

September 16, 2011

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

SUBJECT: Request for Additional Information No. 5892 (NRC Project 0769)

REFERENCE: 1) Letter from NRC Requesting Additional Information No. 5892, dated July 25, 2011 (NRC Project 0769)
2) NuScale Topical Report: Quality Assurance Program Description for Design Certification of the NuScale Power Reactor, Revision 0, October 2010 (NP-TR-1010-859-NP)

NuScale hereby submits a response to the Request for Additional Information (RAI) No. 5892, dated July 25, 2011 (Reference 1). The RAI and this response pertain to NuScale Topical Report NP-TR-1010-859-NP (Reference 2). Responses to specific questions from the RAI are provided in Enclosure 1.

During the preparation of the response to this RAI, it was noted that NuScale answered question 17.5-2 of RAI No. 5452 improperly. This led to unnecessary revision of Section 2.3 of the NuScale Topical Report. Instead, the following text should have been added to Section 2.6.1:

“Procedures for design and installation are also reviewed by the quality group to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence.”

The change to Section 2.3 has been reversed and the above text has been added to Section 2.6.1 of the NuScale Topical Report.

NuScale has identified organizational changes to the Topical Report that cannot be completed at this time due to a pending corporate restructuring. Therefore, NuScale is unable to provide a revised Topical Report at this time, but will provide the updated Topical Report when these changes are made.

Questions or concerns may be directed to Derick Botha at (541) 207-3931 or at dbotha@nuscalepower.com.

Sincerely,



Edward G. Wallace
Senior Vice President, Regulatory Affairs

Enclosure 1: NuScale Power, Inc. Responses to NRC RAIs on NP-TR-1010-859-NP, Rev 0.

cc: Michael Mayfield, NRC TWFN-6 E04
Stuart Magruder, NRC, TWFN-9 F27
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Enclosure 1

NuScale Response to Request for Additional Information No. 5892

- **Question 17.5-1**

The NuScale Quality Assurance Program Description (QAPD) commits to implement the quality standards described in NQA-1-2008, Requirement 2, Sections 100 through 500, with the following clarification:

As an alternative to the requirement of NuScale Quality Assurance NQA-1-2008, Requirement 2, Section 303.3, that prospective lead auditors must have participated in a minimum of five audits in the previous three years, the NuScale QAPD states that the prospective lead auditor shall demonstrate his or her ability to properly implement the audit process, as implemented by NuScale, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification.

However, NQA-1-2008, Requirement 2, Section 303.3 provides for participation in independent assessments as another means to satisfy the requisite number of quality assurance audits, and supplies the acceptance criteria for use of these activities toward lead auditor qualification.

As such, the U.S. Nuclear Regulatory Commission (NRC) staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for NuScale given that NQA-1-2008, Requirement 2, Section 303.3, already contains an alternative means for qualifying prospective lead auditors beyond participation in a minimum of five audits in the previous three years. Please provide a justification for this clarification.

NuScale Response

NQA-1-2008 Section 303.3 provides an alternative means to qualifying lead auditors. NuScale will update Section 2.2.6 by removing the clarification and will follow the alternative means provided in Requirement 2, Section 303.3 to qualify lead auditors.

- **Question 17.5-2**

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 4, Sections 100 through 400, with the following clarifications and exceptions:

NQA-1-2008, Requirement 4, Section 203, requires that QA program requirements be specified in procurement documents. The NuScale QAPD will require that procurement documents for commercial grade items that will be procured by NuScale for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

It is unclear to the NRC staff as to whether the above statement is a clarification or an exception to NQA-1-2008, Requirement 4, Section 203. Technical and quality requirements are provided in Sections 202 and 203, respectively, and would be applicable to the dedication of commercial grade items for use as safety-related equipment. In addition, commercial grade items and services are addressed by NQA-1a-2009, Requirement 7, Section 700, and Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services."

As such, it is not clear to the staff why an exception or clarification to NQA-1-2008, Requirement 4, Section 203, is necessary given that provisions regarding the information contained in the clarification/exception are contained elsewhere in NQA-1-2008 and its addenda. Please provide a justification for this clarification.

NuScale Response

There should be no exception or clarification to NQA-1-2008, Requirement 4, Section 203. With the changes to Requirement 7, Section 700, and Subpart 2.14 in NQA-1a-2009 addenda, there is no need for an exception or clarification for commercial grade items. NuScale will remove this exception.

The answer to RAI 5452, 17.5-1b, has changed. The second indented paragraph will be deleted from the document as part of the response to this RAI. NQA-1a-2009, Subpart 2.14, Section 700 provides an exception that allows suppliers to work under NuScale's Quality Assurance Program for services.

- **Question 17.5-3**

As an alternative to NQA-1-2008, Requirement 7, Section 501, in terms of the requirement that documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use, the NuScale QAPD proposes that documents may be stored in approved electronic media under the applicant's or supplier's control and not physically located at the plant site, as long as they are accessible from the respective facility.

Based on the above provision, as well as the statement that the NuScale records management system will provide for timely retrieval of necessary records, the NRC staff determined that this alternative meets 10 CFR Part 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services." Criterion VII requires documentary evidence that items conform to procurement documents be available at the nuclear facility before installation or use. Therefore, this provision, which would allow for accessing and reviewing the necessary procurement documents at the site before installation or use, meets this requirement.

However, the NRC staff notes that NuScale did not include the latter part of the previously NRC approved alternative which states that "following completion of the construction period, sufficient as-built documentation will be turned over to [NuScale] to support operations. The [NuScale] records management system will provide for timely retrieval of necessary records." While the staff understands that the NuScale QAPD is only applicable to activities associated with the design certification of a NuScale Power Reactor, further clarification is necessary regarding the applicability of the second part of the alternative.

As such, please provide verification and/or clarification of whether the secondary clarification stated above is applicable to the NuScale design certification project.

NuScale Response

NuScale has determined that in the Design Certification phase, there is no facility site. Therefore, this alternative does not apply to NuScale in the Design Certification phase and will be removed in its entirety from the Topical Report. NuScale will require procurement documents to be located at NuScale prior to the item being used.

- **Question 17.5-4**

As an alternative to NQA-1a-2009 Addenda, Requirement 7, Section 700, the NuScale QAPD proposes that NuScale will assume 10 CFR Part 21 reporting responsibility for all items and services that NuScale dedicates for use in safety related applications.

The alternative proposed by the NuScale QAPD, as written, is unacceptable to the NRC staff. The NRC expects that applicants planning to utilize commercial grade items or services commit to the quality assurance requirements specified in NQA-1a-2009, Subpart 2.14.

As such, please clarify the NuScale position regarding NQA-1a-2009, Subpart 2.14, and revise the above alternative as necessary.

NuScale Response

NuScale is committed to NQA-1-2008 and NQA-1a-2009 addenda, including Subpart 2.14, as noted in Section 2.7.2. The statement concerning NuScale's assumption of 10 CFR 21 reporting responsibility is in reference to 10 CFR 21.7, Exemptions, that states, in part, "Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items."

This is to clarify that NuScale, as the dedicating entity, assumes 10 CFR 21 reporting responsibilities and will hold its commercial suppliers commercially accountable for quality requirements in procurement documents, including the reporting of defects.

In Section 2.7.2 additional clarification was added with the following:

"In establishing commercial grade items requirements, NuScale commits to compliance with NQA-1a-2009, Requirement 7, Section 700 and Subpart 2.14."

The Section 2.7.2 statement for 10 CFR 21 reporting has also been updated with the following:

"NuScale will assume 10 CFR Part 21 reporting responsibility for commercial items and services that NuScale dedicates for use in safety-related applications."

- **Question 17.5-5**

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.L, by committing to implement the quality standards described in NQA-1-2008, Requirement 12, Sections 100 through 400, with the following clarifications and exceptions:

The NuScale QAPD clarifies that the out-of-calibration conditions described NQA-1-2008, Requirement 12, Section 302, refer to cases where the measuring and test equipment is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration.

However, the NRC staff notes that this clarification, as written, is not directly applicable to the constraints listed in NQA-1-2008 or NQA-1a-2009, Requirement 12, Section 302, regarding reference standards. Rather, NuScale's statement is a clarification of the methods that will be used when measuring and test equipment is found to be out of tolerance during calibration.

As such, it is not clear to the staff why an alternative to NQA-1-2008, Requirement 12, Section 302 is necessary. In addition, it is not clear to the staff as to why NuScale is not committing to NQA-1a-2009 for Requirement 12.

Please provide verification/explanation regarding whether the clarification stated above is applicable to NQA-1-2008, Requirement 12, Section 302, as well as further information as to whether NuScale is committing to NQA-1a-2009.

NuScale Response

This clarification should state Section 303.2, not Section 302. The topical report has been updated to state Section 303.2.

Requirement 12 of NQA-1 was not updated with the NQA-1a-2009 addenda, as noted in the summary of changes. It appears to be included because Requirement 11 was completely revised and replaced in NQA-1a-2009 addenda, which caused Requirement 12 to be printed on the back of Requirement 11 page. The commitment is still addressed as NQA-1-2008 for Requirement 12.

- **Question 17.5-6**

As an alternative to the NQA-1-2008, Requirement 12, Section 303.6, calibration labeling requirements, the NuScale QAPD proposes that measuring and test equipment are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as when the label will interfere with operation of the device), provided that the required information is maintained in suitable documentation traceable to the device.

However, the NRC staff notes that NQA-1-2008 and NQA-1a-2009, Requirement 12, Section 303.6, as written, already provides for measuring and test equipment to be "otherwise identified" to indicate calibration status and establish traceability to calibration records.

As such, it is not clear to the staff why an alternative to NQA-1-2008, Requirement 12, Section 303.6 is necessary. Please provide a justification for this clarification.

NuScale Response

NuScale has removed this exception since NQA-1-2008, Section 303.6, already provides for this exception.

- **Question 17.5-7**

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.U, for establishing QA program commitments. However, the NRC staff notes that Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," which contains provisions related to the qualification and training of quality assurance personnel, is not committed to by NuScale. Please clarify whether RG 1.8 is applicable to the NuScale design certification project.

NuScale Response

Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants" is applicable to NuScale.

Section 4.1 has been updated to include RG 1.8 as a regulatory commitment.