RAIO-0518-59812

May 03, 2018

Docket No. 52-048

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

SUBJECT: NuScale Power, LLC Response to NRC Request for Additional Information No. 380 (eRAI No. 9394) on the NuScale Design Certification Application

REFERENCE: U.S. Nuclear Regulatory Commission, "Request for Additional Information No. 380 (eRAI No. 9394)," dated March 09, 2018

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

The Enclosures to this letter contain NuScale's response to the following RAI Questions from NRC eRAI No. 9394:

- 18-16
- 18-17
- 18-18

Enclosure 1 is the proprietary version of the NuScale Response to NRC RAI No. 380 (eRAI No. 9394). NuScale requests that the proprietary version be withheld from public disclosure in accordance with the requirements of 10 CFR § 2.390. The enclosed affidavit (Enclosure 3) supports this request. Enclosure 2 is the nonproprietary version of the NuScale response.

This letter and the enclosed responses 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
NuScale Power, LLC

Distribution: Samuel Lee, NRC, OWFN-8G9A
Prosanta Chowdhury NRC, OWFN-8G9A
Demetrius Murray, NRC, OWFN-8G9A

Enclosure 1: NuScale Response to NRC Request for Additional Information eRAI No. 9394, proprietary

Enclosure 2: NuScale Response to NRC Request for Additional Information eRAI No. 9394, nonproprietary

Enclosure 3: Affidavit of Zackary W. Rad, AF-0518-59813

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Enclosure 1:

NuScale Response to NRC Request for Additional Information eRAI No. 9394, proprietary

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Enclosure 2:

NuScale Response to NRC Request for Additional Information eRAI No. 9394, nonproprietary

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

eRAI No.: 9394
Date of RAI Issue: 03/09/2018

NRC Question No.: 18-16

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). Section 10 CFR 50.34(f)(2)(iii) requires an applicant to "Provide, for Commission review, a control room design that reflects state-of-the-art human factor principles prior to committing to fabrication or revision of fabricated control room panels and layouts." Chapter 18, "Human Factors Engineering," of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," and NUREG-0711, "Human Factors Engineering Program Review Model," identify criteria the staff uses to evaluate whether an applicant meets the regulation. The applicant stated in the FSAR, Tier 2, Section 18.0, "Human Factors Engineering - Overview," that its human factors engineering (HFE) program incorporates accepted HFE standards and guidelines including the applicable guidance provided in NUREG-0711, Revision 3.

Question

Criteria 11.4.2.2 (4) and 11.4.2.3 (4) in NUREG 0711, Section 11.4 addresses HED Documentation. These criteria state:

11.4.2.2 (4) "HED Documentation – The applicant should document HEDs in terms of the HSI involved, and how its characteristics depart from a particular guideline."

11.4.2.3 (4) "HED Documentation – The applicant should document HEDs to identify the HSI, the tasks affected, and the basis for the deficiency (what aspect of the HSI was identified as not meeting task requirements).

While the staff understands, via information provided in Section 5.0 of the V&V IP, that HEDs are identified and tracked in the "Human Factors Engineering Issues Tracking System (HFEITS) database, it is not clear to staff the specific information captured for each HED. Please clarify whether the information cited in the above criteria are captured in HFEITS for each HED.

NuScale Response:

The specific information identified in NUREG-0711 Criteria 11.4.2.2 (4) and 11.4.2.3 (4) is captured and documented in the HFEITS database for each HED in accordance with the below guidance.

Human Factors Engineering Program Management Plan, RP-0914-8534, Section 5.4.7 Human Engineering Discrepancy Resolution states:.

> "A human engineering discrepancy (HED) is an issue usually discovered during the verification and validation phase of the HFE program and may require engineering changes and verification. HEDs are identified as personnel task requirements (as defined in the task analysis) that are not fully supported by the human system interface (HSI), and the presence of HSI components that may not be needed to support personnel tasks. HEDs are also identified if the design is inconsistent (does not accommodate human capabilities and limitations) with HFE guidelines, such as NUREG-0700 or any NuScale HSI style guides."

NuScale's procedural guidance for tracking human factors engineering issues is as follows:

- Upon initial entry of an issue into HFEITS, the initiator enters the title, date, and description of issue.
- For each HFE issue, the following information will be entered into the HFEITS record before closure:
    - issue date, source of issue, and sufficient detail to evaluate for proposing a solution
    - any supporting information such as attachments documenting the issue
    - assigned issue owner and evaluator or SME
    - whether or not the issue involves a human engineering discrepancy
    - priority for completion of design change
    - proposed resolution
    - actions taken (i.e., any programmatic or administrative changes determined appropriate to address larger issue); this includes notes if HFEITS assignee changes and/or if individual steps are completed by separate SMEs
    - NuScale documentation of actual resolutions (i.e., changes to design)
    - HFEITS committee acceptance or rejection and detailed justification
    - affected document(s), HSIs, or systems

NuScale's human factors engineering issues are further tracked and categorized as stated below:

"HFE V&V HEDs are categorized based on their principal impact on:

- personnel tasks and functions
- plant systems
- human-system interface feature
- individual HSI component
- operating procedure
- extent of condition and causal effect across the various HSI design features and functions are assessed as part of the HED process. Extent of condition determination considers cumulative or combined effects of multiple HEDs and human engineering discrepancies that may represent a broader issue.
- extent of condition evaluation includes questionnaires and debriefings that include explicit questions for test participants about issues that appear to represent larger underlying problems with the HSI design administrator and observers that review each HED against other HEDs to determine relationships and overlaps between issues. The HFE design team independently reviews each HED to determine relationships and overlaps between issue."

Impact on DCA:

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

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

eRAI No.: 9394
Date of RAI Issue: 03/09/2018

NRC Question No.: 18-17

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). Section 10 CFR 50.34(f)(2)(iii) requires an applicant to "Provide, for Commission review, a control room design that reflects state-of-the-art human factor principles prior to committing to fabrication or revision of fabricated control room panels and layouts." Chapter 18, "Human Factors Engineering," of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," and NUREG-0711, "Human Factors Engineering Program Review Model," identify criteria the staff uses to evaluate whether an applicant meets the regulation. The applicant stated in the FSAR, Tier 2, Section 18.0, "Human Factors Engineering - Overview," that its human factors engineering (HFE) program incorporates accepted HFE standards and guidelines including the applicable guidance provided in NUREG-0711, Revision 3.

NUREG–0711, Section 11.4.4 (4), states, "Design Solution Evaluation – The applicant should evaluate design solutions to demonstrate the resolution of that HED and to ensure that new HEDs are not introduced. Generally, the evaluation should use the V&V method that originally detected the HED."

In Section 5.1 of the V&V IP the applicant explains that after an HED has been prioritized, it is routed to the HFE design team, simulator review board, or both as appropriate for resolution. Please clarify how (i.e. the method by which) design solutions are evaluated to ensure HEDs are resolved and no new HEDs are introduced.

NuScale Response:

RP-0914-8543, Human Factors Verification and Validation Implementation Plan (V&V IP), Section 5.3, Design Solution Testing, has been added to address actions associated with how design solutions are dispositioned for human engineering discrepancies (HEDs). In summary, design solutions are verified to be acceptable using the same V&V method that originally

detected the issue. Because design solution impact varies, engineering judgment is applied to ensure a thorough and appropriate test is conducted. Section 5.3 includes criteria used in applying this judgment. Acceptability of a design solution is based on performance data and not subjective judgments.

A test, as prescribed in Section 5.3 of the V&V IP, is performed to evaluate the design solution. Performance data is collected and compared to objective acceptance criteria. ISV monitoring techniques are utilized during the test to ensure no new HEDs are introduced as a result of the original issue resolution. If a new HED is identified, then either a different resolution is identified and tested or the same process is utilized to resolve the new HED.

Impact on DCA:

RP-0914-8543, Human Factors Verification and Validation Implementation Plan, has been revised as described in the response above and as shown in the markup provided with this response.

Additional Information:

New Section 5.3, Design Solution Testing, was added to the Human Factors Verification and Validation Implemntation Plan.

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Data and data-analysis tools (e.g., equations, measures, spreadsheets, expert opinions, resulting HEDs) are documented for subsequent audit and application during design integration and/or human performance monitoring HFE program elements. Individual HFEITS items are maintained as auditable records in the HFEITS database.

5.3 Design Solution Testing

Generally, design solutions will be verified to be acceptable using the same V&V method that originally detected the issue. For example, if an HED-1 is identified during performance of an ISV scenario, a similar scenario would be run to verify the solution was acceptable. Because the impact of design solutions vary widely this general practice may be adjusted using engineering judgment to ensure a thorough and appropriate test is conducted. The following elements are considered when making this judgment:

- number of procedures affected
- number of HSIs affected
- complexity of the condition under which the design solution is used
- uniqueness of the design solution

If scenario testing is used, one scenario run is sufficient, provided that:

- the scenario tests all aspects of design solution and
- all performance data is collected

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

eRAI No.: 9394
Date of RAI Issue: 03/09/2018

NRC Question No.: 18-18

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). Section 10 CFR 50.34(f)(2)(iii) requires an applicant to "Provide, for Commission review, a control room design that reflects state-of-the-art human factor principles prior to committing to fabrication or revision of fabricated control room panels and layouts." Chapter 18, "Human Factors Engineering," of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," and NUREG-0711, "Human Factors Engineering Program Review Model," identify criteria the staff uses to evaluate whether an applicant meets the regulation. The applicant stated in the FSAR, Tier 2, Section 18.0, "Human Factors Engineering - Overview," that its human factors engineering (HFE) program incorporates accepted HFE standards and guidelines including the applicable guidance provided in NUREG-0711, Revision 3.

NUREG–0711, Section 11.4.4 (5), states, "HED Evaluation Documentation – The applicant should document each HED, including:

- the basis for not correcting an HED
- related personnel tasks and functions
- related plant systems
- cumulative effects of HEDs
- HEDs as indications of broader issues"

In Section 5.0 of the V&V IP, the applicant explains that HFE issues and HEDs are documented and tracked in the Human Factors Engineering Issues Tracking System (HFEITS) database. If an HED is not resolved, "the basis for a decision for accepting an HED without change in the integrated design is documented. It may be based on accepted HFE practices, current published HFE literature, trade-off studies, tests, or engineering evaluations."

Section 5.2 of the V&V IP, the applicant describes how HEDs are categorized based on their impact on:

- personnel tasks and functions
- plant systems
- human-system interface feature
- individual HSI component
- operating procedure

In addition, the applicant describes an extent of condition analysis for HEDs that considers cumulative or combined effects of multiple HEDs and HEDs that may represent a broader issue. While the staff understands that the bulleted information in this criteria are *considered* during the analysis of each HED, it is not clear to the staff whether the information is *documented* in HFEITS (e.g. related task/functions/plant systems) with the exception of the basis for not correcting an HED. Please clarify how and where this information is documented.

NuScale Response:

Human engineering discrepancies (HEDs) are documented in the human factors engineering issues tracking system (HFEITS) database.

A working level HFEITS procedure is used by the NuScale HFE staff to ensure the applicable information related to the five bullets is documented in the HFEITS database. The Human Factors Verification and Validation Implementation Plan (RP-0914-8543) has been revised to reflect this documentation.

Impact on DCA:

RP-0914-8543, Human Factors Verification and Validation Implementation Plan, has been revised as described in the response above and as shown in the markup provided with this response.

Revision History		
Rev	**Date**	**Description**
0	November 18, 2015	Original Issue
1	September 16, 2016	Revised to incorporate NRC comments, on Revision 0, to provide clarification and detail to Human Factors V&V element scope
2	December 2, 2016	Revised to incorporate updates to the Design Verification Methodology (Section 3), ISV (Section 4), and the HED process (Section 5), also added redaction markings
3	July 24, 2017	Revised in response to eRAI 8758. Validation Team (Section 4.1) updated to include additional description on how to mitigate potential test bias. Scenario Sequencing (Section 4.6.1) updated to include a basis for use of a minimum of two test crews.
4	October 30, 2017~~See approval page~~	Revised section 4.1 to state two independent observers will be used and not one
5	See approval page	Added Sections 3.2.3 - 3.2.5 per RAI 9398 18-21 and Section 5.3 per RAI 8758 18-2S2. Revised Section 4.2 per RAI 9414 18-23 and Section 4.1 per RAI 8758 18-2S2. Update to section 5.2 for eRAI 9394 Question 18-18.

The HED is then routed to the appropriate group for resolution. HEDs related to the HSI are sent to the HFE design team, and HEDs related to simulator modeling are sent to the simulator review board. It is possible for HEDs to be routed to both groups.

The HED is then resolved, and the discrepancy entry closed. The HED resolution is reviewed for final closure in the HFEITS database by an HFE Review committee. The HED resolution process is depicted in Figure 5-1.

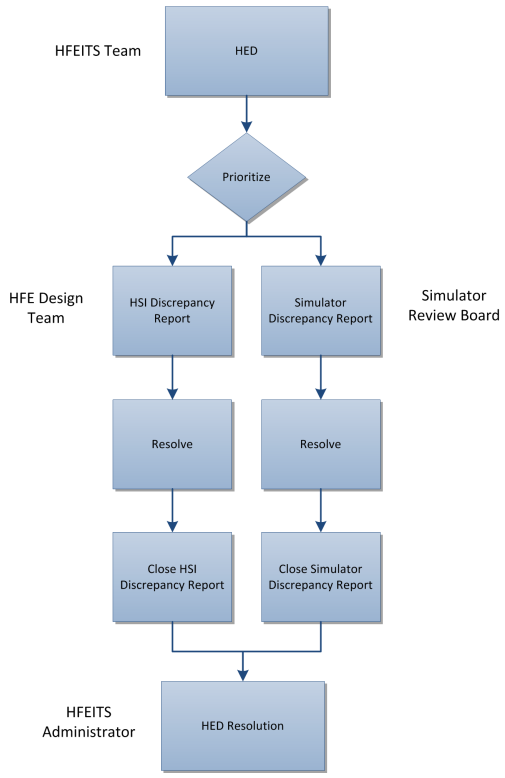

Figure 5-1. Human engineering discrepancy resolution process

5.2 Human Engineering Discrepancy Analysis

HFE V&V HEDs are categorized based on their principal impact on

- personnel tasks and functions
- plant systems
- human-system interface feature
- individual HSI component
- operating procedure

The categorization is documented in the HFEITS database.

Extent of condition and causal effect across the various HSI design features and functions are assessed as part of the HED process and documented in the HFEITS database. Extent of condition determination considers

- cumulative or combined effects of multiple HEDs
- human engineering discrepancies that may represent a broader issue

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}}2(a),(c)

The broad-reaching testing and number of performance measures to be evaluated limit the ability to perform statistical analyses. Testing of multiple scenarios with multiple crews (generally, each crew will develop a different strategy) makes it impractical to make conclusions based on performance of the population or deviations from a norm. Therefore, observer and administrators, test participants, and the Validation Team evaluate any instance where a performance measure is not met to determine causal factors.

- Design-related deficiencies determined for alarms, controls, indications, and procedures are documented in an HED. Any previous HFE program element may need to be evaluated to resolve the deficiency. The HSI design is not considered validated until an HED initiated by pass/fail measures as a result of ISV is resolved.
- Test-related deficiencies are documented in the HFEITS and may result in changes to the test procedure or scenario definition.

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Enclosure 3:

Affidavit of Zackary W. Rad, AF-0518-59813

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NuScale Power, LLC

AFFIDAVIT of Zackary W. Rad

I, Zackary W. Rad, state as follows:

1. I am the Director, Regulatory Affairs of NuScale Power, LLC (NuScale), and as such, I have been specifically delegated the function of reviewing the information described in this Affidavit that NuScale seeks to have withheld from public disclosure, and am authorized to apply for its withholding on behalf of NuScale.
2. I am knowledgeable of the criteria and procedures used by NuScale in designating information as a trade secret, privileged, or as confidential commercial or financial information. This request to withhold information from public disclosure is driven by one or more of the following:
    a. The information requested to be withheld reveals distinguishing aspects of a process (or component, structure, tool, method, etc.) whose use by NuScale competitors, without a license from NuScale, would constitute a competitive economic disadvantage to NuScale.
    b. The information requested to be withheld consists of supporting data, including test data, relative to a process (or component, structure, tool, method, etc.), and the application of the data secures a competitive economic advantage, as described more fully in paragraph 3 of this Affidavit.
    c. Use by a competitor of the information requested to be withheld would reduce the competitor's expenditure of resources, or improve its competitive position, in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
    d. The information requested to be withheld reveals cost or price information, production capabilities, budget levels, or commercial strategies of NuScale.
    e. The information requested to be withheld consists of patentable ideas.
3. Public disclosure of the information sought to be withheld is likely to cause substantial harm to NuScale's competitive position and foreclose or reduce the availability of profit-making opportunities. The accompanying Request for Additional Information response reveals distinguishing aspects about the method by which NuScale develops its human factors engineering.

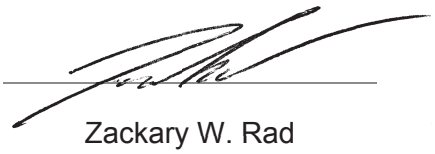
    NuScale has performed significant research and evaluation to develop a basis for this method and has invested significant resources, including the expenditure of a considerable sum of money.

    The precise financial value of the information is difficult to quantify, but it is a key element of the design basis for a NuScale plant and, therefore, has substantial value to NuScale.

    If the information were disclosed to the public, NuScale's competitors would have access to the information without purchasing the right to use it or having been required to undertake a similar expenditure of resources. Such disclosure would constitute a misappropriation of NuScale's intellectual property, and would deprive NuScale of the opportunity to exercise its competitive advantage to seek an adequate return on its investment.

4. The information sought to be withheld is in the enclosed response to NRC Request for Additional Information RAI No. 380, eRAI No. 9394. The enclosure contains the designation "Proprietary" at the top of each page containing proprietary information. The information considered by NuScale to be proprietary is identified within double braces, "{{ }}" in the document.
5. The basis for proposing that the information be withheld is that NuScale treats the information as a trade secret, privileged, or as confidential commercial or financial information. NuScale relies upon the exemption from disclosure set forth in the Freedom of Information Act ("FOIA"), 5 USC § 552(b)(4), as well as exemptions applicable to the NRC under 10 CFR §§ 2.390(a)(4) and 9.17(a)(4).
6. Pursuant to the provisions set forth in 10 CFR § 2.390(b)(4), the following is provided for consideration by the Commission in determining whether the information sought to be withheld from public disclosure should be withheld:
    a. The information sought to be withheld is owned and has been held in confidence by NuScale.
    b. The information is of a sort customarily held in confidence by NuScale and, to the best of my knowledge and belief, consistently has been held in confidence by NuScale. The procedure for approval of external release of such information typically requires review by the staff manager, project manager, chief technology officer or other equivalent authority, or the manager of the cognizant marketing function (or his delegate), for technical content, competitive effect, and determination of the accuracy of the proprietary designation. Disclosures outside NuScale are limited to regulatory bodies, customers and potential customers and their agents, suppliers, licensees, and others with a legitimate need for the information, and then only in accordance with appropriate regulatory provisions or contractual agreements to maintain confidentiality.
    c. The information is being transmitted to and received by the NRC in confidence.
    d. No public disclosure of the information has been made, and it is not available in public sources. All disclosures to third parties, including any required transmittals to NRC, have been made, or must be made, pursuant to regulatory provisions or contractual agreements that provide for maintenance of the information in confidence.
    e. Public disclosure of the information is likely to cause substantial harm to the competitive position of NuScale, taking into account the value of the information to NuScale, the amount of effort and money expended by NuScale in developing the information, and the difficulty others would have in acquiring or duplicating the information. The information sought to be withheld is part of NuScale's technology that provides NuScale with a competitive advantage over other firms in the industry. NuScale has invested significant human and financial capital in developing this technology and NuScale believes it would be difficult for others to duplicate the technology without access to the information sought to be withheld.

I declare under penalty of perjury that the foregoing is true and correct. Executed on 5/3/2018.



Zackary W. Rad