



Revision Log

Revision	Description of Changes
0	Initial issue under new report and project numbers.
1	Quarterly revision to update planned and completed meetings and reports. Various editorial changes and revision of meeting plans to better align with typical practice.
2	Quarterly revision to update planned and completed preapplication engagements and update topical report and application timelines.



Executive Summary

The purpose of this Regulatory Engagement Plan (REP) is to guide interactions and enhance communication between Holtec International (Holtec) and the Nuclear Regulatory Commission (NRC) during the pre-application activities that support the development of a construction permit application (CPA) as part of a two-step license approach under Title 10 of the Code of Federal Regulations (CFR) Part 50, “Domestic licensing of production and utilization facilities”. The objective of these pre-application interactions is to ensure an acceptable future application and to address areas of potential licensing risk early in the licensing process.

Section 4.0 articulates the topics where Holtec intends to proceed with pre-licensing engagement. This REP is intended as a living document and will be updated as additional topics for engagement are identified.



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1.0 INTRODUCTION

1.1 Purpose of Regulatory Engagement Plan

The purpose of this Regulatory Engagement Plan (REP) is to guide interactions and enhance communication between Holtec International (Holtec) and the Nuclear Regulatory Commission (NRC) during the pre-application activities that support the development of a construction permit application (CPA) as part of a two-step license approach under Title 10 of the Code of Federal Regulations (CFR) Part 50, “Domestic licensing of production and utilization facilities”. This REP identifies the planned regulatory approach and describes the interactions and roles and responsibilities between Holtec and the NRC staff to establish open communications and minimize regulatory uncertainty with the licensing process.

This REP contains a register of anticipated pre-application engagement topics and an approximate schedule for each engagement. This REP is expected to be a living document and will be updated and expanded as plans evolve to support future licensing actions and regulatory decisions. All changes to this REP will be discussed and communicated with the NRC staff. The structure of this plan is based on NEI 18-06, “Guidelines for Development of a Regulatory Engagement Plan” [1]. Holtec will maintain this REP and solicit NRC staff input for consideration and inclusion into the REP.

1.2 Contact Information

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1.3 Company and Project Structure

Holtec International is a diversified energy technology company headquartered in Jupiter, FL. SMR, LLC, based in Camden, NJ, is a wholly owned subsidiary of Holtec International whose designated activities include establishing business alliances with other companies, business and project management of small modular reactor projects, and promoting global acceptance of SMR. Licensing interactions for the SMR-300 technology on behalf of SMR, LLC are the responsibility of the Holtec licensing staff. Responsibilities of the Holtec licensing staff will include: (1) develop, maintain and manage the licensing strategy for SMR and (2) act as the primary point-of-contact with the NRC staff.

1.4 Summary of Strategic Approach and Goals

As discussed above, this REP will guide pre-application activities between Holtec and the NRC staff. Holtec plans to use these interactions to inform the pursuit of a multi-step licensing process for the SMR project. Holtec intends to submit a power reactor construction permit application (CPA) under 10 CFR Part 50, "Domestic licensing of production and utilization facilities," for a dual-unit SMR-300 plant collocated with the existing Palisades Nuclear Plant. Holtec plans to submit a limited work authorization (LWA) application as the first part of the CPA under 10 CFR 2.101(a)(9). The LWA application will discuss, at a minimum, the construction of the foundations of several major buildings. The second part of the CPA will cover construction of the remainder of the plant. The LWA is planned to be submitted by the end of 2025, while the second part of the CPA is planned to be submitted by early 2027.

As required by 10 CFR 50.34, the CPA will contain a preliminary safety analysis report (PSAR) and an environmental report as addressed in 10 CFR 51.50. The LWA application (the first part of the CPA) would include the information required by 10 CFR 50.10(d)(3), while the second part of the CPA would contain the remainder of the information required by §50.34. The environmental report associated with an LWA application is governed by 10 CFR 51.49. An application for an operating license (OLA) as described in 10 CFR Part 50, to include submittal of a final safety analysis report and a supplement to the CPA environmental report as addressed in 10 CFR 51.53, would be predicated on approval of the CPA.

2.0 TECHNOLOGY SUMMARY

The SMR-300 is an advanced, passively safe, pressurized light water nuclear power plant with 300 MW(e) rated net electric output. The SMR-300 is designed with forced circulation utilizing two cold legs each with a vertically mounted reactor coolant pump (RCP), two hot legs, and a single once-through steam generator (OTSG) with an integral pressurizer stacked on top of the OTSG (see Figure 2-1). The use of RCPs during normal operation is necessary to produce the rated power; however, the design utilizes passive, gravity driven safety systems that do not rely



on pumps, external water, external power, or operator action. The annular reservoir (AR), the large body of water situated between the containment structure and containment enclosure structure, serves as the SMR-300 ultimate heat sink.

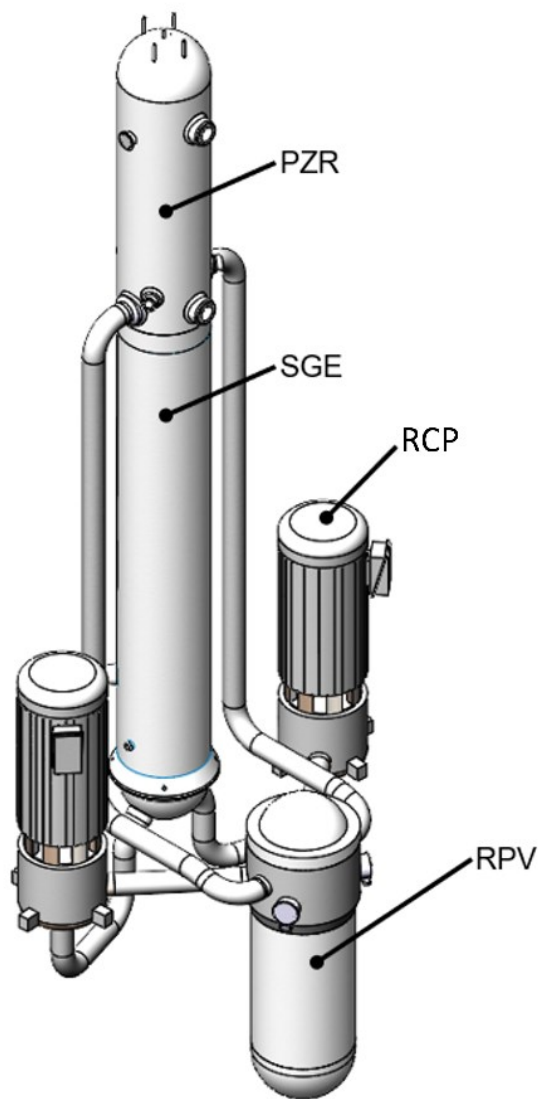


Figure 2-1: SMR-300 Reactor Coolant System



3.0 REP AND PSAR GUIDANCE AND CONTENT

3.1 Selection of Applicable Guidance

Holtec used the following references, in part, for the development of this REP:

- NUREG-0800, Introduction – Part 2: Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Light-water Small Modular Reactor Edition, Revision 0, 2014 [2]
- Regulatory Guide 1.206, Application for Nuclear Power Plants, Revision 1, 2018 [3]
- Regulatory Guide 1.70, Standard Format and Content of Safety Analyses Reports for Nuclear Power Plants, Revision 3, 1978 [4]
- NEI 18-06, Guidelines for Development of a Regulatory Engagement Plan (REP), Revision 0, 2018 [1]

These references inform the content in this REP, and will also be referenced, in part, to support future licensing actions and regulatory decisions as the REP pre-application activities progress.

NUREG-0800 provides the guidance used by NRC staff to perform safety reviews of construction permit or operating license applications under 10 CFR Part 50. While the SRP is not a substitute for the regulations, and compliance is not a requirement, for most application types, the regulation requires an assessment of the facility/design against the SRP in effect six months prior to docketing of the application. The SRP describes review criteria and procedures/methods used by NRC staff to conduct the review. Areas where the review standards are not anticipated to be relevant (e.g., exceptions to review and/or acceptance criteria) to the specific application will be especially important for early engagement and discussion. RG 1.70, like NUREG-0800, describes a standard format and the required content of safety analysis reports for light-water reactors acceptable to NRC staff under 10 CFR 50. RG 1.206 provides additional guidance regarding information to be submitted in a combined license application. All of these references discuss the importance of the REP.

Additionally, Design-Specific Review Standards (DSRSs) are intended to be a design-specific augmentation of the standard review plan (NUREG-0800), adding review criteria where the SRP does not adequately cover the design, or taking exception to SRP criteria where the SRP may not apply to the design. There have been DSRSs developed for other small modular reactors. The general consensus amongst the NRC staff and the industry is that the DSRS effort is a useful concept but is limited in its value because of the natural tension between the need for early identification/resolution of issues and the availability of sufficiently detailed design information to enable the NRC staff to draw final conclusions early enough in pre-application interactions to make binding conclusions in a DSRS. During the pre-application engagement activities, Holtec may consider referencing previous DSRSs to assist in informing the NRC staff's review of specific pre-application topics and elements of the PSAR.

The content and structure of the PSAR are well-defined by existing NRC regulations and guidance. Holtec will be using the REP pre-application engagement activities to inform the development of the PSAR elements provided in Table 3-1 below. RG 1.206 format and content instructions are intended for applications developed under 10 CFR 52. RG 1.70 provides



instructions for the form and content of SARs for applications developed under 10 CFR 50, but it has not been updated since 1978 and is not always consistent with other regulatory guidance. Holtec therefore intends to align the SMR-300 PSAR and FSAR with NUREG-0800 to the extent practical, while incorporating guidance from RG 1.70 and RG 1.206 to provide information in the locations expected by the NRC. This strategy is intended to facilitate and ease NRC review of future applications.

Table 3-1: Proposed PSAR Elements

Ch	RG 1.70	RG 1.206	SMR-300 PSAR
1	Introduction and General Description of Plant	Introduction and Interfaces	Introduction and General Description of Plant
2	Site Characteristics	Site Characteristics and Site Parameters	*Site Characteristics and Site Parameters
3	*Design of Structures, Components, Equipment, and Systems		
4	Reactor		
5	Reactor Coolant System and Connected Systems		
6	Engineered Safety Features		
7	*Instrumentation and Controls		
8	*Electric Power		
9	Auxiliary Systems		
10	Steam and Power Conversion System		
11	*Radioactive Waste Management		
12	Radiation Protection		
13	*Conduct of Operations		
14	Initial Test Program	Initial Test Program and ITAAC	Initial Test Program
15	Accident Analyses	*Transient and Accident Analysis	
16	Technical Specifications		
17	Quality Assurance		
18		Human Factors Engineering	
19		Severe Accidents	PRA and Severe Accident Evaluation

*Chapter title specifically referenced and discussed in DNRL-ISG-2022-01 [5].

3.2 Principal Design Criteria

10 CFR 50, Appendix A, establishes General Design Criteria (GDC) that are considered the “minimum requirements for principal design criteria (PDC) for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission.” § 50.34 requires an application to contain principal design criteria for a construction permit. The PDC establish the “necessary design, fabrication, construction, testing and performance requirements for structures, systems and components important to safety, i.e., structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.” Pursuant to Appendix A, the GDC are not necessarily sufficient for all light water reactor designs, and additional criteria may be needed “in the interest of public safety.” Similarly, not all GDC may be necessary or appropriate for a given design, in which case “departures” from the GDC must be identified and



justified. In past practice, such departures have sometimes required an exemption. Holtec licensing staff plans to engage the NRC staff on selected PDC during the pre-application engagement process as listed in Section 4.1.

3.3 Use of Standards and Industry Guidance

Consensus standards (ANS, ASME, ANSI, IEEE, etc.) and industry guidance (NEI, EPRI, etc.) will be utilized when appropriate during pre-application activities and the development of the PSAR. These consensus standards and industry guidance will assist in describing various aspects of the SMR-300 design, methodology for design and analysis, siting, etc. Particularly to the extent a given standard has not been endorsed by the NRC staff, or is being used in a novel way, Holtec plans to present the specific information as part of the REP to establish dialogue and a common understanding with the NRC staff.

4.0 PRE-APPLICATION ENGAGEMENT

Holtec will facilitate pre-application engagement meetings (teleconferences, videoconferences, and face-to-face) with NRC staff to identify, assess, and mitigate potential regulatory risks associated with the discussion topics listed in this section. These interactions will also inform the development of the PSAR elements and environmental assessments as part of future application development. Primary benefits of pre-application engagement are to inform the NRC of Holtec's planned approach in areas of regulatory risk, and to ensure that eventual applications contain sufficient information to meet NRC expectations. Holtec will engage in frequent open and closed meetings with NRC staff during these pre-application activities to ensure that NRC staff has timely and accurate information to support future safety determinations and agency resource planning. Holtec understands the need to notify the public of agency meetings and will support efforts for early meeting notification. Holtec will also work with the NRC staff to coordinate an appropriate schedule of meetings, taking into account all of the potential attendees.

4.1 Identification of Topics

Table 4-1 below includes topics that have been identified as important to address in pre-application engagements. As the project progresses, Holtec expects that other topics for pre-application engagement may be identified and added to the table below. The NRC will be promptly notified in the event additional topics are added for planning and budgeting purposes. Timely pre-application engagement for each identified topic below will be important to keep the NRC staff informed and aligned on the schedule.



Table 4-1: Topics for SMR Pre-Application Engagement

Topic	Description	Engagement	Approx. Date
REP	Discuss REP content and NRC REP feedback	Informal Discussion	Jul-2022
LOCA Exemption	Discuss LOCA Questions and Previous Topical Report Submittal	Public Meeting ML22243A010	Aug-2022
Critical Piping	Clarification question on SRP Section 3.6	Informal Discussion	Sep- 2022
CRDS Operability QA Program	Discuss CRDS operability QA program with mechanical group	Public Meeting ML22252A181	Sep-2022
Computer Programs	Clarification question on the use of STAAD.PRO	Informal Discussion	Sep- 2022
Seismic Methodology	Discuss seismic methodology for SRP Section 3.7	Public Meeting ML22259A128	Sep-2022
Instrumentation and Control (I&C)	Discuss an overview of the SMR-160 I&C architecture	Public Meeting ML22263A014	Oct-2022
Spent Fuel Pool (SFP) Makeup Systems	Discuss SMR-160 SFP makeup system compliance	Public Meeting ML22263A380	Oct-2022
Follow-up: CRDS Operability QA Program	Discuss CRDS operability QA program with reactors group	Public Meeting ML22263A420	Oct-2022
Technical Specifications (TSs)	Discuss TSs, specifically the requirements and guidance for TSs in an CPA	Public Meeting ML22297A105	Oct-2022
LOCA Exemption Justification List	Discuss a potential LOCA exemption justification items list	Public Meeting ML22263A388	Oct-2022
Containment Heat Removal System Testing (GDC 40)	Discuss passive containment heat removal system testing and potential exemption	Public Meeting ML22305A691	Nov-2022
Closed System Isolation Valves (GDC 57)	Discuss primary and secondary decay heat removal system closed system isolation valves and potential exemption	Public Meeting ML22307A238	Nov-2022
Various Informal Discussions	Discuss various email topics during the 4Q23.	Informal Discussions	Nov-2022
SECY-94-084 PCCS Safe Shutdown Criteria	Discuss safe shutdown criteria applicable to SMR-160 design	Public Meeting ML22304A131	Dec-2022
SMR-160 Quality Assurance Program	Discuss potential revision to SMR-160 approved Quality Assurance Topical Report (2014)	Public Meeting ML22329A005	Dec-2022
RCS Makeup (GDC 33)	Discuss RCS Makeup (GDC 33) Compliance	Public Meeting ML22354A112	Jan-2023
CPA Parts and TOC	Discuss NRC CPA Parts and TOC Expectations	Public Meeting ML22355A658	Jan-2023
Instrumentation and Control (I&C)	Discuss I&C Hazard Analysis Methodology	Public Meeting ML23019A004 ML23137A208	Feb-2023
MELCO I&C LTR	Initial call supporting MELCO with scheduling I&C platform LTR revision.	Phone Call	Feb-2023
Fire Protection	Discuss/Clarify Fire Protection Questions – ensure JH is included in discussion	Public Meeting ML23044A014	Feb 2023
Chapter 15 Analysis Methods	Discuss accident analysis methods, progress, timelines, Appendix K, and expectations	Public Meeting ML23018A009	Feb-2023



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Topic	Description	Engagement	Approx. Date
RG 1.99 Limitation (Embrittlement-Tc / Flux)	Discuss the limitations of RG 1.99 as it relates to the development of P-T curves for SMR-160	Public Meeting ML23045A010	Feb-2023
Simulator and Operator Training/Qualifications	Discuss the SIM CERT process, OP training timelines, HFE OER, ITAAC (staff ideas PT 50)	Public Meeting ML23045A021	Mar-2023
MCR staffing 50.54(m)	Discuss SMR-160 MCR staffing, HFE	Public Meeting ML23045A037	Mar-2023
International Projects	Conduct discussion (part of EDO/COMM drop-in)	Drop-in Visit	Mar-2023
REP (Quarterly Revision)	REP Rev 4	Submission ML23088A003	Mar-2023
LOCA Exemption Justification (Update #1)	Quarterly Update to discuss and present SMR-160 LOCA Exemption justification progress	Public Meeting ML23045A052	Apr-2023 (4/5/23)
Chapter 13 Operational Programs	Discuss Chapter 13 Operational Programs and the expected thresholds for each in the PSAR	Public Meeting ML23045A070	Apr-2023 (4/19/23)
Electronic Submittal Process	Discuss the NRC's License Application Electronic Submittal Process and Lessons-Learned	Clarification Call 10:00-11:00	Apr-2023 (4/19/23)
SMR-160 Design Overview Agenda	Discuss and present a high-level design overview of the SMR-160 to the NRC staff	Closed Meeting ML23115A022	May-2023 (5/3/23)
Fuel Qualification and Testing	Discuss the SMR-160 fuel qualification and testing plan	Public Meeting ML23116A034	May-2023 (5/10/23)
PRA/PSA Topics	Discuss Risk Significance Criteria and RG 1.200 Methodology and Approaches	Public Meeting ML23167A067	May-2023 (5/17/23)
LOCA Roadmap (F/U to 4/5/23 Mtg)	Discuss Potential LOCA Exemption Roadmap and Wording	Public Meeting ML23116A066	May-2023 (5/25/23)
Discuss ATWS	Discuss SMR-160 Compliance with the ATWS Rule (50.62) and potential exemptions	Public Meeting ML23200A002	Jun-2023 (6/7/23)
HFE Program	Discuss HFE Program, Procedures, Methodology, Questions	Public Meeting ML23216A133	Jun-2023 (6/20/23)
Discuss Appendix K Applicability	Discuss 10 CFR 50 Appendix K applicability to SMR-160 and potential exemptions	Public Meeting ML23151A629	Jun-2023 (6/28/23)
REP (Quarterly Rev)	REP Rev 5	Submission ML23180A006	Jul-2023 (7/1/23)
EP/EPZ Development Methodology *	Discuss EP and EPZ development methodology and results	Public Meeting ML23216A092	Jul-2023 (7/12/23)
Discuss V&V of Codes	Discuss V&V plans, timelines, potential LTRs, potential code-to-code benchmarking	Public Meeting ML23121A009	Jul-2023 (7/19/23)
Instrumentation and Control (I&C)	Discuss I&C D3 assessment and coping analysis	Public Meeting ML23156A182	Jul-2023 (7/26/23)
Instrumentation and Control (I&C)	Discuss I&C unit bus design, bidirectional communication, and system independence	Public Meeting ML23289A099	Aug-2023 (8/23/23)
Follow-up on RG 1.99 Limitations	Discuss (follow-up) RG 1.99 Limitation topic from February 2023.	Public Meeting ML23254A242	Aug-2023 (8/30/23)
Instrumentation and Control (I&C)	Discuss IEEE 603 applicability to the SMR-160 design	Public Meeting ML23296A004	Sep-2023 (9/13/23)
Dual Unit Simulator Fidelity	Discuss questions related to dual unit simulator fidelity	Public Meeting ML23292A255	Sep-2023 (9/20/23)
Fuel Management *	Discussion of fuel management plan for life cycle including licensing aspects.	Public Meeting ML23293A049	Sep-2023 (9/27/23)



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Topic	Description	Engagement	Approx. Date
QAPD LTR	Submit QAPD LTR	Submission ML23271A009	Sep-2023 (9/29/23)
REP (Quarterly Rev)	REP Rev 6	Submission ML23270B183	Oct-2023 (10/1/23)
TMI Requirements	Discuss TMI requirements and compliance table for SMR-160 applicability. Also, discuss potential exemptions to these requirements.	Public Meeting ML23291A017	Oct-2023 (10/4/23)
Risk Significance Methodology Pre-Meeting	Provide an overview of the SMR Risk Significance Methodology LTR prior to formal submission	Public Meeting ML23318A080	Oct-2023 (10/25/23)
Limited Work Authorization for Part 50	Discuss process and expectations for an LWA coupled with a Part 50 CPA	Public Meeting ML23276B487	Nov-2023 (11/1/23)
Update on Seismic Methodology Results	Discuss non-linear SSI methodology and results	Public Meeting ML23339A050	Nov-2023 (11/8/23)
Chapter 16 TS Development	Provide an update on technical specification development for the SMR design	Public Meeting ML24002A707	Nov-2023 (11/29/23)
REP (Quarterly Rev)	REP Rev 7	Submission ML23356A136	Dec-2023 (12/22/23)
GDC 17 Exemption Request	Inform NRC of anticipated GDC 17 exemption request	Public Meeting ML24033A291	Feb 2024 (2/7/24)
Fire Protection	Discuss the SMR-300 approach to compliance with RG 1.189	Public Meeting ML24058A341	Feb 2024 (2/26/24)
REP (Quarterly Rev)	REP Rev 0 (Issued under new report number)	Submission ML24087A212	Mar 2024 (3/26/24)
Environmental and Site Characterization Overview	Provide an overview of Palisades site characterization work and schedule that will support the SMR-300 Environmental Report	Public Meeting	April 2024 (4/3/24)
Risk Significance Methodology Update	Provide an update of the SMR Risk Significance Methodology LTR prior to formal submission	Public Meeting ML24176A109	May 2024 (5/1/24)
SMR-300 Design Overview	Discuss and present a high-level design overview of the SMR-300 to the NRC staff	Public Meeting ML24197A246	May 2024 (5/8/24)
I&C Overview	Discuss skipped session from the May 8th Design Overview meeting.	Public Meeting ML24180A171	June 2024 (6/5/24)
Risk Significance LTR	Submit Risk Significance Determination Methodology licensing topical report	Submission ML 24163A399	June 2024 (6/11/24)
Environmental Qualification	Discuss the SMR-300 Environmental Qualification Program	Public Meeting ML24215A393	July 2024 (7/11/24)
LWA Scope*	Discuss planned SMR-300 LWA application, including scope, timeline, and how it fits into the overall licensing strategy	Public Meeting (in person)	July 2024 (7/19/24)
Reliability Assurance Program	Discuss development of the SMR-300 Reliability Assurance Program	Public Meeting ML24229A132	July 2024 (7/24/24)
Cyber Security	Discuss SMR-300 Cyber Security Plan and architecture	Public Meeting	August 2024 (8/13/24)
LWA Letter		Submission ML24250A155	September 2024 (9/6/24)
Nuclear Codes Verification and Validation	Provide an update on the SMR-300 core design and discuss code V&V plans	Public Meeting	September 2024



Topic	Description	Engagement	Approx. Date
			(9/10/24)
Integral and Separate Effects Testing Programs	Discuss SMR-300 I/SET facility scaling and test plan	Public Meeting	September 2024 (9/19/24)
Modularity	Discuss the use of modularity for constructing SMR-300 structures and how modules will be accounted for in structural analysis	Public Meeting	September 2024 (9/23/24)
CRDS Update	Update the NRC on SMR-300 CRDS including testing plans.	Public Meeting	October 2024 (10/1/24)
SMR-300 I&C Topical Report Overview	Discuss scope and timing of the SMR-300 I&C topical report.	Public Meeting	November 2024
SMR-300 Radiological Consequences Methodology Overview	Discuss scope and timing of the SMR-300 Radiological Consequences Methodology topical report.	Public Meeting	December 2024
10 CFR 50.2 Exemption Request	Discuss intended exemption request to support SMR-300 use of the 10 CFR 50.160 Emergency Preparedness for SMRs rule.	White Paper followed by Public Meeting	Q4 2024
Structural Modularity Design Philosophy	Provide design philosophy of structural modules to be used in the SMR-300 at Palisades, including analysis methodology, acceptance criteria, and testing plan	Public Meeting	Q1 2025
<i>Additional Items TBD</i>			

Note (*) designates a topic of interest to environmental stakeholders (NMSS).

4.2 Type and Frequency of Interactions

The type and frequency of interactions with the NRC will be managed by Holtec licensing staff and coordinated with the SMR project team and the NRC staff. The number and frequency of these interactions will be key to maintaining a consistent understanding of the status of issue identification and resolution. These interactions will include frequent phone calls, emails, teleconferences, and meetings to solicit feedback on proposed technical approaches, review of licensing topical reports, technical reports and white papers, audits of engineering information and potential inspections of testing facilities that support the pre-application engagement topics and PSAR development.

Holtec is proposing the following meetings with NRC staff:

- Monthly calls between NRC Director, Division of New and Renewed Licenses (DNRL) and Holtec Vice President, Licensing and SMR Managing Director.
- Monthly, or more frequent, calls established between the NRC Branch Chief, New Reactor Licensing Branch (NRLB) and Holtec Director of Licensing, SMR.
- Biweekly (every two weeks), or more frequent, calls established between the assigned NRC project manager (PM) and Holtec Director of Licensing, SMR, or designated SMR Licensing Engineer.



- Additional planning meetings and drop-ins, as needed.

In addition, with respect to the pre-application engagement topics presented in Table 4-1, Holtec proposes engaging with the NRC using any of the following methods for each topic:

- Conduct a meeting, typically a remote session with presentation materials that describe the SMR-300 approach to the topic and any questions for the NRC staff.
- Submit a white paper, letter, technical report, or licensing topical report on the selected topic for the NRC staff's review. Feedback for white papers may be provided in written form, in a subsequent meeting, or informally.

4.3 Technical Discussions and Written Submittals

Initial discussions between Holtec and NRC staff will be concerned primarily with the planned strategies for development of the PSAR. Topics for these discussions, as well as follow-up interactions, will be developed by the Holtec Director of Licensing, SMR, and shared with the NRC staff and may focus on individual topics or several topics combined for efficiency.

Written submittals will be provided on the docket, including white papers, letters, presentations, technical reports, and licensing topical reports. White papers will be employed to address high level issues, summarize proposed approaches, and describe positions on a specific topic. To ensure clarity with respect to the use, application, and review of all written submittals (white papers and/or technical reports) during preapplication activities, frequent communication between Holtec and NRC staff will be conducted as detailed above. Licensing topical reports will be submitted when seeking an NRC safety evaluation for a specific topic that may be referenced in future licensing submittals. The anticipated licensing topical report submittal schedule is provided in Table 4-2.

Table 4-2: Anticipated Licensing Topical Report Submittals

Topic	Projected Submittal Date
MELTAC Safety System Digital Platform	Under NRC Review ML23167C168
Quality Assurance Program Description	Approved ML24248A162
Risk Significance Determination Methodology	Under NRC Review ML24163A399
SMR-300 I&C Design	Mid 2025
SSI Analysis Methodology	Mid 2025
Nuclear Analysis Codes and Methods Qualification	Mid 2025
Radiological Consequences Methodology	Mid 2025
SMR-300 Structural Modularity Design	End 2025
Applicability of Framatome Fuel Methodology, CHF Correlations, and COBRA FLX to SMR-300	Early 2026
Subchannel Analysis Methodology	Early 2026
Internals Structural Analysis Methodology	Early 2026
Applicability of GOTHIC to SMR-300	Mid 2026



Topic	Projected Submittal Date
Large-Break LOCA Evaluation Methodology	End 2026
Small-Break LOCA Evaluation Methodology	End 2026
Non-LOCA Evaluation Methodology	Early 2027
Long-Term Cooling Methodology	Early 2027
Rod Ejection Accident Methodology	Early 2027

4.4 Information Sharing and the Potential Escalation of Issues

A Holtec electronic reading room will be established to allow Holtec to share documents with the NRC staff, including program procedures, presentations, drawings, white papers, and technical reports. A more detailed discussion of the electronic reading room can be found in the SMR, LLC Online Reference Portal Information Access Agreement [6].

As part of the pre-application activities, it may be necessary to resolve conflicts between existing regulatory infrastructure and new features in the SMR-300 design. Early identification and appropriate escalation of the issues will be useful in ensuring a timely resolution. Holtec licensing staff will work with the NRC staff to resolve these issues early in the process and at the appropriate level. As the REP is updated and expanded throughout the pre-application activities, Holtec may reassess issues and/or conclusions reached in previous discussions to identify needed exemptions from NRC regulations and/or deviations from regulatory guidance.

4.5 Schedule Considerations

Holtec and the NRC held initial meetings to establish the REP and initiate preapplication engagements in 2022. Regular meetings have continued as cataloged in Table 4-1 and are planned to proceed in accordance with the schedule proposed therein. Any potential program audits and inspections will be coordinated with the NRC staff.

5.0 OTHER TOPICS

5.1 Readiness Assessment Audit and Application Submittal

A readiness assessment audit should occur with sufficient time to resolve any identified issues prior to the submittal of an application. Holtec may request that the NRC staff conduct a readiness assessment audit of a completed, or nearly completed draft PSAR. This readiness assessment is a comprehensive review of the material over several days. The conclusion of the audit is a series of observations by the NRC staff, focusing on issues that might preclude acceptance of the application if left unresolved or uncorrected. A secondary objective of the readiness assessment audit is to identify areas for which clarifications or supplemental information could preclude or minimize staff requests for additional information. Depending on the complexity and results of the various pre-application engagement activities and reviews discussed above, the schedule for submittal of a PSAR may change. Changes to the PSAR schedule will be noted in regular updates to the REP and routine discussions between Holtec and NRC staff.



5.2 Budget

Budgeting considerations are important in establishing and maintaining the pre-application engagement schedule. NRC staff review fees, including review hours, will be estimated at the time the selected topic is presented for review and monitored on an ongoing basis. Both Holtec and NRC staff will communicate any expected changes in the level of estimated NRC staff review fees, resource availability, or funding restrictions. The Holtec budget estimate for each topic listed in Table 4-1 will be in the range of 30 – 100 hours.

6.0 REFERENCES

- [1] Nuclear Energy Institute (NEI) 18-06, Guidelines for Development of a Regulatory Engagement Plan (REP), Revision 0, 2018
- [2] NUREG-0800, Introduction – Part 2: Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Light-water Small Modular Reactor Edition, Revision 0, 2014
- [3] Regulatory Guide 1.206, Application for Nuclear Power Plants, Revision 1, 2018
- [4] Regulatory Guide 1.70, Standard Format and Content of Safety Analyses Reports for Nuclear Power Plants, Revision 3, 1978
- [5] DNRL-ISG-2022-01, Safety Review of Light-Water Power Reactor Construction Permit Applications, Interim Staff Guidance, October 2022
- [6] SMR, LLC Online Reference Portal Information Access Agreement, (ML22215A031), August 23, 2022.

7.0 LIST OF APPENDICES

None.