July 17, 2017

MEMORANDUM TO: Samuel S. Lee, Chief
Licensing Branch 1
Division of New Reactor Licensing
Office of New Reactors

FROM: Demetrius Murray, Project Manager ***/RA/***
Licensing Branch 1
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SUBJECT: AUDIT REPORT SUMMARY FOR THE REGULATORY AUDIT OF NUSCALE POWER, LLC DESIGN CERTIFICATION APPLICATION HUMAN FACTOR ENGINEERING

The U.S. Nuclear Regulatory Commission (NRC) issued by memorandum dated April 25, 2017, NRC issued an audit plan memo for the regulatory audit of NuScale Power, LLC Design Certification Application Human Factors Engineering Topics (Agencywide Documents Access and Management System Accession No. ML17110A254).

The purpose of the audit was to (1) review related documentation and non-docketed information; (2) verify information; (3) identify information that will require docketing to support the basis of the licensing or regulatory decision; and (4) gain a better understanding of the NuScale design.

All of these objectives were met during or shortly after the audit. The attached report summarizes the staff's activities during audit.

Docket No.: 52-048

Enclosure:
As stated

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SUBJECT: AUDIT REPORT SUMMARY FOR THE REGULATORY AUDIT OF NUSCALE POWER, LLC DESIGN CERTIFICATION APPLICATION HUMAN FACTOR ENGINEERING DATED: 7/17/2017

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HUMAN FACTORS ENGINEERING AUDIT SUMMARY REPORT

Background and Audit Bases

By letter dated December 31, 2016, NuScale Power, LLC (NuScale) submitted a design certification application (DCA) for review (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17013A229). The DCA includes design control document (DCD) Tier 2, Chapter 18, "Human Factors Engineering," which describes the human factors engineering (HFE) program for the NuScale Power Plant (ADAMS Accession No. ML17013A289). Consistent with NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Chapter 18, "Human Factors Engineering," the U.S. Nuclear Regulatory Commission (NRC) staff is using the review criteria in NUREG-0711, Revision 3, to determine whether the NuScale design complies with HFE-related NRC requirements. The HFE Program Review Model described in NUREG-0711 consists of 12 elements (refer to Figure 1-1, "Elements of the HFE program's review model," of NUREG-0711 for additional information).

DCD Tier 2, Section 18.0, "Human Factors Engineering – Overview," states the NuScale HFE program incorporates accepted HFE standards and guidelines including the applicable guidance provided in NUREG-0711, "Human Factors Engineering Program Review Model," Revision 3. NuScale submitted two types of technical reports with the DCA to address the 12 elements in NUREG-0711: implementation plans (IPs) and results summary reports (RSRs). NUREG-0711, Section 1.2.2, "Review Elements," explains that IPs describe processes and methods for performing HFE activities, and RSRs describe the results of performing those activities.

NuScale submitted RSRs for the operating experience review (OER), task analysis (TA), functional requirements allocation (FRA) and function allocation (FA) elements with the DCA. The OER, TA, FRA and FA RSRs contained a limited number of examples of the results and analyses performed for those elements. Therefore, the NRC staff determined an audit was necessary to select and review additional samples of the OER, TA, FRA and FA results and analyses described in the RSRs to independently confirm that acceptable methods were used to develop the results and analyses.

NuScale also submitted an IP for the HFE verification and validation (V&V) element. V&V includes the integrated system validation (ISV), which is an evaluation, using performance-based tests, to determine whether an integrated system's design (i.e., hardware, software, and personnel elements) meets performance requirements and supports the plant's safe operation. At a public meeting with NRC staff and NuScale on February 8, 2016 (ADAMS Accession No. ML16060A221), the NRC staff stated the DCA review could commence if NuScale submitted an IP for the V&V element with the DCA; however, a final safety evaluation for the design cannot be issued until the review of the V&V RSR is complete. The NRC staff also stated that the V&V RSR should be submitted no later than the start of Phase 4 of the design certification review. In a letter dated April 8, 2016, from Mr. Thomas Bergman, NuScale, Vice-President, Regulatory Affairs; to Mr. Frank Akstulewicz, Director, Division of New Reactor Licensing (DNRL), NRC (ADAMS Accession No. ML 16099A270); NuScale stated that NuScale would submit the V&V

RSR prior to Phase 4 of the NRC's review of the NuScale DCA. A letter dated January 14, 2016, from Mr. Frank Akstulewicz, Director, DNRL, NRC; to Mr. Thomas Bergman, NuScale, Vice-President, Regulatory Affairs (ADAMS Accession No. ML15302A516); says that submitting the V&V RSR in Phase 4 of the review could place the design certification review at substantial risk of not being completed according to schedule. For example, if the V&V RSR is not of sufficient quality, or if the V&V activities are not performed in an acceptable manner, then the NRC staff may not be able to complete the review according to the published schedule. NUREG-0711, Section 1.2.2, says:

> An IP review gives the applicant the opportunity to obtain an NRC staff review of, and concurrence with the methodology before the applicant conducts the work associated with the element. This type of review is desirable from the NRC staff's perspective because it offers the staff an opportunity to identify issues with the methodology and provide input early in the analysis or design process when the applicant more easily can address staff concerns than when the element is completed.

The V&V IP (ADAMS Accession No. ML16364A348) says, "…the ISV scenarios and test plan will be available for review or audit by the NRC sufficiently before the conduct of ISV so that comments or concerns can be adequately addressed prior to commencing ISV." Therefore, this audit also provided the opportunity for the NRC staff to review the scenarios and the ISV test plan to identify any issues with NuScale's methodology so that they may be addressed prior to the conduct of the ISV and the other V&V activities.

Audit Activities

The NRC staff developed the following audit objectives:

- **Objective 1:**

  Verify the scenarios selected for V&V activities conform to acceptance criteria in NUREG-0711, "Human Factors Engineering Program Review Model," Revision 3, Section 11.4.1, "Sampling of Operational Conditions."

- **Objective 2:**

  Verify the ISV methodology conforms to acceptance criteria in NUREG-0711, Section 11.4.3.1, "Validation Team," and Section 11.4.3.6, "Test Design."

- **Objective 3:**

  Verify the results of the functional requirements analysis (FRA)/ FA described in DCD Tier 2, Section 18.3.3, "Results," were generated using a method that conforms to NUREG-0711, Section 4.4, "Functional Requirements Analysis and Function Allocation."

- **Objective 4:**

  Verify the results of the TA described in DCD Tier 2, Section 18.4.3, "Results," were generated using a method that conforms to NUREG-0711, Section 5.4, "Review Criteria." Additionally, the NRC staff wanted to gain an understanding of the tasks

allocated to the licensed operators during refueling operations when operations are performed outside of the main control room (MCR) as described in DCD Tier 2, Section 18.4.1, "Objectives and Scope."

- **Objective 5:**

  Verify the results of the OER described in Section 18.2.3, "Results," were generated using a method that conforms to NUREG-0711, Section 3.4, "Review Criteria."

To accomplish the audit objectives, the NRC staff reviewed a sample of the non-docketed OER, TA, FRA and FA analyses contained in NuScale's HFE databases and discussed the analyses with NuScale staff. The NRC staff used the guidance in NUREG-0711, Section 3.4.1, "Scope," and Section 5.4, "Review Criteria," Criterion 1, as well as guidance in NUREG/CR-7202, "NRC Reviewer Aid for Evaluating the Human-Performance Aspects Related to the Design and Operation of Small Modular Reactors," which identifies human-performance issues unique to small modular reactors, to select analyses from the HFE databases for review.

Additionally, the NRC staff reviewed the following proprietary documents in NuScale's Electronic Reading Room:

- NuScale System Master Task List, May 4, 2017
- PL-1102-53167, Integrated Systems Validation Test Plan, Revision 0
- RP-0415-13407, Human System Interface Design and Validation Process, Revision 1
- RP-0915-17295, NuScale Plant Notifications Management, Revision B
- RP-1215-19690, Concept of Automation, Revision A
- ISV Scenario #1 Basis Document, Original Revision
- ISV Scenario #2 Basis Document, Original Revision
- ISV Scenario #3 Basis Document, Original Revision
- ISV Scenario #4 Basis Document, Original Revision
- ISV Scenario #5 Basis Document, Original Revision
- ISV Scenario #6 Basis Document, Original Revision
- ISV Scenario #7 Basis Document, Original Revision
- ISV Scenario #8 Basis Document, Original Revision
- ISV Scenario #9 Basis Document, Original Revision
- ISV Scenario #10 Basis Document, Original Revision
- ISV Scenario #11 Basis Document, Original Revision
- ISV Scenario #12 Basis Document, Original Revision

Audit Results

Objective 1:

NUREG-0711, Section 11.4.1, "Sampling of Operational Conditions," identifies a method for selecting a range or sample of operational conditions (SOC) to guide the HFE V&V activities (i.e., task support verification, design verification, and ISV). It contains three subsections relevant to V&V activities for a new control room design, which are listed below:

- Subsection 11.4.1.1, "Sampling Dimensions," lists various plant conditions, personnel

- tasks, situational factors, and error forcing contexts known to challenge human. performance that should be included in the SOC.

- Subsection 11.4.1.2, “Identification of Scenarios,” contains guidance for combining the sampling dimensions to develop a set of V&V scenarios to guide the V&V activities.

- Subsection 11.4.1.3, “Scenario Definition,” contains guidance for the detailed development of the V&V scenarios.

The NRC staff reviewed the Integrated Systems Validation Test Plan and found that it listed all of the sampling dimensions in NUREG-0711, Subsection 11.4.1.1, as the dimensions that will be included in the SOC. The Integrated Systems Validation Test Plan also contains the same guidance for identifying scenarios and defining the scenarios contained in NUREG-0711, Subsections 11.4.1.2 and 11.4.1.3.

The NRC staff also reviewed 12 ISV scenario basis documents, which NuScale explained will be used to develop the detailed scenario guides. The NRC staff observed that the scenario basis documents identify the sampling dimensions associated with each event included in the scenarios. The NRC staff noted that one scenario included an event that was identified as producing varying workload (WL) conditions, but it was not clear how the event produced such a condition. Another scenario identified an event as a task that was not well-defined by procedures (i.e., a knowledge-based task), but it was not clear to the NRC staff how the event included knowledge-based tasks. The NRC staff asked NuScale to describe how error-forcing contexts and tasks that are not well-defined by procedures and were selected and incorporated into the scenarios. As a result of the discussion, the NRC staff gained an understanding of the bases for selecting particular events for each scenario. The NRC staff concluded that the method described in the Integrated Systems Validation Test Plan and the scenario descriptions contained in the scenario bases documents will provide for V&V scenarios that conform to NUREG-0711, Section 11.4.1, “Sampling of Operational Conditions.”

Objective 2:

The NRC staff reviewed the ISV test method described in the Integrated Systems Validation Test Plan and in the V&V IP. The NRC staff and NuScale discussed the following issues related to the composition of the validation team, test procedures, and validation conclusions:

Validation Team

Criterion 11.4.3.1 in NUREG-0711 states,

> The applicant should describe how the team performing the validation has independence from the personnel responsible for the actual design. Additional Information: The members of the validation team should have no responsibility for the design; i.e., they should never have been part of the design team. While they may work for the same organization, their responsibilities must not include contributions to the design, other than validating it.

The V&V IP, Section 4.1, “Validation Team,” says that the validation team members can be selected from the HFE Design Team. Including members of the HFE Design Team on the Validation Team does not conform to Criterion 11.4.3.1. The NRC staff explained that the main

intent of Criterion 11.4.3.1 is to ensure that bias is minimized when the validation team members collect data, analyze the data, and decide whether design changes are necessary to resolve human engineering discrepancies. The NRC staff also said that bias cannot be eliminated from personnel who have been responsible for the design, and therefore it is necessary to ensure that team members with independence from the HFE Design Team are included on the validation team. The NRC staff said that a request for additional information (RAI) will be issued for NuScale to address this issue.

Test Procedures

NUREG-0711, Section 11.4.3.5, "Performance Measurement, explains that diagnostic performance measures are used to better understand personnel performance and to facilitate the analyses of errors and human engineering discrepancies. Diagnostic performance measures include situation awareness (SA) and WL. The V&V IP, Section 4.5.2.1, "Collection Methods," says SA and WL questionnaires will be administered to the ISV test participants at the end of the scenarios. The NRC staff and NuScale discussed the timing for administering the SA and WL questionnaires. The NRC staff explained that measuring SA and WL at multiple times during the ISV scenarios provides greater diagnostic value than measuring SA and WL following completion of the scenarios, when responses from test personnel may be most reflective of the activities they performed at the end of the scenario. Additionally, measuring SA only at the end of the scenario does not allow for assessment of the test participants' ability to project into the future, which is one of the three levels of SA. The NRC staff said an RAI will be issued to address this issue.

Validation Conclusions

The V&V IP, Section 4.6.1, "Scenario Sequencing," says a minimum of two operating crews will perform each scenario, and the Integrated Systems Validation Test Plan describes the conditions that require more than two crews to perform a given scenario. The NRC staff said that other applicants proposed using or used more than a minimum of two crews to perform each scenario. Performing more scenario trials provides the opportunity for additional users to interact with the integrated system, which provides more opportunities to identify aspects of the design that do not support the safe operation of the plant. Running fewer scenario trials limits the opportunity to identify aspects of the system that do not support safe operation of the plant and therefore provides less of a basis for determining that performance of the integrated system will be acceptable. The NRC staff referred to Criterion 11.4.3.8, "Validation Conclusions," in NUREG-0711, which says, "The applicant should document the statistical and logical bases for determining that the performance of the integrated system is, and will be acceptable." The NRC staff said that an RAI will be issued for NuScale to explain the logical bases for determining the performance of the integrated system will be acceptable if a minimum of two trials will be performed.

Objective 3:

The NRC staff discussed how NuScale identified and verified the safety functions during the FRA process. NuScale explained that identification and selection of safety functions resulted from activities performed as part of the Design-Reliability Assurance Program (D-RAP) described in DCD Tier 2, Chapter 17.4, "Reliability Assurance Program," and the results of the D-RAP activities were inputs to the FRA.

The NRC staff sampled the results of the FA process for the containment flood and drain system (CFDS), which is a plant system that is unique to the NuScale design. The NRC staff observed that functions associated with operating the CFDS were broken down into discrete tasks, and a level of automation was assigned to each task. Justification was provided for the level of automation that was selected for each task. The NRC staff observed that the justifications were reasonable. For example, some tasks will be automated because manual task performance would require the operators to perform repetitive actions that could increase the opportunity for errors to be made.

Additionally, the NuScale staff explained that the HFE Design Team is in the process of coordinating with other design staff at NuScale to confirm that levels of automation selected during FA can be achieved given the constraints imposed by the plant system designs and the instrumentation and controls system design. The NRC staff concluded FA is ongoing.

Objective 4:

The NRC staff used the NuScale System Master Task List dated May 4, 2017, to identify a sample of tasks included in the scope of tasks described in NUREG-0711, Criterion 5.4(1). The NRC staff reviewed the results of analyses performed for a sample of six tasks. For three of the tasks, the NRC staff observed that the results addressed, at a minimum, all of the topics listed in NUREG-0711, Table 5-1, "Task Considerations." For the other three, the NRC staff observed that the tasks were still in the process of being analyzed.

The NRC staff asked NuScale to characterize the maturity of the TA results that were used as an input to the development of scenarios that were administered during the staffing plan validation (SPV)[1] and the design of human system interface (HSIs) that were used during the SPV. NuScale staff explained that to prepare for the SPV, the HFE Design Team analyzed tasks for the major plant systems that operators will interact with during plant operation (e.g., the emergency core cooling system, the reactor coolant system, and the containment flood and drain system), and the HFE Design Team identified what the team members considered to be the most challenging and WL-intensive tasks associated with operating those plant systems. The HFE Design Team then developed the simulation facility to be able to run scenarios that would require the test participants to perform the challenging and WL-intensive tasks during the SPV scenarios. The NRC staff observed that the sampled tasks that had been identified in the database but have not yet been analyzed were associated with auxiliary plant systems (e.g., the pool cleanup system), or were tasks that will be performed during normal operations, or are not required to be performed within restrictive time limits (e.g., the task may be performed within hours of an event). The NRC staff concluded TA is ongoing.

Additionally, NuScale explained the concept for refueling and described the tasks that will be performed outside of the MCR during refueling. The NRC staff also found that one of the ISV scenarios will include tasks associated with refueling. The NRC staff gained an understanding of the tasks performed outside of the control room by licensed operators during refueling operations.

Objective 5:

The NRC staff observed that NuScale had over 700 records in the OER database. NuScale explained that applicable OE from industries other than nuclear are included in the review

1 The Audit Summary Report dated November 30, 2016 (ADAMS Accession No. ML16259A110), documents the NRC staff's audit of the SPV.

because of the lack of OE in the nuclear industry related to the operation of small modular reactors. NuScale also explained that there are some open items in the human factors issue tracking system that resulted from the OER. These open items are in the process of being addressed. The NRC staff concluded OER is ongoing.

Conclusion

The NRC staff conducted an audit exit brief with NuScale staff on May 10, 2017. The NRC staff stated they were able to accomplish the audit objectives by reviewing documents in NuScale's Electronic Reading Room, sampling analyses contained in the HFE databases, and by having discussions with NuScale staff. The NRC staff gained an understanding of the methods NuScale is using to develop the ISV scenarios and to conduct OER, FRA, FA, and TA. Also, the NRC staff said all of the samples of the OER, FRA, FA, and TA analyses that the staff reviewed and that were found to be complete conformed to guidance in NUREG-0711.
The NRC staff said that some samples of OER, FRA, FA and TA analyses were found to still be in progress. NUREG-0711, Section 11.4.3.3, "Validation Testbeds," Criterion 1 says the testbed used for ISV should represent completely the integrated system, and it should include HSIs and procedures not specifically required by the test scenarios. The results of OER, FRA, FA and TA are input to the design of HSIs and procedures. Accordingly, the NRC staff stated that these activities need to be complete prior to the NuScale ISV.

The NRC staff informed NuScale on June 20, 2017, that the NRC staff will conduct a follow-up audit of the OER, FRA, FA, and TA results when OER, FRA, FA, and TA are complete such that (1) NuScale has resolved open items in the OER database, (2) identified functions have been allocated, and (3) tasks associated with the plant systems and events described in the DCD have been identified and analyzed if the tasks are in the scope of tasks to be analyzed. A follow-up audit will allow the NRC staff to select samples from the complete set of results and verify that the complete set of analyses conform to the guidance in NUREG-0711. The NRC staff will conduct the follow-up audit when NuScale informs the NRC staff that OER, FRA, functional requirement, and TA are complete. Considering the schedule for the completion of HFE activities that NuScale discussed during the May 9-10, 2017 audit, the NRC staff expects to conduct the follow-up audit sometime between late 2017 and mid-2018. The audit should be scheduled with adequate time in advance of the ISV to allow for resolution of any issues that may be identified during the audit and the ISV.