



December 04, 2017

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 Supplemental Response to NRC Request for Additional Information No. 90 (eRAI No. 8758) on the NuScale Design Certification Application

REFERENCES: 1. U.S. Nuclear Regulatory Commission, "Request for Additional Information No. 90 (eRAI No. 8758)," dated July 10, 2017
2. NuScale Power, LLC Response to NRC "Request for Additional Information No. 90 (eRAI No.8758)," dated July 26, 2017

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

The Enclosures to this letter contain NuScale's supplemental response to the following RAI Question from NRC eRAI No. 8758:

- 18-2

Enclosure 1 is the proprietary version of the NuScale Supplemental Response to NRC RAI No. 90 (eRAI No. 8758). 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,

A handwritten signature in black ink, appearing to read "Zackary W. Rad".

Zackary W. Rad
Director, Regulatory Affairs
NuScale Power, LLC

Distribution: Gregory Cranston, NRC, OWFN-8G9A
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Enclosure 1: NuScale Supplemental Response to NRC Request for Additional Information eRAI No. 8758, proprietary

Enclosure 2: NuScale Supplemental Response to NRC Request for Additional Information eRAI No. 8758, nonproprietary

Enclosure 3: Affidavit of Zackary W. Rad, AF-1217-57470



Enclosure 1:

NuScale Supplemental Response to NRC Request for Additional Information eRAI No. 8758,
proprietary



Enclosure 2:

NuScale Supplemental Response to NRC Request for Additional Information eRAI No. 8758,
nonproprietary

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

eRAI No.: 8758

Date of RAI Issue: 07/10/2017

NRC Question No.: 18-2S1

Question 2

Criterion 11.4.3.1 of NUREG 0711 states, "The applicant should describe how the team performing the validation has independence from the personnel responsible for the actual design." Additionally it states, "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."

Section 4.1 of the Human Factors Verification and Validation Implementation Plan (V&V IP) states,

"Validation team members can be selected from the HFE Design Team. There is very low risk of impact to the validity of the ISV [integrated systems validation] results. Objective performance measures and success criteria are developed as part of the methodology...The Validation Team members are trained and qualified to conduct the ISV in an objective and unbiased manner." In addition FSAR Tier 2, Chapter 18, Section 18.10.2.3.1, states, "The test team administers the ISV and collects data via questionnaires, post-scenario debriefing, personal observations...Bias is reduced by the training program applicable to each validation team member; in addition, the test results are obtained by consensus of the test team rather than individual observations."

The staff understands that objective performance and success criteria will be used to determine the results of the ISV; however, questionnaires and personal observations, which are subjective in nature, are also used to collect data and to determine the results and any design changes that may need to be made. The main intent of Criterion 11.4.3.1 of NUREG 0711 is to ensure that bias is reduced to the greatest extent during ISV data collection (e.g. observer notes/evaluations) and when the results of ISV are analyzed and evaluated to determine whether design changes are necessary.

Clarify whether the validation will include members who were not part of the design team
Explain how training and results by consensus minimize bias and ensure objectivity of the validation team members who are part of the HFE Design Team. Also, if any other means will



be established to maximize objectivity, please revise the application to describe them.

NuScale Response:

This response supplements NuScale's RAI response letter RAIO-0717-55049 submitted to the NRC on July 26, 2017 (ML17212A819).

The observation team consists of five individuals; the test lead, and normally two operations-focused, and two HFE-focused individuals. Some validation team members can be selected from the HFE design team but at least two of the observers must have independence from ISV test design. Additional validation team members may contribute at scenario debriefs to provide context or insight to observed behaviors.

In order to mitigate potential bias from observers that have been involved in ISV design activities the following controls are implemented:

- Objective performance measures and success criteria are developed as part of the methodology. The acceptance criteria used to determine priority-one HED issues is completely objective. Subjective measures are intended to be used only to identify lower level issues.
- The methodology, including the detailed scenarios and the ISV test plan, are available for internal or external audit well in advance of the conduct of the ISV.
- The conduct of the ISV is scheduled such that all or any portion is available for internal or external audit during ISV performance.
- The validation team members are trained and qualified to conduct the ISV in an objective manner. This training will include the specific roles of the two independent observers and their importance to mitigate team bias. Additionally, validation team members that have been involved in design activities will receive training on the importance of independent observer input.
- At least two of the observers in each test performance must have independence from the ISV test design.
- At least one internal assessment will be completed during the conduct of the ISV to review the effectiveness of the independent observers and verify compliance with the test plan.

The inclusion of at least two observers during each scenario performance who are independent



from task analysis and ISV and HSI design activities is intended to provide valuable insights while minimizing the potential for design bias.

Additionally, a review of the test results and priority-one HED resolution actions will be performed by an independent individual or group to ensure actions have been properly characterized and dispositioned appropriately. This will be a management review board, an outside consultant or peer group, or a team comprised of individuals within NuScale that have not been involved with task analysis or ISV or HSI design activities.

RP-0914-8543, Human Factors Verification and Validation Implementation Plan was revised to include the requirement for at least two independent observers.

The Integrated System Validation Test Plan was revised to include additional details specified above.

Impact on DCA:

FSAR Section 18.10.4 and the Human Factors Verification and Validation Implementation Plan have been revised as described in the response above and as shown in the markup provided with this response.

- design changes made for individual HEDs and their status.
- compliance of design change with V&V evaluation criteria.
- the basis for not correcting an HED.

18.10.3 Results

Once the V&V activities are completed, the results will be compiled in an RSR. The contents of the RSR will be consistent with the methodology described in Reference 18.10-1 and the applicable NUREG-0711 guidance.

18.10.4 References

RAI 18-1, 18-2, RAI 18-2S1

- 18.10-1 NuScale Power, LLC, "~~Human Factors Engineering~~ Human Factors Verification and Validation Implementation Plan," RP-0914-8543-P, Revision ~~4~~2.
- 18.10-2 ANSI/ANS-3.5-2009, Nuclear Power Plant Simulators for Use in Operator Training and Examination, American National Standards Institute.

4.0 Integrated System Validation

The ISV is the process by which an integrated system design (i.e., hardware, software, and personnel elements) is evaluated using performance-based tests to determine whether it acceptably supports safe operation of the plant. The ISV is undertaken only after HEDs that were identified in the upstream process, including design verification, have been resolved and the resulting changes implemented.

Scenarios are developed using the guidance described in the implementing procedures. Performance measures used for assessing the results of an ISV are summarized in Section 4.5 and further described in implementing procedures.

4.1 Validation Team

Some validation team members can be selected from the HFE design team but at least two of the observers must have independence from ISV test design. ~~Some validation team members can be selected from the HFE Design Team with at least one observer for each test that is selected outside of the design team.~~ Objective performance measures and success criteria are developed as part of the methodology and listed within the scenario guides used for the conduct of ISV tests. Objective performance measures are designed to trigger evaluation of the condition regardless of observation comments, and are purposely set at a low threshold. The methodology, scenarios, ISV test plan, and ISV test performance are available for NuScale management assessment or NRC audit well in advance of or during the conduct of the ISV in order to allow for an outside perspective to detect and influence potential bias concerns. The validation team members are trained and qualified to conduct the ISV in an objective and unbiased manner. A detailed ISV test report is developed which supports the results documented in the V&V RSR; both documents will be submitted to the NRC. The HFE Design Team developing and conducting the ISV is analogous to a commercial nuclear plant's Training Department developing and conducting an NRC license exam or annual requalification exam.

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}}^{2(a),(c)} The observers are trained and qualified using the NuScale training program. At least one of the selected observers in each ISV test performance must have independence from HFE Design Team (i.e. has not been involved in the design, development, or testing of the NuScale HFE program, HSI, or



RAIO-1217-57469

Enclosure 3:

Affidavit of Zackary W. Rad, AF-1217-57470

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 methods by which NuScale develops its human factors verification and validation.

NuScale has performed significant research and evaluation to develop a basis for these methods 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 No. 90, eRAI No. 8758, Question No. 18-2. 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 12/4/2017.



Zackary W. Rad