RAIO-0118-57981

January 02, 2018

Docket No. 52-048

U.S. Nuclear Regulatory Commission
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SUBJECT: NuScale Power, LLC Response to NRC Request for Additional Information No. 278 (eRAI No. 9123) on the NuScale Design Certification Application

REFERENCE: U.S. Nuclear Regulatory Commission, "Request for Additional Information No. 278 (eRAI No. 9123)," dated November 03, 2017

The purpose of this letter is to provide the NuScale Power, LLC (NuScale) response to the referenced NRC Request for Additional Information (RAI).

The Enclosure to this letter contains NuScale's response to the following RAI Question from NRC eRAI No. 9123:

- 18-12

This letter and the enclosed response make no new regulatory commitments and no revisions to any existing regulatory commitments.

If you have any questions on this response, please contact Steven Mirsky at 240-833-3001 or at smirsky@nuscalepower.com.

Sincerely,

Zackary W. Rad
Director, Regulatory Affairs
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Enclosure 1: NuScale Response to NRC Request for Additional Information eRAI No. 9123

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NuScale Response to NRC Request for Additional Information eRAI No. 9123

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Response to Request for Additional Information
Docket No. 52-048

eRAI No.: 9123
Date of RAI Issue: 11/03/2017

NRC Question No.: 18-12

REGULATORY BASIS

Title 10 of the Code of Federal Regulations (10 CFR) Section 52.47(a)(8) requires an applicant for a design certification to provide a final safety analysis report (FSAR) that must include the information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v). Specifically, 10 CFR 50.34, in part, requires that applicants design the main control room representing state-of-the-art human factors principles.

Chapter 18, “Human Factors Engineering,” of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” identifies NUREG-0711, "Human Factors Engineering Program Review Model” as the source of acceptance criteria the staff uses to evaluate whether an applicant meets the regulation.

BACKGROUND INFORMATION

HUMAN FACTORS REGULATORY GUIDANCE IN NUREG-0711

NUREG-0711 provides acceptance criteria for 12 human factors program elements that the NRC considers to be part of an acceptable human factors program. The various analyses described in NUREG-0711 help to form a systematic and scientific basis for different design and evaluation assumptions used in the NUREG-0711 process. For instance Section 11.4.3.3, “Validation Testbeds,” Criterion 1 states, “The applicant’s testbed represent completely the integrated system, and it should include human- system interfaces (HSI) and procedures not specifically required by the test scenarios.” The results of analytical processes described in NUREG-0711 such as operating experience review (OER), functional requirements analysis & function allocation (FRA/FA), task analysis (TA), and treatment of important human actions (TIHA) are inputs to the design of HSI and procedures. Therefore, these activities need to be complete prior to conducting ISV activities in order to ensure adequate test fidelity.

NUREG-0711 PRODUCT SUBMITTALS

Each NUREG-0711 program element contains descriptions of appropriate applicant products and submittals. There are two types of submittals described in NUREG-0711: implementation

plans and results summary reports (RSRs). The process allows for applicants to submit implementation plans for work that is not yet complete at the time of the design certification application. Implementation plans describe detailed methods that the applicant intends to follow while conducting human factors analysis, design, and evaluation work. Implementation plans are to be followed by an RSR when the design work is ultimately finished.

Alternatively, an applicant can submit an RSR at the time of the design certification application. RSRs describe the results of the human factors analyses and design activities along with a summary of the methods used to generate these results.

The NRC expectation for an RSR is that the work associated with a particular NUREG-0711 element should be complete at the time of submittal. NUREG-0711 uses language to specifically call out those areas that must be complete in an RSR using terminology like: "complete", "results should be enumerated" (which implies that a complete list of results should be provided for review), or use other similar language. For instance, Section 3.3 of NUREG-0711 indicates that an applicant submitting a results summary report should include an "*enumeration* of open issues still being tracked in the HFE issues-tracking system." An understanding of unresolved issues is critical to both the designer and to the regulator while considering design assumptions, human performance evaluation techniques, and other human factors considerations.

DESCRIPTION OF PROBLEM

In a letter dated, April 8, 2016, NuScale described a proposed approach to submitting the Chapter 18 portion of the design certification application (DCA). This letter describes the contents of RSRs that were proposed to be submitted as part of the DCA. The letter states, "Unless otherwise noted, the contents of the RSRs will be in accordance with the applicable guidance of NUREG-0711" (see ADAMS Accession No. ML16099A270). The letter indicated that RSRs would be provided for most NUREG- 0711 elements at the time of the DCA with exception of the RSR for the human factors verification and validation element which would be submitted prior to the NRC phase 4 review. NRC has accepted this as an acceptable strategy.

NuScale submitted a series of RSRs summarizing the work that has been done to support NUREG-0711 human factors design efforts as part of the DCA. The staff found that some samples of results were provided in the DCA. The staff requested an audit to independently select samples of the results to determine whether the results conformed to the guidance in NUREG-0711.

On May 9-10, 2017, NRC staff conducted an audit of the results of several human factors analyses (OER, FRA/FA, TA, and TIHA) used in support of the Chapter 18 submittal (ADAMS Accession No.ML17181A415). Staff reviewed the contents of several NuScale databases in an attempt to confirm that the sample of results provided in the RSRs were truly representative of a full set of analytical results. Staff identified multiple areas where human factors analyses are not yet complete. Therefore, staff could not yet conclude that the results described in the RSRs are representative of the full set of results (which do not yet exist).

NRC staff discussed the issue with NuScale staff during the audit as well as during a

clarification call on June 20, 2017. A schedule to complete all analyses was discussed.

POTENTIAL IMPACT ON PROJECT & NRC REVIEW SCHEDULE

Based on the schedule discussion described above, the applicant's schedule appears to support the applicant's human factors verification and validation activities. This schedule, if adhered to, should ensure that the analyses are complete prior to the integrated system validation (as is expected based on NUREG-0711). It appears as if the applicant's project schedule is suitable to meet their needs. However, this strategy poses new potential schedule threats to the NRC review.

1. The NRC expected to complete confirmation that the analytical human factors work (OER, FRA/FA, TA, & TIHA) was complete and consistent with NUREG-0711 during the May 2017 audit. Staff were unable to complete this process, therefore a follow-up audit will need to be scheduled when the analyses are complete.
2. NRC staff have the option to use "open items" in the Phase 2 safety evaluation report. As a result of the incomplete human analyses, the staff will need to track many of these as open items into the phase 2 of the review. Open items do not necessarily pose a problem for the review, however many open items that need to be closed late in the review process may require NRC staff to do significant review late in the review process (Phase 4 safety evaluation). Significant issues that arise late in the review may threaten project review schedules.
3. The audit (described in point 1) and the closing of open items (described in point 2) will now need to occur within a small window of time just before the Phase 4 technical review due date. NRC resources were already allocated to support verification and validation activities during this time of the review, consistent with the April 8, 2016 letter. Additional NRC resources may be needed to support this increase in workload and/or adjustments to the schedule may need to be made if at some point NuScale can no longer support this schedule due to unforeseen issues.

HOW TO RESOLVE THE ISSUE

Conducting an additional audit and using open items in the staff safety evaluation report may provide an acceptable path to success within the scope of the NRC review process. However, additional information is necessary to help the NRC allocate resources to support the unexpected issues with the review.

Specifically:

1. The scope of the remaining work should be identified. Provide a list all specific human factors analyses that are not yet completely entered into the corresponding OER, FRA/FA, and TA databases. These analyses should support the assumptions and design decisions used in creating the final MCR design, procedures, and training that will ultimately be used in the ISV. (See figure 1-1 from NUREG-0711 illustrates how the human factors analyses are intended to support the design process.)
2. Provide a schedule for the completion of outstanding analysis work which includes all of the items identified in item 1 above. Include expected dates for completion of each

NUREG-0711 program element.

3. Propose approximate dates for future regulatory interactions which will be conducted by the NRC.
    - NRC audit(s) of the complete OER, FRA/FA, TA, & TIHA analyses
    - NRC audit of the human factors verification and validation process (staff may also consider HSI design, Staffing and Qualifications, Procedures, and Training at this time)
    - Potential HED Resolution Audit –staff may need to review the resolutions to issues identified during the ISV Please provide additional information addressing the points listed above.

Please provide additional information addressing the points listed above.

NuScale Response:

Part 1 of the RAI Response

The “Planning and Analysis” portion of the HFE program, as described in NUREG-0711, Figure 1-1, Elements of the HFE program’s review model, includes:

- HFE Program Management
- Operating Experience Review (OER)
- Functional Requirements Analysis and Function Allocation (FRA/FA)
- Task Analysis (TA)
- Staffing and Qualification (S&Q)
- Treatment of Important Human Actions (TIHA)

All of the analyses related to the elements listed above and in support of licensed operators in the main control room during normal, abnormal, and emergency operating conditions are complete, with the exception of 15 OER items.

The OER database contains a broad scope of events that were evaluated with respect to the NuScale design. Entries that are considered “in-scope” for this RAI question are those entries that are deemed applicable to the NuScale design and whose evaluation indicates resolution through a physical plant or HSI design solution. For example, an OE item that is addressed by the functionality of the computer-based procedure HSI would be considered in-scope, whereas an OE item that is addressed by training or procedural content would not be considered in-scope since Training Program Development and Procedure Development are COL action items per FSAR Sections 13.2 and 13.5, respectively. Therefore, there may be open items in the OER or HFEITS databases with resolution assigned to the COL applicant, but those entries are not considered in this response.

Part 2 of the RAI Response

All required human factors analyses associated with the “Planning and Analysis” portion of the HFE program are complete, with the exception of 15 OER items. The open OER items will be closed by June 4, 2018.

The following HFE program elements are complete:

- HFE Program Management
- Functional Requirements Analysis and Function Allocation (FRA/FA)
- Task Analysis (TA)
- Staffing and Qualification (S&Q)
- Treatment of Important Human Actions (TIHA)
- Human-System Interface Design (HSI Design)

The Human Factors Verification and Validation (HF V&V) element is the final HFE element for which NuScale will submit an RSR. This element is scheduled for completion before 8/28/2019, the beginning of the DCA review Phase 4, with the submittal of the HF V&V RSR.

Part 3 of the RAI Response

The following dates are proposed for follow-up audit activities:

- NRC audit(s) of the complete OER, FRA/FA, TA, & TIHA analysis - March 5, 2018
- NRC audit of the human factors verification and validation process (staff may also consider HSI design, Staffing and Qualifications, Procedures, and Training at this time) - June 4, 2018
- Potential HED Resolution Audit - staff may need to review the resolutions to issues identified during the ISV - October 22, 2018

Impact on DCA:

There are no impacts to the DCA as a result of this response.