

**U.S. NUCLEAR REGULATORY COMMISSION SUMMARY OF THE JUNE 20, 2023,
OBSERVATION PREAPPLICATION PUBLIC MEETING WITH SMR, LLC (A HOLTEC
INTERNATIONAL COMPANY) TO DISCUSS THE SMR 160 HUMAN FACTORS
ENGINEERING**

Meeting Summary

The U.S. Nuclear Regulatory Commission (NRC) held an observation public meeting on June 20, 2023, with SMR, LLC (SMR), a Holtec International Company (Holtec), to discuss preapplication information related to the SMR-160 design.¹ Specifically, SMR (Holtec) requested the meeting to provide a high-level overview of the SMR -160 Human Factors Engineering (HFE) milestones, to discuss the HFE implementation plans, and obtain feedback from the NRC staff on the HFE implementation plans and examples of Operating Experience Review (OER), Functional Requirements Analysis/Function Allocation (FRA/FA) and Task Analysis (TA) elements. SMR provided the proprietary and non-proprietary slides for this public meeting.^{2,3}

This virtual observation preapplication meeting had attendees from SMR, NRC staff, and members of the public. Since proprietary information was not discussed, a closed session was not needed.

The following summarizes key discussions during the meeting primarily based on questions by SMR (Holtec) included in the presentation slides.

- Regarding the presentation of the overview of the HFE program, SMR (Holtec) asked how Implementation Plans (IPs) can be submitted to the NRC for review and feedback.
 - NRC staff responded that the answer depends on the nature of the feedback being sought and the timeframe during the application process. Informal feedback can be obtained via several means, including, in part, 1) providing the plans to the NRC in the form of a white paper or 2) providing the material in question as part of a preapplication audit by the NRC staff. In both cases, the feedback received would not include any regulatory findings and typically would be conveyed in the form of a letter. If it is desired to submit completed IPs for the purpose of the staff making a regulatory finding, then the approach would likely instead need to either include the material in a topical report (TR) or within the operating license (OL) application (note that while nothing would prevent including portions of this material in a construction permit application, the developmental state of the design at that phase may not be conducive to doing so). The staff can review a docketed TR or material included with a construction

¹ Letter from J. Hawkins, SMR, LLC Preapplication Meeting Materials for June 20, 2023, dated June 13, 2023, Agencywide Documents and Access Management System (ADAMS) Accession No. ML23165A081, part of ML23165A080.

² Enclosure 1: SMR, LLC Meeting Presentation Materials for June 20, 2023 (Proprietary),” dated June 14, 2023, ML23165A082, part of ML23165A080.

³ Enclosure 2: SMR, LLC Meeting Presentation Materials for June 20, 2023 (Non-Proprietary),” dated June 14, 2023, ML23165A083, part of ML23165A080.

- permit (CP) or OL application and make a regulatory finding via a safety evaluation. In the case of a TR, a subsequent CP or OL application can then incorporate the included material by reference. Another factor to be considered is the required staff review time associated with white papers and TRs. While white papers yield only informal feedback from the staff, the review timeframe is typically significantly less compared to a TR due to the lack of a regulatory finding being made.
- Regarding staffing and qualification, SMR (Holtec) asked how scenario workload for any unaffected units should be determined.
 - NRC staff responded that there are several NUREG-series documents that provide a wide range of information related to these topics. Approaching multi-unit scenario workload issues should include consideration of the relevant guidance documents listed below, in light of the planned concept of operations, and using those insights to inform scenario development:
 - NUREG-0711, (Revision 3), Section 11, “Human Factors Verification and Validation”
 - NUREG-0800, Chapter 18, (Revision 3), Attachment B, “Methodology to Assess the Workload of Challenging Operational Conditions in Support of Minimum Staffing Level Reviews”
 - NUREG-1791, Chapter 10 (staffing plan validation review guidance)
 - NUREG/CR-6838, (technical basis document for NUREG-1791)
 - NUREG/CR-7190, “Workload, Situation Awareness, and Teamwork”
 - NUREG/CR-7126, “Human-Performance Issues Related to the Design and Operation of Small Modular Reactors”
- Regarding OER, FRA/FA and TA elements, SMR (Holtec) asked how can examples of documentation for completed HFE elements such as OER, FRA/FA and TA elements receive NRC review and feedback.
 - NRC staff responded that the documentation associated with HFE elements such as the OER, FRA/FA, and TA consist of both IPs and Results Summary Reports (RSRs). Both types of documents and how they relate to these HFE elements are discussed under NUREG-0711, Revision 3. The IP aspect of the question is covered under the first discussion topic above. For RSRs, similar principles would apply as to what was discussed for IPs, with the understanding that RSRs (unlike IPs) typically do not get docketed as part of an application but normally get audited by the staff via an applicant’s electronic reading room. Variations in this process do exist and it is possible to just submit the completed RSR for an HFE element in lieu of preceding the RSR with a separate IP submittal (NUREG-0711 notes the potential for a single report). Under such an approach, the type of information normally found in a standalone IP would be expected to be included within the RSR as well. If only an RSR will be submitted, an applicant should coordinate with the NRC staff to ensure that any material that will be needed to

support a regulatory finding is docketed (in contrast to other information that serves to confirm a finding and might not necessarily need to be docketed).

- Regarding simulator testing SMR (Holtec) noted that Regulatory Guide (RG) 1.149, “Nuclear Power Plant Simulation Facilities for Use in Operator Training, License Examinations, and Applicant Experience Requirements,” Revision 4, currently endorses the 2009 version of ANSI/ANS-3.5, “Nuclear Power Plant Simulators For Use In Operator Training And Examination.” SMR (Holtec) asked if they could use the 2018 version of ANSI/ANS-3.5.
 - NRC staff responded that the NRC is currently working on its review of ANSI/ANS-3.5-2018 and plans to issue a related revision of RG 1.149 to this effect in the future. However, this endorsement work needs to account for the implications of the proposed Part 50 and 52 alignment/lessons learned rulemaking, which has extended the timeframe needed to accomplish this. In the meantime, it is important to recognize that RGs such as RG 1.149 serve only to describe specific methods that the NRC has previously identified as constituting acceptable methods of meeting certain regulations. The key point here is that regulatory guidance does not specify the only possible method by which given regulations might be met. Facility license applicants are free to propose alternative methods for meeting NRC regulations that do not follow associated regulatory guidance. But, in so doing, the burden is upon the applicant to demonstrate how the alternative method will meet the associated regulations otherwise addressed by the RG. In utilizing an unendorsed standard, care would need to be exercised to ensure that all required regulations would still be met, including supplementing, or modifying, the approach specified by the unendorsed standard when needed to ensure regulatory compliance.
- SMR (Holtec) stated that Section 5.1 of ANSI/ANS-3.5 implies that a subject matter expert (SME) can verify the simulator configuration. SMR (Holtec) asked what training documentation is required for an SME.
 - NRC staff responded that ANSI/ANS-3.5-2009, which is endorsed by RG 1.149, Revision 4, describes a SME as someone with the education, license, experience, or qualifications to perform assessments within a given area. Since operator licensing is not an option early in the facility licensing process, factors such as education, experience, and qualifications will be important. For example, an individual might have had prior experience as a licensed operator at a different commercial nuclear facility and then completed operator training from the vendor of the new facility (e.g., a vendor “certification”). Summaries of the education, experience, and qualifications of the individuals acting in these SME roles should be made available to NRC reviewers if needed. Fundamentally, SMEs will need to have a sufficient understanding of a design’s components, systems, controls, and operations to be able to implement procedures across normal, abnormal, and emergency operations such that they can identify where issues with human-system interfaces, simulator modeling, etc., exist.
- SMR (Holtec) asked, regarding configuration control, if the NRC will want to see a configuration control program during simulator development. Also, SMR (Holtec) asked whether the NRC will want to see it after HFE verification and validation, but prior to the completion of the plant-referenced simulator.

- NRC staff responded that, in general, there are two broad categories of simulator-related issues that arise during facility licensing for which the NRC staff will need to see processes in place to address simulator performance discrepancies and human engineering discrepancies (HEDs). Each of these involve simulator-related issues that will require evaluation and/or being addressed prior to a facility commencing operations under Part 50. HEDs are identified during verification and validation activities (namely during the integrated system validation stage) and are related to the adequacy of the HFE design. HEDs serve to remedy issues in the control room design that might contribute to human error and are systematically assessed to determine if improvements should be made to the HFE design, provided that such changes are feasible and that modification to the HFE design is the most appropriate approach to addressing the discrepancy. The implementation of an adequate HED process will be needed to support the adequacy of an applicant's overall HFE program. The other broad category, simulator performance discrepancies, are specific to simulator functionality as it relates to the ability of the simulator to replicate reference plant performance and configuration and are identified during vendor and site acceptance testing (e.g., a component/indication not responding as it would in the reference plant, incorrect labeling of indications, incorrect core physics modeling, etc.). These types of performance discrepancies affect the ability of the simulator to meet performance testing acceptance criteria which, in turn, is linked to the ability of a plant referenced simulator to both be declared and satisfactorily inspected.
- SMR (Holtec) asked the NRC staff to discuss load following considerations.
 - NRC staff stated that load following in which nuclear plant output changes directly in response to demands from a grid operator is not currently done in the United States. The regulatory requirements of 10 CFR 50.54, "Conditions of license," paragraphs (i) and (j) place restrictions upon who can conduct operations that result in direct changes to reactor power level and reactivity (i.e., only licensed operators and senior operators), as well as imposing requirements for other types of operations that could affect reactor power level and reactivity. Designers and vendors that are considering the incorporation of load following as part of their concept of operations should engage with the NRC staff during pre-application activities to ensure that the approach used will comply with relevant regulations and, if not, to consider potential exemption requests where they may be both appropriate and consistent with statute. Furthermore, designers and vendors pursuing such discussions should be aware of the interdisciplinary nature of load following considerations (e.g., human factors engineering, operator licensing, instrumentation and controls, fuel qualification/performance, accident analysis, etc.) and be prepared to discuss a broad range of related aspects as part of such preapplication engagements.