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

August 6, 2024

MEMORANDUM TO: Michelle W. Hayes, Chief
Licensing and Regulatory Infrastructure Branch
Division of New and Renewed Licenses
Office of Nuclear Reactor Regulation

FROM: Emmanuel Sayoc, Project Manager
Licensing and Regulatory Infrastructure Branch
Division of New and Renewed Licenses
Office of Nuclear Reactor Regulation

Signed by Sayoc, Emmanue
on 08/06/24

SUBJECT: AUDIT PLAN FOR THE REGULATORY AUDIT OF SMR, LLC SUBMITTAL OF HOLTEC PSA RISK SIGNIFICANCE DETERMINATION METHODOLOGY LICENSING TOPICAL REPORT (PROJECT NO. 99902049)

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]

As part of the TR review, NRC staff will conduct an audit to better understand the information submitted by SMR (Holtec). This virtual audit will be held from August 15, 2024, through November 7, 2024. There will be an entrance meeting to discuss the audit process and an exit meeting to summarize the activities and status of each item. The NRC staff will issue an audit report within approximately 90 days following the exit meeting. The audit plan is included as an enclosure to this letter.

---

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.

2 U.S. NRC, "SMR-Holtec Risk Significance Methodology Topical Report Acceptance Review," July 10, 2024," part of package (ML24192A233).

This audit will be conducted in accordance with the guidance provided in the Office Instruction LIC-111, Revision 1, “Regulatory Audits.”[3]

CONTACT: Emmanuel Sayoc, NRR/DNRL
301-415-4084

Docket No. 99902049

Enclosure:
Audit Plan

[3] U.S. NRC, LIC-111, Revision 1, "Regulatory Audits,” October 31, 2019, (ML19226A274).

SUBJECT: AUDIT PLAN FOR THE REGULATORY AUDIT OF SMR, LLC SUBMITTAL OF HOLTEC PSA RISK SIGNIFICANCE DETERMINATION METHODOLOGY LICENSING TOPICAL REPORT (PROJECT NO. 99902049)
DATE: AUGUST 05, 2024

DISTRIBUTION:
PUBLIC
ESayoc, NRR
MHayes, NRR
CLauron, NRR
SGreen, NRR
IBanks, NRR
SVasavada, NRR
SAlferink, NRR
MSwim, NRR
SGarza, NRR
SRosenberg, NRR
ANeuhausen, NRR
MPohida, NRR
MBiro, NRR
CMoulton, NRR
ERobinson, NRR
KMott, NRR
RidsNrrDnrl
RidsNrrDra
RidsNsirDpr

ADAMS Accession No.: ML24211A226 E-concurrence NRR-106

OFFICE	NRR/DNRL/NLIB:PM	NRR/DNRL/NLIB:LA	NRR/DNRL/NLIB:PM	NRR/DNRL/NLIB: BC
NAME	ESayoc	SGreen*	CLauron	MHayes
DATE	07/31/2024	08/01/2024	08/1/2024	08/5/2024

OFFICE	NRR/DNRL/NLIB:PM
NAME	ESayoc
DATE	08/5/2024

OFFICIAL RECORD COPY

UNITED STATES NUCLEAR REGULATORY COMMISSION

AUDIT PLAN FOR THE SMR, LLC SUBMITTAL OF HOLTEC PSA RISK SIGNIFICANCE DETERMINATION METHODOLOGY LICENSING TOPICAL REPORT (PROJECT NO. 99902049) (EPID: L-2024-TOP-0024)

Docket No. 99902049

AUDIT PLAN

APPLICANT: SMR, LLC, a Holtec International Company

CONTACTS: Emmanuel Sayoc, India Banks

DURATION: August 15 to November 7, 2024 (Approximate Audit Exit)

AUDIT TEAM: Steven Alferink, Technical Reviewer (NRR)
Michael Swim, Technical Reviewer (NRR)
Stephanie Garza, Technical Reviewer (NRR)
Emmanuel Sayoc, Project Manager (NRR)
Tim Parkes. Observer, United Kingdom Office of Nuclear Regulation (UK ONR)
Joshua Gordon, Observer, UK ONR
Stephen Wardle, Observer, UK ONR
Robert Le Grove, Observer, UK ONR
Becky Mogridge, Observer, UK ONR
Webley, Mike , Observer, UK ONR

Additional audit team members may be added as needed.

I. BACKGROUND AND AUDIT BASIS

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.” The U.S. Nuclear Regulatory Commission (NRC) accepted the TR for review on July 10, 2024.

This audit will be conducted in accordance with the guidance provided in the Office Instruction LIC 111, Revision 1, “Regulatory Audits.”

II. OBJECTIVES

The NRC staff will seek clarification, gain understanding, and verify information related to the subject TR. The audit will identify if information is needed to support a regulatory finding so it can be placed on the docket. Additionally, review and discussion of the audit material will help focus any subsequent requests for additional information.

Enclosure

III. REGULATORY AUDIT SCOPE

The audit team will examine supporting documentation provided by SMR (Holtec) in the on-line portal and hold discussions during virtual meetings. Audit topics include the initial information needs described below and any additional items identified during the audit.

IV. INFORMATION AND OTHER MATERIAL NECCESSARY FOR THE REGULATORY AUDIT

Standard Review Plan (SRP), NUREG-0800, Section 19.0, "Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors," provides the NRC staff review guidance for the probabilistic risk assessment acceptance (PRA) for new reactors.[4] The acceptance criteria state that, in the context of the PRA results and insights, the term "significant" is intended to be consistent with its definition in Regulatory Guide (RG) 1.200, Revision 3, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," and that using any other definition of "significant" inconsistent with the definitions provided by RG 1.200 shall be subject to additional staff review and approval.[5]

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."[6] [**emphasis added**]

   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," and approved by the NRC staff in NUREG-1966, Volume 4, "Final Safety Evaluation Report Related to the Certification of the Economic Simplified Boiling-Water Reactor Standard Design."[7,8] 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.

---

[4] U.S. NRC, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition, Chapter 19," December 31, 2015, (ML15089A068).

[5] U.S. NRC, RG 1.200, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," January 31, 2018, (ML17317A256).

[6] Title *10* of the *Code of Federal Regulations* (CFR), 10 CFR 50.2, "Definitions."

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

[8] 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).

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.

3. 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," applies a sliding scale for acceptable increases in risk based on the baseline risk.[9] 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 staff seeks additional clarification on:

   a. How uncertainty is considered in the proposed methodology.

   b. 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 $5x10^{-7}$ per year or a baseline LRF of $5x10^{-8}$ 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?

   c. 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 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?

---

[9] U.S. NRC, RG 1.174, Revision 3, "An Approach For Using Probabilistic Risk Assessment In Risk-Informed Decisions on Plant-Specific Changes to the Licensing," January 31, 2018, (ML17317A256)

d. 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 $1x10^{-6}$ per year and $5x10^{-7}$ per year in Table 5, “SMR-300 Basis for CDF BE FV Values,” and remains constant for a baseline LRF of $1x10^{-7}$ per year and $5x10^{-8}$ 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 $1x10^{-6}$ per year or $5x10^{-7}$ per year or the baseline LRF is $1x10^{-7}$ per year or $5x10^{-8}$ 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 Determination.”[10] 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.

   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, how does the PRA model evaluates multi-module risk and how the risk significance of these shared SSCs is evaluated.

V. SPECIAL REQUESTS

The NRC staffs requests that SMR (Holtec) provide subject matter expert(s), if necessary, to discuss the details of the audit material.

---

[10] 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).

VI. LOGISTICS AND DELIVERABLES

Entrance Meeting:	August 15, 2024
Exit Meeting:	approximately 5 weeks later

The audit team will hold audit calls and/or meetings with SMR (Holtec) as necessary to understand audit material. The team will inform SMR (Holtec) of any emerging information needs.

An audit report will be issued within 90 days following the exit meeting. The NRC points of contact for this audit are Emmanuel Sayoc at emmanuel.sayoc@nrc.gov, and India Banks at india.banks@nrc.gov.