The basis for this criterion is that, due to the potentially significant impact of a loss of a system due to CCF, Holtec lowered the multiplication factor from 10 to 7 to reflect the lower CDF.

- When the baseline CDF is less than 1×10^{-7} per year, a multiplication factor of 2 is used, so a system-level basic event with a RAW greater than 60 is identified as candidate risk significant. The basis for this criterion is that, due to the potentially significant impact of a loss of a system due to CCF, Holtec lowered the multiplication factor from 7 to 2 to reflect the lower CDF.

The NRC staff finds that, as the baseline CDF decreases, the proposed criteria result in a decreasing absolute risk threshold for an SSC to be identified as candidate risk significant. This decreasing absolute risk threshold accounts for uncertainty, which is expected to increase as the baseline risk decreases. The NRC staff finds that this basis adequately addresses uncertainty considerations associated with the proposed system-level RAW criteria.

The NRC staff reviewed the guidance in RG 1.200, RG 1.201, RG 1.174, the criteria approved for the ESBWR design, and the criteria approved for the NuScale design. The NRC staff finds that the proposed component-level RAW criteria, based on order of magnitude differences in the baseline CDF, are consistent with the approach in RG 1.174 for acceptable increases in risk based on order of magnitude differences in the baseline risk, provide sufficient margin to the NRC safety goal for CDF to account for PRA uncertainties, and provide additional margin as the baseline risk decreases. The NRC staff finds that the proposed system-level RAW criteria are consistent with the guidance in RG 1.201 and provide additional margin as the baseline risk decreases. Based on its review, the NRC staff finds the proposed thresholds for RAW based on the baseline CDF acceptable for identifying candidate risk-significant SSCs for the SMR-300 design.

4.2.2 Large Release Frequency

The proposed methodology uses the same approach for LRF as it does for CDF, except the baseline LRF values are reduced by an order of magnitude from the baseline CDF values. This is consistent with the Commission's CCFP goal of less than 0.1 for new reactors and the approach in RG 1.174.

Holtec did not explicitly address uncertainty considerations relative to LRF. However, the proposed methodology uses the same approach for LRF as it does for CDF, except the baseline LRF values are reduced by an order of magnitude from the baseline CDF values. Holtec stated that this is consistent with the Commission's CCFP goal of less than 0.1 for new reactors and the approach in RG 1.174. In addition, Holtec stated that the proposed component-level and system-level RAW criteria meet the intent of RG 1.200 and RG 1.174.

In SRM-SECY-90-016, the Commission approved the overall mean frequency of a large release of radioactive material to the environment from a reactor accident as less than 1×10^{-6} per year of reactor operation. In SRM-SECY-89-102, "SECY-89-102 – Implementation of the Safety Goals" (Ref. 15), the Commission described that this frequency is inherently more conservative, but within an order of magnitude of, the quantitative health objectives. As such:

- When the baseline LRF is greater than or equal to 1×10^{-8} and less than 1×10^{-7} per year, a RAW of 5 provides a factor of 2 margin to the NRC safety goal for LRF.

- When the baseline LRF is less than 1×10^{-8} per year, a RAW of 30 provides a factor of 3.33 margin to the NRC safety goal for LRF.

The NRC staff finds that, as the baseline LRF decreases, the proposed criteria result in a decreasing absolute risk threshold for an SSC to be identified as candidate risk significant. The NRC staff finds that this adequately addresses uncertainty considerations associated with the proposed component-level LRF RAW criteria.

Holtec provided a similar basis for the proposed RAW criteria for identifying system-level basic events as candidate risk significant using LRF as the proposed RAW criteria for identifying system-level basic events as candidate risk significant using CDF. Based on the above discussion, the NRC staff finds that this basis adequately addresses uncertainty considerations associated with the proposed system-level RAW criteria.

The NRC staff reviewed the guidance in RG 1.174 and the Commission direction in SRM-SECY-90-16 and SRM-SECY-12-0081. The NRC staff finds that the proposed LRF criteria are consistent with the Commission's CCFP goal of less than 0.1 for new reactors and the approach in RG 1.174 and provide additional margin as the baseline risk decreases. Based on its review, the NRC staff finds the proposed thresholds for RAW based on the baseline LRF or LERF, as applicable, acceptable for identifying candidate risk-significant SSCs for the SMR-300 design.

4.3 Selection of the Fussell-Vesely Thresholds

To supplement the RAW criteria, the proposed methodology uses the FV importance to identify those SSCs that have the largest fractional contribution to risk. Holtec stated that the focus of these criteria is on identifying SSCs for which reliability and availability have the greatest influence on the risk profile.

The FV importance enables SSCs to be ranked according to their contribution to risk for each hazard group and mode of plant operation, and it is used to identify SSCs that contribute a significant fraction of the risk from a hazard with very low risk. The basis for the proposed thresholds for FV is summarized in the following sections.

4.3.1 Core Damage Frequency

Holtec provided the following basis for the FV criteria for identifying SSCs as candidate risk significant using CDF:

- When the baseline CDF is greater than or equal to 1×10^{-6} per year, a basic event with a FV greater than 0.005 is identified as candidate risk significant. The basis for this criterion is that it is the same as the current FV criterion for CDF in RG 1.200.

- When the baseline CDF is greater than or equal to 1×10^{-7} and less than 1×10^{-6} per year, a basic event with a FV greater than 0.02 is identified as candidate risk significant. The basis for this criterion is that it maintains the same risk contribution of 2×10^{-8} per year that is used when the baseline CDF is 1×10^{-7} per year.

- When the baseline CDF is less than 1×10^{-7} per year, a basic event with a FV greater than 0.2 is identified as candidate risk significant. The basis for this criterion is that the current FV criterion for CDF in RG 1.200 corresponds to a risk contribution of 5×10^{-8} per year, based on an operating reactor with a nominal CDF of 1×10^{-5} per year. When the baseline CDF is 1×10^{-7} per year, (1) a risk contribution of 5×10^{-8} per year corresponds to a FV of 0.5 and (2) using a relative risk criterion of FV greater than 0.5 does not reflect the intent to use FV for identifying SSCs that contribute a significant portion of the risk because some important contributors could be screened out. Holtec adjusted the relative risk criterion and proposed that a basic event with a FV greater than 0.2 is identified as candidate risk significant.

The NRC staff reviewed the guidance in RG 1.200, the criteria approved for the ESBWR design, and the criteria approved for the NuScale design. The NRC staff finds that the proposed FV thresholds are consistent with the guidance in RG 1.200 and provide additional margin as the baseline risk decreases. The NRC staff finds that uncertainty is addressed by maintaining the same risk contribution of 2×10^{-8} per year as the baseline risk decreases, which is more conservative than the current FV criterion for CDF in RG 1.200. Based on its review, the NRC staff finds the proposed thresholds for FV based on the baseline CDF acceptable for identifying candidate risk-significant SSCs for the SMR-300 design.

4.3.2 Large Release Frequency

The proposed methodology uses the same approach for LRF as it does for CDF, except the baseline LRF values are reduced by an order of magnitude from the baseline CDF values. This is consistent with the Commission's CCFP goal of less than 0.1 for new reactors and the approach in RG 1.174.

The NRC staff reviewed the guidance in RG 1.200 and the Commission direction in SRM-SECY-90-16 and SRM-SECY-12-0081. The NRC staff finds that the proposed FV thresholds are consistent with the guidance in RG 1.200 and provide additional margin as the baseline risk decreases. The NRC staff finds that uncertainty is addressed by maintaining the same absolute risk contribution of 2×10^{-9} per year as the baseline risk decreases, which is more conservative than the current FV criterion for LERF in RG 1.200. Based on its review, the NRC staff finds the proposed thresholds for FV based on the baseline LRF or LERF, as applicable, acceptable for identifying candidate risk-significant SSCs for the SMR-300 design.

4.4 Application of the Risk Metrics

In the TR, Holtec proposed a methodology for identifying candidate risk-significant SSCs using the SMR-300 PRA. The NRC staff notes that important implementation details were not addressed in the TR. For example, the TR did not address (1) the way in which a RAW or FV is assigned to an SSC based on the RAW and FV computed for basic events associated with the failure of the SSC and (2) the specific techniques for assessing risk significance of SSC failures caused by specific hazards such as fires and floods. The NRC staff normally considers such issues in its review of a specific application that involves assessment of risk significance, such as the identification of SSCs to be included in the design reliability assurance program or categorization of SSCs for treatment under the requirements in 10 CFR 50.69. Such applications are submitted after the PRA has been completed and is available for audit by the NRC staff. For this reason, use of the TR in specific risk-informed applications will be reviewed on a case-by-case basis by the NRC staff when those risk-informed applications are submitted for review.

5.0 Staff Conclusions

The NRC staff reviewed the proposed methodology and risk significance criteria described in the TR and finds them acceptable for identifying candidate risk-significant SSCs for the SMR-300 design using the SMR-300 PRA. The NRC staff's conclusions for specific technical topics are found within the respective technical evaluation sections of this report. The NRC staff approves the use of the TR, subject to the conditions and limitations in section 6.0, by Holtec in support of licensing applications.

6.0 Conditions and Limitations

1. The NRC staff's approval of this TR is specific to the Holtec SMR-300 design. Any use in whole or in part for other designs would require an additional applicability review by the NRC staff. Use of the TR in specific risk-informed applications will be reviewed on a case-by-case basis by the NRC when those risk-informed applications are submitted for review.

2. The methodology in the TR can only be used in concert with a PRA and analysis of CDF and either LRF or LERF, as applicable, that the NRC staff has determined to be technically acceptable and addresses internal and external hazards and all operating modes, including low-power and shutdown, as required for specific licensing submittals. The SMR-300 CDF must be less than 1×10^{-6} per year and the LRF must be less than 1×10^{-7} per year.

3. The methodology in the TR identifies candidate risk-significant SSCs from the SMR-300 PRA, but it is not the sole determinant of risk significance. To ensure that a holistic risk-informed approach is taken, additional consideration of uncertainties, sensitivities, traditional engineering evaluations and regulations, and maintaining sufficient defense in

depth and safety margin will be used to determine a complete list of risk-significant SSCs and will be identified in a future application that references this TR.

7.0 References

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3. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.200, Revision 3, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," December 2020 (ML20238B871).

4. U.S. Nuclear Regulatory Commission, NUREG-0800, Section 19.0, Revision 3, "Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors," December 2015 (ML15089A068).

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6. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance," May 2006 (ML061090627).

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13. U.S. Nuclear Regulatory Commission, SRM-SECY-12-0081, “Staff Requirements – SECY-12-0081 – Risk-Informed Regulatory Framework for New Reactors,” October 22, 2012 (ML12296A158).

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15. U.S. Nuclear Regulatory Commission, SRM-SECY-89-102, “SECY-89-102 – Implementation of the Safety Goals,” June 15, 1990 (ML003707881).

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Section B

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SMR, LLC		8002
Sponsoring Company		**Project No.**
HI-2230875	1	18 Oct 2024
Company Record Number	**Revision No.**	**Issue Date**
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Nuclear	No	
Quality Class	**Export Control Applicability**	

Record Title:

Holtec PSA Risk Significance Determination Methodology Licensing Topical Report

Prepared by:	**Reviewed by:**	**Approved by:**
S.Mccloskey, 17 Oct 2024	H.Hovhannisyan, 17 Oct 2024	A.Brenner, 18 Oct 2024

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Revision Log

Revision	Description of Changes
0	Initial Issue.
1	Section 3.1.2 revised to clarify that an SSC is a risk-significant candidate if the sum of FV values for all failure modes of an SSC exceeds the risk significance criterion for FV. Intermediate risk significance thresholds are removed from Tables 1 through 7 so that thresholds align with order-of-magnitude decades only (e.g. 1 x 10^{-6}/yr and 1 x 10^{-7}/yr). One column was added to Tables 5 and 6 to distinguish between Risk Contribution and Decreased Risk values. Risk importance thresholds in Tables 5 and 6 were conservatively modified to address NRC staff questions and the text explaining the tables was edited accordingly. Various clarifications made per NRC requests. Section 3.2 was added to address NRC question of how the criteria consider PSA uncertainties.

Executive Summary

This report describes the methodology that SMR, LLC (Holtec) has developed to identify candidate risk-significant systems, structures, and components (SSCs) using the SMR-300 probabilistic safety assessment (PSA). It should be noted that use of the term “PSA” by Holtec is intended to be consistent with the use of the term “probabilistic risk assessment” (PRA) by U.S. entities, including the Nuclear Regulatory Commission (NRC).

This methodology uses alternative risk significance criteria than those given in Regulatory Guide (RG) 1.200 [1]. Section 19.0 of the NUREG-0800 Standard Review Plan (SRP) [2] states that the term ‘significant’ is intended to be consistent with the definition provided in RG 1.200 when used in the context of PSA results and insights. RG 1.200 discusses ‘significant’ in terms of relative risk criteria and defines the basic events (i.e., equipment unavailabilities and human failure events) that have a Fussell-Vesely (FV) importance greater than 0.005 or a risk-achievement worth (RAW) greater than 2 as ‘significant’.

Because the relative importance measures in RG 1.200, RAW and FV, are based on the relative risk associated with the operating fleet of reactors, they do not account for the lower risk profile of the passive SMR-300 design. Applying the relative risk criteria outlined in RG 1.200 to SMR-300 would artificially elevate the significance of SSCs that do not have commensurate contribution to risk in the SMR-300 design. This artificially inflated significance of SSCs would not be risk-informed because it would result in unnecessary resource allocation for both the licensee and regulatory staff. Therefore, an alternative methodology to determine risk significance is needed that is sensitive to the lower risk profile of the SMR-300 design.

For the SMR-300 design, Holtec is directly addressing the ratio limitations of the RAW and FV traditional importance measures by implementing an alternative methodology that adjusts these ratio limits based on the estimated risk level to ensure that measurable contributors to risk are identified regardless of the risk profile. The principles and guidelines of RG 1.174 [3] are used to risk-inform this alternative methodology of identifying candidate risk-significant SSCs. The Holtec criteria ensures margins to NRC Safety Goals [4] are maintained while also taking credit for the significantly lower risk profile of the SMR-300 design.

The risk significance criteria proposed for the SMR-300 are summarized in Table 7.

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1.0 PURPOSE

This report provides SMR, LLC's (Holtec's) SMR-300 Probabilistic Safety Analysis (PSA) methodology for identifying candidate risk-significant SSCs and the basis for the risk significance criteria used. Holtec requests NRC approval that the methodology provided herein is technically acceptable and consistent with current regulations. This report includes the following:

- Discussion of the need for alternative risk significance criteria specific to the SMR-300 design that deviate from Regulatory Guide (RG) 1.200 [1].
- Description of the alternative SMR-300 risk significance criteria for risk achievement worth (RAW) and Fussell-Vessely (FV) importance measures dependent on baseline core damage frequency (CDF) and large release frequency (LRF) (or large early release frequency (LERF), as applicable) values.
- The basis for the SMR-300 risk significance criteria with a comparison to the NRC Safety Goals.

This report outlines the approach used to identify structures, systems, and components (SSCs) within the PSA that qualify as potential risk-significant candidates. The methodology is applicable for both internal and external hazards, covering all operational modes, including low-power and shutdown scenarios. The methodology is also applicable for a range of CDF and LRF for each individual SMR-300 unit.

The SSCs not included in the PSA are outside of the scope of this methodology. The SSCs typically not modeled in the PSA include those that do not result in a reactor trip, do not perform a safety-related function as defined in 10 CFR 50.2 [5] (or support or complement a safety function), do not support operator actions credited in the PSA (including recovery actions), and are not part of a system that acts as a barrier to fission product release during a severe accident.

2.0 BACKGROUND

Reactor risk metrics quantify the potential risk posed to the public by reactor operations including severe core damage accidents. The two primary risk metrics commonly employed in evaluating operating reactors are CDF and LERF/LRF. These metrics serve as proxies for the Quantitative Health Objectives (QHOs). Specifically, CDF is considered a surrogate for the individual cancer fatality risk QHO, while LERF/LRF adequately represents the individual early fatality risk QHO [6]. It is important to note that, while CDF and LERF/LRF serve as surrogates for risk, their application in the context of the SMR-300 design is more conservative compared to the operating fleet.

It should be noted that this report establishes risk significance criteria against LRF since LRF and conditional containment failure probability (CCFP) are used during modern application reviews. As discussed in SECY-12-0081 [7], the staff recommends transitioning at or before initial fuel load from LRF and CCFP to LERF. Also, as discussed in SECY-13-0029 [6], "the staff's view is that the objective of using LRF as a basis for determining whether a level of safety ascribed to a plant is consistent with the safety goal policy statement is fulfilled today by the use of LERF and CDF guidelines for operating reactors." As such, the SMR-300 criteria for identifying candidate risk-significant SSCs based on LERF would be the same as those proposed for LRF. This is conservative based on the LRF goal of < 10^{-6} per year being more restrictive than the LERF goal of < 10^{-5} per year.

In SECY-12-0081, the NRC reaffirmed that existing Safety Goals, subsidiary risk goals and associated risk guidance, and quantitative metrics for implementing risk-informed decision making are sufficient for new plants. Currently, the NRC employs a risk-informed and performance-based approach to shape its initiatives, aligning with the overarching goal of establishing a comprehensive regulatory framework. The NRC has issued several guidance documents that specifically address situations where licensees opt to utilize risk-based arguments to address licensing issues [8] [9] [10] [3].

2.1 Regulatory Guidance for Treatment of Risk

The NRC issued a series of policy statements regarding Safety Goals for operating reactors and expectations for new reactors [4] over the past four decades. In the NRC's policy statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants [11] the Commission stated that it "expects that vendors engaged in designing new standard (or custom) plants will achieve a higher standard of severe-accident safety performance than their prior designs." Also, in the NRC's policy statement on Regulation of Advanced Nuclear Power Plants [12] the Commission further stated that it "expects that advanced reactors will provide enhanced margins of safety and/or utilize simplified, inherent, passive, or other innovative means to accomplish their safety and security functions." The following provides a summary of the NRC Safety Goals and subsidiary objectives applicable to new reactors [11] [13]:

- CDF < 10^{-4} per reactor year
- LRF < 10^{-6} per reactor year
- CCFP less than approximately 0.1

These quantitative Safety Goals are identified as acceptance criteria for risk in the NUREG-0800 Standard Review Plan (SRP) Section 19.0 [2]. Section 19.0 of the SRP pertains to the NRC review of the PSA and severe accident analysis for licensing applications. Acceptance Criterion No. 17 in Section 19.0 of the SRP provides a definition for "significant" in the context of the PSA, which states:

> In the context of the [PSA] results and insights, the term "significant" is intended to be consistent with its definition provided in RG 1.200. The definitions of "significant accident sequence" and "significant contributor" are suitable for both CDF and LERF/LRF. Using any other definition of "significant" inconsistent with the definitions provided by RG 1.200 shall be subject to additional staff review and approval.

In RG 1.200, the following numerical criteria are used for defining significance:

- Basic events (BEs)/contributors that have a RAW > 2
- BEs/contributors that have a FV importance > 0.005
- Set of sequences (defined at the functional or systemic level) that compose 95 percent of the CDF or LERF/LRF, or that individually contribute more than one percent to CDF or LERF/LRF

Within these documents, significance is measured with respect to the contribution to the total CDF or LERF/LRF, or with respect to the contribution to the CDF or LERF/LRF for a specific hazard group or plant operating state. RAW measures the risk impact of specific failures or component unavailabilities, while FV measures the overall fractional contribution to risk. The following equations provide details on how RAW and FV importance measures are calculated:

$$RAW = R1/Rb \text{ (range} \geq 1)$$

Where:

R1 = increased risk with BE set to true (i.e., 1.0, failed), “conditional CDF” or “conditional LRF”

Rb = baseline PSA risk metric (i.e., CDF or LRF)

$$FV = 1 - R0/Rb \text{ (range 0 to 1)}$$

Where:

R0 = decreased risk with BE or initiating event set to false (i.e., 0.0, perfectly reliable)

Rb = baseline PSA risk metric (i.e., CDF or LRF)

RG 1.174 provides an integrated decision-making framework that incorporates risk insights to facilitate permanent modifications to a licensee’s approved licensing basis. The acceptance guidelines outlined in RG 1.174 are rooted in subsidiary objectives derived from the NRC Safety Goals and their QHOs. A fundamental tenet of risk-informed regulations is that any proposed changes in CDF and risk should be small and aligned with the Safety Goals.

RG 1.174 guidelines are founded on the principles and expectations for risk-informed regulation, supporting licensing basis changes for an operating plant. Figure 1 illustrates the guidelines from RG 1.174. It depicts the permissible changes in CDF and LERF/LRF that the NRC deems acceptable when implementing permanent modifications to a plant’s licensing basis. Notably, for scenarios where the baseline CDF and LERF/LRF are small, the NRC may accept larger risk increases.

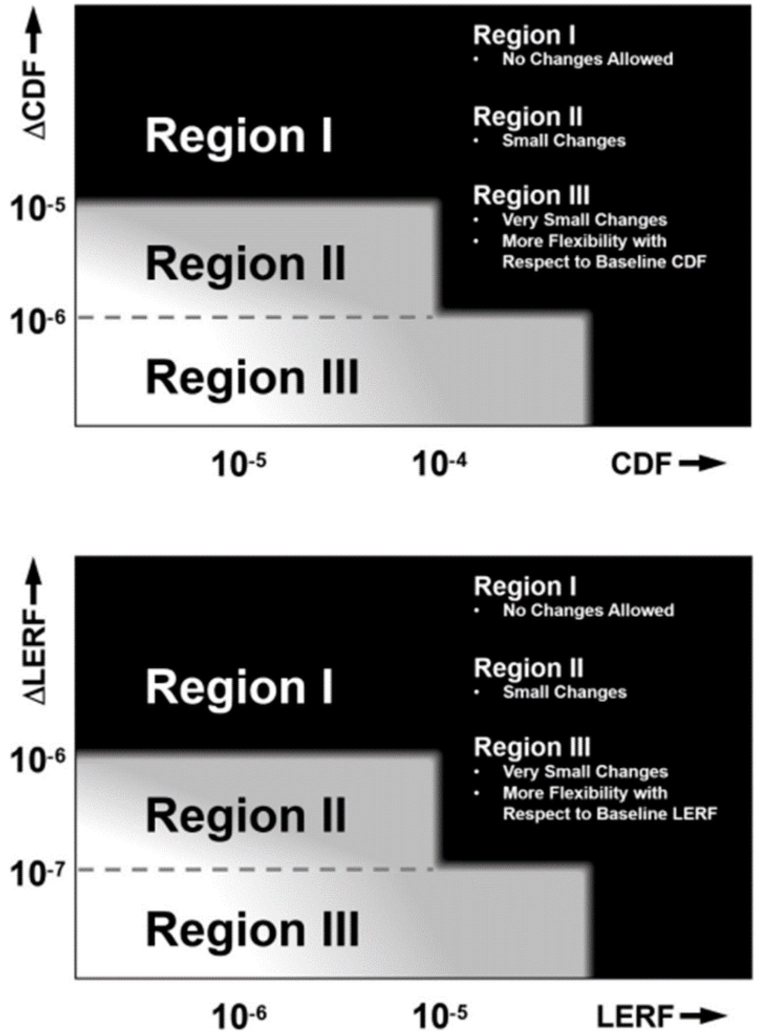

Figure 1: RG 1.174 Acceptance Guidelines

While RG 1.174 provides guidance on permanent plant changes, one key principle is that proposed increases in CDF and LERF/LRF are small and are consistent with the intent of the NRC's Safety Goals. While importance measures for component failures and unavailabilities do not directly correlate with risk changes due to permanent plant modifications, component failures and unavailabilities similarly impact the overall CDF and LERF/LRF of the plant. As such, the SMR-300 methodology described herein for identifying candidate risk-significant SSCs aligns with the principles of RG 1.174 that changes in CDF and LERF/LRF are small and sufficient safety margins are maintained.

2.2 Impetus for SMR-300 Alternative Risk Significance Criteria

The SMR-300 design, characterized by its simplicity and passive safety features, yields baseline CDF or LERF/LRF risk estimates at least an order of magnitude lower than those associated with operating plants. The RG 1.200 risk significance criteria, which are determined as a ratio to the total CDF or LERF/LRF, are suitable for the current fleet of large operating LWRs. However, applying these criteria to the SMR-300 would artificially result in components being perceived as risk-significant although they would have a low contribution to CDF or LERF/LRF relative to the current operating fleet of LWRs. Considering the RG 1.200 criterion of RAW > 2 for BEs, a currently operating reactor with a CDF of 1 x 10^{-5} per reactor year would only identify a BE as risk-significant if its R1 exceeds 2 x 10^{-5} per year. Applying the same criterion if the baseline CDF is approximately 1 x 10^{-7} per year, then a BE would be identified as risk-significant if its R1 is only 2 x 10^{-7} per year. This is a substantial difference of two orders of magnitude. This approach to defining risk significance is also contradictory to the RG 1.174 guidance that considers a change in CDF of less than 1 x 10^{-6} to be very small or not risk significant.

The adoption of alternative criteria to RG 1.200 is not unprecedented. The Advisory Committee on Reactor Safeguards (ACRS) highlighted implications of using the RG 1.200 criteria for new plant designs because a large number of SSCs may be identified as risk-significant [14]. The ACRS stated, in part, that this is especially true for new plant designs that have very low estimated frequencies of core damage and large releases and universal application of the RG 1.200 criteria may produce an inappropriately large population of SSCs that are subject to enhanced availability and reliability controls, with commensurate undue burden for both the licensee and regulatory staff. For these reasons, new light water reactors (LWRs) have adopted alternative criteria for identifying potentially risk-significant BEs.

The Economic Simplified Boiling-Water Reactor (ESBWR) was approved [15] to employ the following alternative criteria:

- RAW > 5 for individual events
- FV > 0.01 for individual events
- RAW > 50 for common-cause failure (CCF) events

Additionally, the NRC approved the following alternative criteria for the NuScale design [16]:

- Conditional CDF $\geq$ 3 x 10^{-6} per year for component level BE
- Conditional CDF $\geq$ 1 x 10^{-5} per year for system level BE
- Conditional LRF $\geq$ 3 x 10^{-7} per year for component level BE
- Conditional LRF $\geq$ 1 x 10^{-6} per year for system level BE
- Total FV $\geq$ 0.20 of base CDF for BE/contributor

3.0 METHODOLOGY

3.1 SMR-300 PSA Risk Significance Determination Criteria

The SMR-300 criteria for identifying candidate risk-significant SSCs within the PSA are rooted in the acceptance guidelines for small changes in CDF and LRF, while ensuring that the total CDF and LRF remain well below the NRC Safety Goals. Based on the RG 1.174 approach for acceptable increases in risk based on the baseline risk, the SMR-300 risk significance methodology similarly applies a tailored approach for its risk significance criteria.

3.1.1 Risk Achievement Worth Criteria

3.1.1.1 Core Damage Frequency

The RG 1.200 criterion uses a RAW of greater than 2 for components to determine risk significance. As such, for a baseline CDF of 1 x 10^{-5} per year, an increase in CDF by a factor of 2 represents a significant loss in safety margin with respect to the NRC Safety Goal for CDF of 1 x 10^{-4} per year. However, if the baseline CDF is on the order of 1 x 10^{-6} to 1 x 10^{-7} per year, an increase in CDF by a factor of 2 does not represent a significant loss in safety margin with respect to the 1 x 10^{-4} per year Safety Goal for CDF. Therefore, for a baseline CDF of 1 x 10^{-5} per year or greater, a RAW of greater than 2 (which is equivalent to R1 $\geq$ 2 x 10^{-5} per year) is considered risk significant. However, using this same R1 for baseline CDFs in the ranges discussed above would result in very few BEs being considered as risk significant as the total CDF lowers. To account for the lower baseline CDF of the SMR-300 design, but still identify the BEs that drive the risk, the R1 is adjusted as shown in Table 1 to derive BE RAW criteria dependent on baseline CDF.

Table 1 SMR-300 Basis for CDF BE RAW Values

RAW	CDF (Rb)	Increased Risk (R1)	Basis
2	1 x 10^{-5}/yr	2 x 10^{-5}/yr	Current criteria for CDF of 1 x 10^{-5}/yr
5	1 x 10^{-6}/yr	5 x 10^{-6}/yr	R1 lowered to reflect lower CDF but still identify risk-significant BEs – using R1 of 2 x 10^{-5}/yr would result in few to no BEs being considered risk-significant
30	1 x 10^{-7}/yr	3 x 10^{-6}/yr	Equivalent to NRC-approved methodology where R1 = 3 x 10^{-6}/yr for CDF of 1 x 10^{-7}/yr

The tailored approach increases the RAW BE risk significance criterion from the RG 1.200 RAW criterion applicable to the operating fleet with baseline CDF of approximately 1 x 10^{-5} per year to the RAW value that correlates to the R1 approved for a baseline CDF of 1 x 10^{-7} per year by the NRC for the NuScale design. The CDF BE RAW criteria presented in Table 1 are considered to meet the intent of RG 1.200 and RG 1.174.

For a system-level criterion (CCF event), guidance from NEI 00-04 [17], as endorsed in Regulatory Guide 1.201 [18], were considered; specifically, the importance measure criterion for CCF events is considered to be a RAW value of 20. This value reflects that a CCF is measuring the failure of two or more trains, including the higher failure likelihood for the second train due to common causes. As such, this system-level criterion applies to CCF BEs. Most systems expected to provide or assist safety missions in the SMR-300 design typically include some inter- and intra-system redundancy, which is the rationale for using an order of magnitude increase for system-level criteria compared to component-level criteria, e.g., 20 vs. 2 for RAW.

A factor of 10 could be applied to the individual BE RAWs shown in Table 1. However, to ensure conservatism, the factor is lowered as the CDF lowers: from a factor of 7 for a CDF of 1 x 10^{-6} per year down to a factor of 2 for a CDF of 1 x 10^{-7} per year as shown in Table 2.

Table 2 SMR-300 Basis for CDF CCF RAW Values

CDF (Rb)	BE RAW	Factor Increase for CCF	CCF RAW	Basis
1 x 10^{-5}/yr	2	10	20	Current criteria for CDF of 1 x 10^{-5}/yr
1 x 10^{-6}/yr	5	7	35	Due to potentially significant impact of a loss of a system due to CCF, the factor was conservatively lowered to reflect the lower CDF
1 x 10^{-7}/yr	30	2	60	Due to potentially significant impact of a loss of a system due to CCF, the factor was conservatively lowered to reflect the lower CDF

These criteria are applied at a single unit level and are applicable to all initiating events collectively and aggregated across all hazards and operating modes (i.e., internal events, low-power and shutdown conditions, internal flooding, internal fires, and external hazards).

The CDF CCF RAW criteria provided in Table 2 are similar to the NRC-approved criteria for the ESBWR (RAW > 50 for CCF events) and NuScale (CCDF > 1 x 10^{-5} per year for system level BE, which corresponds to a RAW of 100 for a CDF of 1 x 10^{-7} per year) and are considered to meet the intent of RG 1.200 and RG 1.174.

3.1.1.2 Large Release Frequency

In addition to core damage, BEs are evaluated for risk significance against LRF, the PSA Level 2 risk metric. The SMR-300 risk significance approach for LRF is similar to that for CDF, but the LRF criteria are reduced by an order of magnitude, which is consistent with the Commission's CCFP goal of less than 0.1 for new reactors and the approach taken for the guidelines in RG 1.174. The LRF criteria and basis for RAW for the SMR-300 are shown in Table 3.

Table 3 SMR-300 Basis for LRF BE RAW Values

RAW	LRF (Rb)	Increased Risk (R1)	Basis
2	1 x 10^{-6}/yr	2 x 10^{-6}/yr	Current criteria for LRF of 1 x 10^{-6}/yr
5	1 x 10^{-7}/yr	5 x 10^{-7}/yr	R1 lowered to reflect lower LRF but still identify risk-significant BEs – using R1 of 2 x 10^{-6}/yr would result in few to no BEs being considered risk-significant
30	1 x 10^{-8}/yr	3 x 10^{-7}/yr	Equivalent to NRC-approved methodology where R1 = 3 x 10^{-7}/yr for LRF of 1 x 10^{-8}/yr

The tailored approach increases the RAW risk significance criterion from the RG 1.200 RAW criterion applicable to the operating fleet with baseline LERF of approximately 1 x 10^{-6} per year to the RAW value that correlates to the R1 approved for a baseline LRF of 1 x 10^{-8} per year by the NRC for the NuScale design. The LRF BE RAW criteria provided in Table 3 are considered to meet the intent of RG 1.200 and RG 1.174.

For the evaluation of CCF events, the same approach as used for the CDF CCF RAW determinations is used. Similarly, a factor of 10 could be applied to the individual BEs shown in

Table 3. However, to ensure conservatism, the factor is lowered as the LRF lowers, from a factor of 7 for a LRF of 1 x 10^{-7} per year to a factor of 2 for a LRF of 1 x 10^{-8} per year as shown in Table 4.

Table 4 SMR-300 Basis for LRF CCF RAW Values

LRF (Rb)	BE RAW	Factor Increase for CCF	CCF RAW	Basis
1 x 10^{-6}/yr	2	10	20	Current criteria for LRF of 1 x 10^{-6}/yr
1 x 10^{-7}/yr	5	7	35	Due to potentially significant impact of a loss of a system due to CCF, the factor was conservatively lowered to reflect the lower LRF
1 x 10^{-8}/yr	30	2	60	Due to potentially significant impact of a loss of a system due to CCF, the factor was conservatively lowered to reflect the lower LRF

These criteria are applied at a single unit level and are applicable to all initiating events collectively and aggregated across all hazards and operating modes (i.e., internal events, low-power and shutdown conditions, internal flooding, internal fires, and external hazards).

The LRF CCF RAW criteria provided in Table 4 are similar to the NRC-approved criteria for the ESBWR (RAW > 50 for CCF events) and NuScale (CLRF > 1 x 10^{-6} per year for system level BE, which corresponds to a RAW of 100 for a LRF of 1 x 10^{-8} per year) and are considered to meet the intent of RG 1.200 and RG 1.174.

As discussed in Section 2.0, the presented risk significance criteria for SMR-300 are based on LRF; LRF and CCFP are being used for modern application reviews. Because the objective of using LRF is fulfilled today by the use of LERF for operating plants, the criteria for LERF would be the same as those proposed for LRF and applicable to licensing of new operating SMR-300 plants.

3.1.2 Fussell-Vesely Criterion

To supplement the RAW criteria, the FV importance measure is used to identify those SSCs that have the largest fractional contribution to risk. The focus of this criterion is on identifying SSCs for which reliability and availability have the greatest influence on the risk profile. This criterion is used to identify BEs/contributors that are a significant fraction of a hazard with very low risk. In addition to equipment unavailabilities and human failures, internal initiator BEs are also evaluated using FV because they represent failures of plant components. External initiator BEs are excluded because they do not represent plant components.

For a baseline CDF of 1 x 10^{-5} per year, when setting a BE or initiating event to false, the RG 1.200 FV criterion (i.e., 0.005 or 0.5 percent) translates to a decrease in CDF of 5 x 10^{-8} per year. Applying the same decrease in CDF of 5 x 10^{-8} per year to a plant with a baseline CDF of 1 x 10^{-7} per year corresponds to an FV of 0.5 or 50 percent. However, using a FV criterion of 0.5 does not reflect the intent to use FV for identifying those components that contribute a significant portion of the risk because some important contributors could be screened out by using a FV criterion as high as 0.5. Thus, a FV criterion of 0.2 is applied for a baseline CDF

(LRF) of 1 x 10^{-7}/yr (1 x 10^{-8}/yr) or smaller, consistent with the criteria approved by the NRC for the NuScale design.

Similar to the tailored approach to the RAW risk significance criteria, the FV risk significance criterion is also adjusted as shown in Table 5 and Table 6 to ensure that the reduction in CDF/LRF if the BE is perfectly reliable is maintained for the 1 x 10^{-6}/yr and 1 x 10^{-7}/yr CDF thresholds and 1 x 10^{-7}/yr and 1 x 10^{-8}/yr LRF thresholds.

Table 5 SMR-300 Basis for CDF BE/Contributor FV Values

CDF (Rb)	FV	Risk Contribution (Rb-R0)	Decreased Risk (R0)	Basis
1 x 10^{-5}/yr	0.005	5 x 10^{-8}/yr	9.95 x 10^{-6}/yr	Current criteria for CDF of 1 x 10^{-5}/yr
1 x 10^{-6}/yr	0.02	2 x 10^{-8}/yr	9.8 x 10^{-7}/yr	Decreased FV to yield same risk contribution as for CDF of 1 x 10^{-7}/yr
1 x 10^{-7}/yr	0.2	2 x 10^{-8}/yr	8 x 10^{-8}/yr	Equivalent to NRC-approved methodology where the risk contribution is 2 x 10^{-8}/yr for CDF of 1 x 10^{-7}/yr

Table 6 SMR-300 Basis for LRF BE/Contributor FV Values

LRF (Rb)	FV	Risk Contribution (Rb-R0)	Decreased Risk (R0)	Basis
1 x 10^{-6}/yr	0.005	5 x 10^{-9}/yr	9.95 x 10^{-7}/yr	Current criteria for LRF of 1 x 10^{-6}/yr
1 x 10^{-7}/yr	0.02	2 x 10^{-9}/yr	9.8 x 10^{-8}/yr	Decreased FV to yield same risk contribution as for LRF of 1 x 10^{-8}/yr
1 x 10^{-8}/yr	0.2	2 x 10^{-9}/yr	8 x 10^{-9}/yr	Equivalent to NRC-approved methodology where the risk contribution is 2 x 10^{-9}/yr for LRF of 1 x 10^{-8}/yr

The tailored approach increases the FV risk significance criterion from the RG 1.200 FV criterion applicable to the operating fleet with a baseline CDF of 1 x 10^{-5} per year (LRF of 1 x 10^{-6} per year) to the FV value approved for a baseline CDF of 1 x 10^{-7} per year (LRF of 1 x 10^{-8} per year) by the NRC for the NuScale design. The FV criteria provided in Table 5 and Table 6 are considered to meet the intent of RG 1.200 and RG 1.174.

The FV for each BE (failure mode) of an SSC (contributor) is summed to yield the total FV for the SSC. SSCs are identified as risk-significant candidates if the sum exceeds the risk significance criterion for FV.

The FV criterion is applied at a single unit level and is applied individually to each hazard group and mode of plant operation. For example, SSCs are identified as risk-significant candidates if the SSC exceeds the criterion for internal events risk, or seismic risk, or external flood risk, etc. It is also applied individually to CDF and LRF because the focus is on identifying SSCs for which the reliability and availability have the greatest influence on risk.

3.1.3 Consolidated SMR-300 PSA Risk Significance Determination Criteria

Table 7 provides the consolidated criteria used to determine SMR-300 candidate risk-significant SSCs. The FV and RAW criteria are applied independently for CDF and LRF based on baseline CDF and baseline LRF values.

Table 7 SMR-300 Criteria for Risk Significance Determination

CDF (/yr)	LRF (/yr)	FV	RAW	
			BE	CCF
$1 \times 10^{-6} > CDF \geq 1 \times 10^{-7}$	$1 \times 10^{-7} > LRF \geq 1 \times 10^{-8}$	0.02	5	35
$1 \times 10^{-7} > CDF$	$1 \times 10^{-8} > LRF$	0.2	30	60

3.2 Consideration for PSA Uncertainties

The SMR-300 risk significance criteria provide sufficient margin to NRC CDF safety goal to account for PSA uncertainties.

In Section 4 of [19], the NRC staff identifies that the ratio of the 95th percentile to mean value for CDF is less than a factor of 10 for the NPPs analyzed in NUREG-1150 [20] and two NPP designs certified by the NRC that include passive safety systems. The SMR-300 PSA is also expected to have a ratio of the 95th percentile to mean value for CDF that is less than a factor of 10 for the following reasons:

- The SMR-300 design uses proven LWR technology similar to the NPPs analyzed in NUREG-1150.
- The SMR-300 design relies on automatic actuation of passive safety systems to accomplish its safety functions.
- PSA modeling practices used to evaluate the SMR-300 design are consistent with industry standard practices described in RG 1.200.

The increased risk given an SSC fails (R1) is combined with the expected uncertainty ratio (factor of 10) to demonstrate sufficient margin to the NRC safety goal. Table 8 determines the 95th percentile of the R1 value implied by the CDF RAW criteria and compares them to the NRC safety goal for CDF (1×10^{-4}/yr).

Table 8 Margin to NRC Safety Goal for CDF

RAW	CDF (Rb)	Increased Risk (R1)	95th Percentile of Increased Risk (R1)	Margin to Safety Goal (Ratio)
5	1×10^{-6}/yr	5×10^{-6}/yr	5×10^{-5}/yr	2
30	1×10^{-7}/yr	3×10^{-6}/yr	3×10^{-5}/yr	3.33

For a baseline CDF between 1×10^{-6}/yr and 1×10^{-7}/yr, the RAW value of 5 provides a factor of 2 margin to the NRC safety goal. A larger threshold would reduce or eliminate the margin. A smaller threshold would be inconsistent with the intent to reduce the number of SSCs identified as risk significant candidates compared to the number of SSCs that would be identified using the traditional RG 1.200 RAW value of 2. For a baseline CDF less than 1×10^{-7}/yr, the RAW value of 30 provides a factor of 3.33 margin to the NRC safety goal, consistent with the

NRC-accepted methodology in [19]. The margin incorporated in the CDF RAW criteria to account for PSA uncertainties is considered reasonable.

3.3 Applicability and Limitations of Methodology

The following applicability conditions and limitations apply to this methodology:

1. This methodology is specific to the SMR-300 design.
2. This methodology can only be used in concert with a PSA and analysis of CDF and LRF/LERF that the NRC has determined to be technically adequate. The SMR-300 CDF must be less than 1 x 10^{-6} per year and the LRF must be less than 1 x 10^{-7} per year.
3. This methodology identifies candidate risk-significant SSCs from the SMR-300 PSA but is not the sole determinant of risk significance. To ensure a holistic risk-informed approach is taken, additional consideration of uncertainties, sensitivities, traditional engineering evaluations and regulations, and maintaining sufficient defense-in-depth and safety margin will be used to determine a complete list of risk-significance and will be identified in a future application that references this report.

4.0 SUMMARY AND CONCLUSIONS

A methodology for identifying candidate risk-significant SSCs for the SMR-300 design is presented and justified in this report. Applying existing guidance from RG 1.200 to the SMR-300 design would be overly conservative and inappropriately identify an excessive list of candidate risk-significant SSCs. The RG 1.200 guidance was developed for the CDF and LRF risk profiles of the operating fleet, and therefore does not adequately consider the lower risk profiles of new reactors such as the SMR-300 design. Given the SMR-300 PSA is under development, risk significance criteria are presented for a range of baseline CDF and LRF to ensure appropriate criteria can be applied independent of the final CDF and LRF values for the SMR-300 design. The SMR-300 alternative risk-significance criteria meet the intent of RG 1.200 and RG 1.174. The specific risk-significant criteria are presented in Table 7.

5.0 REFERENCES

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