Revision Log

Revision	Description of Changes
0	Initial issue under new report and project numbers.

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” (Reference 1). Holtec will maintain this REP and solicit NRC staff input for consideration and inclusion into the REP.

1.2 Contact Information

The following are points of contact for all correspondence:

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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 two-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.” Per regulation 10 CFR 50.34, the application for a construction permit will contain a preliminary safety analysis report (PSAR) and an environmental report as addressed in 10 CFR 51.50. The application for an operating license (OLA) as described in 10 CFR Part 50, to include submittal of the final safety analysis report and an environmental report as addressed in 10 CFR 51.50, would be predicated on 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 reactor coolant pumps 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.

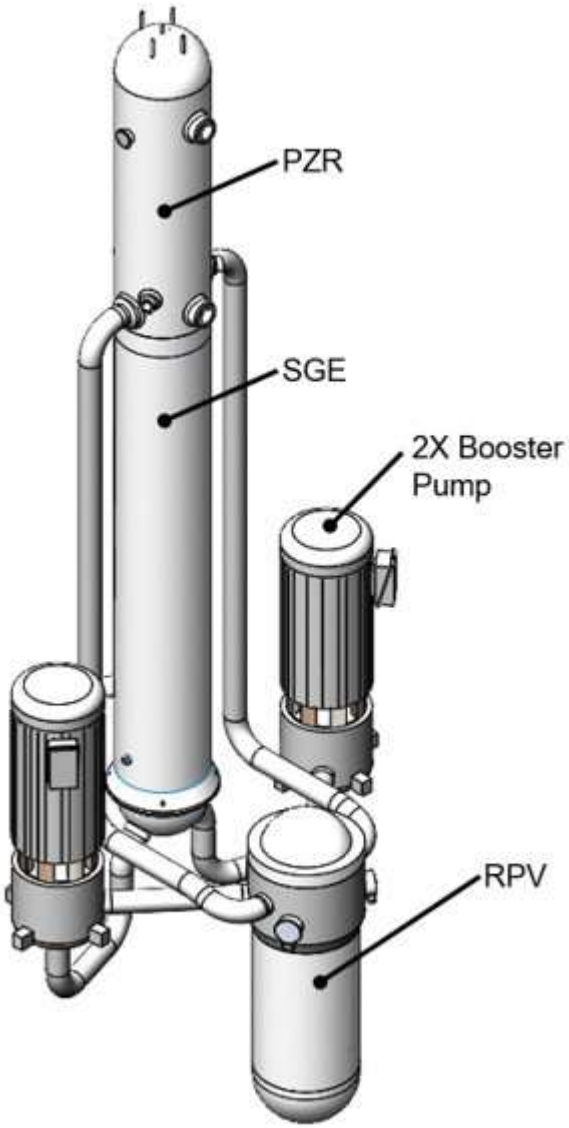

Figure 2-1: SMR-300 Reactor Coolant System

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, Standard Review Plan, Introduction – PART 2 for the Review of Safety Analysis Reports for Nuclear Power Plants: Light-water Small Modular Reactor Edition, Revision 0, 2014
- Regulatory Guide 1.206, Application for Nuclear Power Plants, Revision 1, 2018

- Regulatory Guide 1.70, Standard Format and Content of Safety Analyses Reports for Nuclear Power Plants, Revision 3, 1978
- NEI 18-06, Guidelines for Development of a Regulatory Engagement Plan (REP), Revision 0, 2018

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. Regulatory Guide 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 and 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 SMR DSRSs to assist in informing the NRC staff's review of specific pre-application topics and elements of the PSAR. See Section 4.1 for selected REP discussion topics.

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 Safety Analysis Reports for applications developed under 10 CFR 50, but that guidance has not been updated since 1978 and is not consistent with other regulatory guidance. Holtec therefore intends to align the SMR PSAR and FSAR with the NUREG-0800 sections as best as possible, 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 licensing applications.

Table 3-1: Proposed PSAR Elements

Ch	RG 1.70	RG 1.206	SMR 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.

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." Part 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 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 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 any 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. The primary benefit of this planned engagement is alignment on the risk-informed content of the topics, and the scope and depth of the NRC review. 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

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)

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	Feb 2024 (2/26/24)
REP (Quarterly Rev)	REP Rev 0 (Issued under new report number)	Submission	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)
SMR-300 Chapter 15 Analysis Overview	Provide an update on the planned methodologies and schedules for SMR-300 PSAR Chapter 15 safety analyses	Public Meeting	April 2024 (4/10/24)
I/SET Scaling	Discuss the scaling methodology to be used for the SMR-300 Integral and Separate Effects Test Facility	Public Meeting	April 2024 (4/24/24)
Risk Significance Methodology Update	Provide an update of the SMR Risk Significance Methodology LTR prior to formal submission	Public Meeting	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	May 2024 (5/8/24)
Environmental Qualification	Discuss the SMR-300 Environmental Qualification Program	Public Meeting	June 2024
Risk Significance LTR	Submit Risk Significance Determination Methodology licensing topical report	Submission	Q2 2024
Cyber Security	Discuss SMR-300 Cyber Security Plan and architecture	Public Meeting	Q3 2024
SMR-300 I&C LTR Scope	Provide an overview of the intended scope for a future SMR-300 I&C design licensing topical report	Public Meeting	Q3 2024
Modularity	Discuss the use of modularity for constructing SMR-300 structures and how modules will be accounted for in structural analysis	Public Meeting	TBD
Security	Discuss target-set development for the SMR-300	Closed Meeting	TBD

Topic	Description	Engagement	Approx. Date
CRDS Update	Update the NRC on SMR-300 CRDS including testing needs.	Public Meeting	TBD
ISI/IST Programs	Discuss example in-service inspection and in-service testing PSAR content	Public Meeting	TBD
Additional Items TBD			

Note (*) designates the topic for interest to environmental stakeholders (NMSS).

4.2 Types 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:

- bi-monthly (every 2 weeks) meeting with NRC project managers and technical reviewers
- quarterly status that describes accomplishments, progress, remaining outstanding items and additional areas of focus to assess the status of the pre-application engagement
- 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 pre-submittal meetings with the NRC for a selected topic, typically a remote session with presentation materials describing expectations (including a potential schedule and budget) for the associated review
- Submit white paper or technical report on the selected topic presented to provide material for the NRC staff's review
- Receive feedback from NRC staff regarding alignment on expectations, allocated resources, budget and schedule for the review of the selected item
- Hold a post-review meeting with the NRC staff to obtain feedback (the format of this should be agreed on between Holtec licensing and NRC staff, and may be in the form of a phone call or another informal method of interaction)

Prior to and following the submittal of white papers or technical reports for the selected pre-application engagement topics, routine and frequent interaction is expected via phone and email between the NRC and Holtec. The communication plan and interaction frequency listed below can be amended as necessary to support healthy communications and common understanding of the status of all the pre-application engagement activities:

- 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

- Weekly, or more frequent, calls established between the assigned NRC project manager (PM) and Holtec Director of Licensing, SMR, or designated SMR Licensing Engineer.

Periodic drop-in visits and meetings between Holtec and NRC staff (which may include participation by various levels of Holtec and NRC management) will be conducted to exchange general information on nontechnical topics such as planning for future interactions and status/schedule updates. Limited discussion of technical issues can occur, but typically it will be in the context of status of review or identification of topics for separate discussion.

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, presentations, technical reports, and licensing topical reports. White papers will be utilized to present information and describe positions on a specific topic with the objective of increasing understanding and seeking alignment with NRC staff. The use of white papers will be employed to address high level issues, summarize proposed approaches, and seek clarification on methodologies, guidance, and technical issues. 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	Q2 2023
Quality Assurance Program Description	Q4 2023
Risk Significance Determination Methodology	Q2 2024
SMR-300 I&C Design	Q1 2025
SSI Analysis Methodology	Mid 2025
Nuclear Analysis Codes and Methods Qualification	Mid 2025
Radiological Consequences Methodology	Mid 2025
Applicability of Framatome Fuel Methodology, CHF Correlations, and COBRA FLX to SMR-300	Mid 2025
Rod Ejection Accident Methodology	End 2025
Subchannel Analysis Methodology	End 2025
Applicability of GOTHIC to SMR-300	End 2025
Internals Structural Analysis Methodology	Early 2026
Large-Break LOCA Evaluation Methodology	Mid 2026
Small-Break LOCA Evaluation Methodology	Mid 2026
Non-LOCA Evaluation Methodology	Mid 2026
Long-Term Cooling Methodology	Mid 2026

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 and online reference portal information access agreement can be found in the NRC Agencywide Documents Access and Management System (ADAMS) under ML22215A031 dated August 23, 2022.

As part of the pre-application activities, it may be necessary to resolve conflicts between existing regulatory infrastructure and new features in the SMR 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 any 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 the 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 material 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, Standard Review Plan (SRP), Introduction – PART 2 SRP 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] NEI white paper, “Issue Escalation Process (Model for ROP Task Force),” (ADAMS Accession No. ML20017A089), dated January 13, 2020
[6] DNRL-ISG-2022-XX, Safety Review of Light-Water Power-Reactor Construction Permit Applications, Draft Interim Staff Guidance (ML21165A157)
[7] DRAFT Pre-application Engagement to Optimize Advanced Reactors Application Reviews, May 2021 (ML21145A106)

7.0 LIST OF APPENDICES

None.