

LIST OF INFORMATION NEEDS/OBSERVATIONS

The table below lists each of the information needs identified by the NRC along with the outcome. Item 1 was resolved during the audit and items 2 through 9 were resolved with the submittal of SMR (Holtec) Licensing Topical Report (LTR), Revision 1¹.

	Information Need
1	In Section 1.0, "Purpose," SMR (Holtec) states: "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 (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." Clarify the meaning of the word "typically".
2	In Section 2.2, "Impetus for SMR-300 Alternative Risk Significance Criteria," SMR (Holtec) references the risk significance determination acceptance criteria for the Economic Simplified Boiling-Water Reactor (ESBWR) that are described in GE Hitachi Nuclear Energy (GEH) Licensing Topical Report NEDO-33411, Revision 2, "Risk Significance of ESBWR Structures, Systems, and Components ² ," and approved by the NRC staff in NUREG-1966, Volume 4 ³ , "Final Safety Evaluation Report Related to the Certification of the Economic Simplified Boiling-Water Reactor Standard Design." One risk significance determination criterion for the ESBWR is that Fussell-Vessely (FV) > 0.01 for individual events. In NEDO-33411, GEH states that the FV values for basic events representing the same component are summed and then compared to the threshold. Clarify how the FV values are calculated in the proposed methodology, including if the FV values are calculated separately for each failure mode modeled in the PRA for a specific SSC (e.g., pump A fails to start, pump A fails to run, etc.) or if the FV values are calculated by adding the FV values for each failure mode of the SSC. See Audit Plan for further details.
3a	In Section 3.1, "SMR-300 PSA Risk Significance Determination Criteria," SMR (Holtec) notes that RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis ⁴ ," applies a sliding scale for acceptable increases in risk based on

¹ SMR, LLC, "SMR, LLC, Submittal of Holtec PSA Risk Significance Determination Methodology Licensing Topical Report, Revision 1," October 28, 2024 (ML24292A045).

² U.S. NRC, "Transmittal of Revision 2 to NEDO-33411, "Risk Significance of ESBWR Structures, Systems & Components," March 2, 2010, (ML100610417).

³ U.S. NRC, NUREG-1966, "Final Safety Evaluation Report Related to the Certification of the Economic Simplified Boiling-Water Reactor Standard Design," Volume 4, April 11, 2014, (ML14100A187, part of package ML14100A304).

⁴ U.S. NRC, RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes

	Information Need
	the baseline risk. SMR (Holtec) also states that the proposed risk significance determination methodology similarly applies a sliding scale for its risk significance criteria. In RG 1.174, the NRC staff notes that it is important to recognize that the risk metrics calculated using PRA models are a function of the assumptions and approximations made in the development of these models. The NRC staff also states that the comparison of the PRA results with the acceptance guidelines should be based on an understanding of the contributors to the PRA results; the robustness of the assessment of those contributors, including any conservative or nonconservative biases resulting from modeling assumptions and approximations; and the impacts of uncertainties, including uncertainties that are explicitly accounted for in the results and those that are not. In RG 1.174 the sliding scale is based on the order of magnitude of the baseline core damage frequency (CDF) or large early release frequency/ large release frequency (LRF). Regarding the use of a half order of magnitude in the proposed risk significance determination criteria, the NRC staff seeks additional clarification on: 3a. How uncertainty is considered in the proposed methodology.
3b	Same background as Item 3a. Regarding the use of a half order of magnitude in the proposed risk significance determination criteria, the NRC staff seeks additional clarification on: 3b. What studies were performed to evaluate the difference in risk significance determination results if the proposed sliding scale only considers the order of magnitude of the baseline CDF and LRF (i.e., the risk significance determination criteria associated with a baseline CDF of 5×10^{-7} per year or a baseline LRF of 5×10^{-8} per year were removed)? What were the results and how did they inform the selection of the thresholds for the baseline CDF and LRF. If no study was performed, why wasn't the difference in risk significance determination results evaluated?
3c	Same background as Item 3a. Regarding the use of a half order of magnitude in the proposed risk significance determination criteria, the NRC staff seeks additional clarification on: 3c. What studies were performed to evaluate the sensitivity of the risk significance determination results to the values selected for the basic event risk achievement worth (RAW), common-cause failure (CCF) RAW, and FV risk significance determination criteria? What were the results and how did they inform the selection

Information Need	
	of values provided in Table 7, “SMR-300 Criteria for Risk Significance Determination?” If no study was performed, why wasn’t the sensitivity of the risk significance determination results evaluated?
3d	Same background as Item 3a. Regarding the use of a half order of magnitude in the proposed risk significance determination criteria, the NRC staff seeks additional clarification on: 3d. How do the values selected for the basic event RAW, CCF RAW, and FV risk significance determination criteria provide sufficient margin to account for uncertainties in the PRA model.
4	In Section 3.1.1, “Risk Achievement Worth Criteria,” SMR (Holtec) proposes a sliding scale for the basic event RAW and CCF RAW risk significance determination criteria such that the allowable risk increase (R1) becomes smaller as the baseline risk metric decreases. In Section 3.1.2, “Fussell-Vesely Criterion,” SMR (Holtec) proposes a sliding scale for the FV risk significance determination criterion such that the decreased risk (R0) remains constant for a baseline CDF of 1×10^{-6} per year and 5×10^{-7} per year in Table 5, “SMR-300 Basis for CDF BE FV Values,” and remains constant for a baseline LRF of 1×10^{-7} per year and 5×10^{-8} per year in Table 6, “SMR-300 Basis for LRF BE FV Values.” Clarify why the decreased risk (R0) values in Tables 5 and 6 are not decreased when the baseline CDF is 1×10^{-6} per year or 5×10^{-7} per year or the baseline LRF is 1×10^{-7} per year or 5×10^{-8} per year similar to how the increased risk (R1) values were increased for the same baseline CDF and LRF values.
5	In Section 3.2, “Applicability and Limitations of Methodology,” SMR (Holtec) proposes applicability conditions and limitations to the proposed methodology. These conditions and limitations are similar to the conditions and limitations provided in the safety evaluation (SE) for NuScale Licensing Topical Report TR-0515-13952-NP-A, “Risk Significance Determination⁵.” Condition and limitation 3 from the SE for TR-0515-13952-NP-A states that the PRA considers the criteria noted in Section 19.0, Revision 3, “Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors,” of the SRP regarding the impact of other modules or shared SSCs on the reactor module under analysis.

⁵ NuScale Power, LLC, “NuScale Power, LLC, Submittal of the Accepted Version of Licensing Topical Report: TR-0515-13952-NP-A, “Risk Significance Determination,” Revision 0, (TAC No. RN6110),” October 10, 2016, (ML16284A016).

	Information Need
	In several sections, SMR (Holtec) notes that the proposed criteria are applied at a single unit level. Clarify if there are any shared SSCs between multiple units located at the same site. If there are shared SSCs between multiple units located at the same site, discuss how the PRA model evaluates multi-module risk and how the risk significance of these shared SSCs is evaluated.
6	In Section 3.0, "Summary of Technical Information," of the safety evaluation for NuScale TR-0515-13952-NP-A, the NRC staff stated, "NuScale's rationale for the component-level CCDF threshold is that the value provides an order of magnitude margin to the NRC goal of 1×10^{-4} per year for CDF, with an extra half-order of magnitude (on a log scale) of margin to account for uncertainties in the PRA model." In Section 4.0, "Technical Evaluation," of the safety evaluation for NuScale TR-0515-13952-NP-A, the NRC staff evaluated additional information provided by NuScale in its response to RAI 17.04-3 by reviewing uncertainty results for commercial nuclear power plants documented in NUREG-1150 and PRA results for nuclear power plant designs certified by the NRC that include passive safety systems. The NRC staff concluded that "the staff finds that margin incorporated to account for PRA uncertainties is reasonable and acceptable." The NRC staff notes that the proposed RAW criterion of 5 when the baseline CDF is 1×10^{-6} per year corresponds to an increased risk of 5×10^{-6} per year, which represents an order of magnitude margin to the NRC goal of 1×10^{-4} per year with an extra factor of 2 margin (on a linear scale). The NRC staff notes that it used information similar to the following items in its basis for the approval of NuScale TR-0515-13952-NP-A and that this information is not provided in SMR (Holtec's) topical report: • A rationale for selecting the RAW value of 5, as opposed to another threshold between the anchor RAW values of 2 and 30. • A statement that the factor of 2 margin when the baseline CDF is 1×10^{-6} per year is sufficient to account for uncertainties in the SMR-300 PRA model. • A statement that the extra half-order of magnitude of margin when the baseline CDF is 1×10^{-7} per year is sufficient to account for uncertainties in the SMR-300 PRA model.
6a	SMR (Holtec) is requested to provide additional justification for the selection of the RAW values. As part of the justification: Clarify if the extra factor of 2 margin is sufficient to account for uncertainties in the SMR-300 PRA model if the baseline CDF is 1×10^{-6} per year and, if not, provide additional justification for the acceptability of using a RAW value of 5 to identify candidate risk significant SSCs that accounts for

Information Need	
	uncertainties in the SMR-300 PRA model
6b	SMR (Holtec) is requested to provide additional justification for the selection of the RAW values. As part of the justification: Clarify if the extra half-order of magnitude of margin is sufficient to account for uncertainties in the SMR-300 PRA model if the baseline CDF is 1×10^{-7} per year and, if not, provide additional justification for the acceptability of using a RAW value of 30 to identify candidate risk significant SSCs that accounts for uncertainties in the SMR-300 PRA model.
6c	SMR (Holtec) is requested to provide additional justification for the selection of the RAW values. As part of the justification: Clarify if the discussion of uncertainties contained in NuScale's response to RAI 17.04-3 and the NRC staff's evaluation of uncertainties contained in section 4.0 of the safety evaluation for NuScale TR-0515-13952-NP-A are applicable to the SMR-300 PRA model.
6d	SMR (Holtec) is requested to provide additional justification for the selection of the RAW values. As part of the justification: Discuss if there are any characteristics of the SMR-300 design (e.g., the use of components with substantial operating experience) that are expected to significantly reduce uncertainties in the SMR-300 PRA model compared to commercial nuclear power plants or nuclear power plant designs certified by the NRC that include passive safety systems.
7	In Section 3.1.2, "Fussell-Vesely Criterion," SMR (Holtec) states, "In addition to equipment unavailabilities and human failures, internal initiating event contributors are also evaluated using FV because they play an important role in a PSA. External initiating events are excluded because they are not initiated by plant components." In section 3.1.2, SMR (Holtec) also states, "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 any one of the SSC's failures modes (BEs) exceeds the criterion for internal events risk, or seismic risk, or external flood risk, etc." The NRC staff acknowledges that similar language is included in NuScale TR-0515-13952-NP-A. The NRC staff believes that the two statements can be interpreted as potentially contradicting each other.

	Information Need
	SMR (Holtec) is requested to clarify its interpretation and intended application of the first sentence, especially as it relates to determining the risk significance of SSCs.
8	In Section 3.0, "Summary of Technical Information," of the safety evaluation for NuScale TR-0515-13952-NP-A, the NRC staff stated: NuScale selected a significance threshold of 20% with the objective of maintaining consistency between the absolute value of risk associated with significant contributors for NuScale and the absolute value of risk associated with significant contributors in current operating plants... NuScale, however, chose a threshold of 20 % because it believed that some important contributors could be screened out by using a value as high as 50 %. The NRC staff acknowledges that NuScale TR-0515-13952-NP-A does not explicitly state that some important contributors could be screened out by using a value as high as 50%. The NRC staff notes that SMR (Holtec's) topical report similarly does not include a statement that important contributors could be screened out by using an absolute risk reduction that is equivalent to the definition in RG 1.200. In Section 3.1.3, "Criteria Based on Contribution," of NuScale TR-0515-13952-NP-A, NuScale stated, "this criteria ensures that any SSC that has an unusually large contribution to risk is identified and the reasons for that contribution are examined, regardless of CDF or LRF." (emphasis added) In Section 3.1.2, "Fussell-Vesely Criterion," SMR (Holtec) states, "This criterion is used to identify BEs/contributors that are a significant fraction of a hazard with very low risk." (emphasis added) SMR (Holtec) is requested to provide additional justification for the selection of the FV values. As part of the of the justification: Clarify if some important contributors could be screened out by using a FV value as high as 0.5 if the baseline CDF is 1×10^{-7} per year or 0.05 if the baseline CDF is 1×10^{-6} per year. Clarify if there is an intended distinction between identifying SSCs that contribute a significant fraction to risk and identifying SSCs that have an unusually large contribution to risk.
9	From tables 1–6, the NRC staff understands that the risk significance criteria for RAW and FV are considered separately for CDF and LRF. The NRC staff notes that table 7 is ambiguous in this regard. Specifically, it is not clear from table 7 what the appropriate RAW and FV values are if the baseline CDF is 1×10^{-6} per year and the baseline LRF is 1×10^{-8} per year. SMR (Holtec) is requested to clarify the application of table 7 when the baseline CDF is 1×10^{-6} per year

		Information Need
	and the baseline LRF is 1×10^{-8} per year.	