

17 QUALITY ASSURANCE AND RELIABILITY ASSURANCE

This chapter of the safety evaluation report (SER) documents the U.S. Nuclear Regulatory Commission (NRC or Commission) staff's (hereinafter referred to as the staff) review of Chapter 17, "Quality Assurance and Reliability Assurance," of the NuScale Power, LLC (referred to hereinafter as the applicant) Design Certification Application, Part 2, Tier 2, "Final Safety Analysis Report (FSAR)," Revision 2. Chapter 17 of the application discusses quality assurance (QA) during the design phase, QA during the construction and operation phases, the QA program, the reliability assurance program, and the QA program description for the design certification (DC). It also discusses the combined license (COL) applicant's responsibility for developing a quality assurance program (QAP) for the construction and operations phases and a program for implementing Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" (the Maintenance Rule) in Section 17.6. The QAP described in Sections 17.1, "Quality Assurance during the Design Certification Phase," 17.2, "Quality Assurance during the Operations Phase," 17.3, "Quality Assurance Program Description," and 17.5, "Quality Assurance Program Description," of Chapter 17 of the Design Certification Application (DCA) Tier 2 applies to QA during the design certification phase for NuScale standard plant design activities. The reliability assurance program (RAP) described in Section 17.4 of DCA Tier 2 applies to those structures, systems, and components (SSCs) identified as being risk significant or important contributors to plant safety.

17.0 Quality Assurance

Licensing Topical Report (TR), TR-1010-859-NP-A, Revision 3, "Quality Assurance Program Description for the NuScale Power Plant," issued October 2016 (Agencywide Documents Management and Access System (ADAMS) Accession No. ML16347A405), explains the applicant's quality assurance program description (QAPD) used for the NuScale standard plant DC. The staff approved this QAPD on September 22, 2016 (ADAMS Accession No. ML16196A391). The NuScale QAPD TR covers the activities associated with the certification of the NuScale power plant. The QAPD is based on the applicable portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-2008 and NQA-1a-2009, "Quality Assurance Requirements for Nuclear Applications."

17.1 Quality Assurance during the Design Phase

The DCA Tier 2, Section 17.5, describes the NuScale QAP for the NuScale standard plant during the DC phase. The staff reviewed Section 17.5 in accordance with Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP). The staff includes that evaluation in Section 17.5 of this SER.

17.2 Quality Assurance during the Construction and Operation Phase

The QA during the construction and operating phase is not applicable to design certification. Section 17.5 of this SER addresses QA for DC, early site permit, and new license applicants.

17.3 Quality Assurance Program Description

Section 17.5 of this SER addresses the QAPD.

17.4 Reliability Assurance Program

17.4.1 Introduction

DCA Part 2 Tier 2, Section 17.4 describes the applicant's Reliability Assurance Program (RAP). The program applies to safety-related and non-safety-related SSCs identified as being risk significant. Probabilistic risk assessment (PRA), deterministic, or other methods of analysis determine the risk significance.

17.4.2 Summary of Application

DCA Tier 1: N/A.

DCA Tier 2: The applicant stated the objectives of the RAP and described a two-stage implementation process for the program in the application. The first stage of the program encompasses the reliability assurance activities that occur during detailed design of the plant before initial fuel load (i.e., design reliability assurance program (D-RAP)). The second stage consists of the operational phase of the plant's life to ensure that the reliability of the SSCs within the scope of the RAP is maintained during operations. Consistent with this approach, the applicant included action items in the DCA for COL applicants referencing the certified NuScale power plant design.

ITAAC: DCA Part 2, Tier 1, addresses the proposed inspections, tests, analyses, and acceptance criteria (ITAAC), as required by 10 CFR 52.47(b)(1). These ITAAC are evaluated in Section 14.3 of this SER.

Technical Specifications: N/A.

Technical Reports: N/A.

17.4.3 Regulatory Basis

The following NRC regulations contain the relevant requirements for this review:

- 10 CFR Part 52.47(a)(9) requires an evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP is not a substitute for the regulations, and compliance is not a requirement.

The guidance in SRP Section 17.4, Revision 1, "Reliability Assurance Program," issued May 2014, lists the acceptance criteria adequate to meet the above requirements, as well as review interfaces with other SRP sections. The guidance addresses the Commission policy

stated in Item E of the staff requirements memorandum (SRM) for SECY-95-132, “SECY-95-132—Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084),” dated June 28, 1995, which discusses the practice of codifying a RAP through incorporation into the design-specific rulemaking for a DC applicant.

17.4.4 Technical Evaluation

The staff reviewed the NuScale DCA Part 2 Tier 2, Section 17.4, and NuScale RAI response letters, dated August 28, 2017 (ADAMS Accession No. ML17241A139), and September 18, 2017 (ADAMS Accession No. ML17261A335). Additionally, the staff audited non-docketed information during two audits, the first conducted between April 3, 2017, and August 17, 2017 (ADAMS Accession No. ML17305A024) and the second between March 6, 2018, and April 26, 2018 (ADAMS Accession No. ML18254A340) to support the review. All references to an audit, or audits, in this section (17.4) refer to either or both of these regulatory audits. The staff based its evaluation on the guidance in SRP Section 17.4, which implements the Commission policy stated in SRM-SECY-95-132.

17.4.4.1 Description of Design Reliability Assurance Program

The staff verified that the applicant’s description in DCA Part 2, Tier 2, Section 17.4 included the details of the RAP that will be implemented during the DC and COL design and construction activities preceding initial fuel load. The staff confirmed that the scope, purpose, objectives, framework, and activities of the applicant’s RAP are consistent with those described in Subsection I of SRP Section 17.4, Revision 1. The staff also confirmed that the applicant established an appropriate COL item (COL Item 17.4-1) to provide assurance that a COL applicant that references the NuScale power plant DC will propose a process for integrating the RAP into operational programs. Based on its review as described above, the staff finds that the description of the RAP is acceptable because it is consistent with SRP Section 17.4.

17.4.4.2 Programmatic Controls of Design Reliability Assurance Program

The staff verified that the applicant has established the appropriate RAP programmatic controls to support DC phase design activities. Consistent with guidance in SRP Section 17.4, the programmatic controls established by the applicant address organizational responsibilities, design control activities, procedures and instructions, records control, corrective actions, and audit plans. The latter four controls were developed by the applicant in accordance with the applicable provisions of the QAPD, addressed in Section 17.5 of this report. The staff finds that the applicant has established programmatic controls for the RAP consistent with guidance in SRP Section 17.4, which the staff considers adequate.

The staff also confirmed that the applicant established an appropriate COL Item (COL Item 17.4-3) to provide assurance that a COL applicant referencing the NuScale power plant DC will identify the QA controls for the RAP SSCs during site-specific design, procurement, fabrication, construction, and preoperational testing activities. This provides assurance that the latter four controls listed above will be in place during the COL design and construction phases. The staff finds this COL item to be clear and to provide an appropriate level of assurance.

17.4.4.3 Methodology for Identifying Structures, Systems, and Components within the Scope of the Reliability Assurance Program

DCA Part 2 Tier 2, Figure 17.4-1, “NuScale D-RAP Process for SSC Risk Significance Determination,” describes the applicant’s process for determining the risk significance of SSCs and indicates that insights from the PRA and the importance of an SSC as a provision for defense-in-depth are factors considered in identifying SSCs within the scope of the RAP. The staff verified that the methodology is based on a combination of probabilistic, deterministic, and other methods of analysis; and that it accounted for multi-module considerations in the development of the D-RAP list.

The candidate risk-significant SSCs were determined using criteria described in the NRC approved NuScale Licensing Topical Report, TR-0515-13952-NP-A, Revision 0, “Risk Significance Determination,” issued October 2016 (ADAMS Accession No. ML16284A016). As discussed in Section 19.1.4.4.8 of this report, this TR is acceptable for use with this DCA.

In addition, the staff found that the expert panel utilized deterministic and other qualitative considerations in its selection of SSCs for the D-RAP list. Therefore, the applicant’s methodology is acceptable because it is consistent with the staff’s expectations as described in SRP Section 17.4, Revision 1.

17.4.4.4 Expert Panel

The applicant’s RAP includes use of a panel of experts to determine which SSCs in the design should be considered risk significant. The application describes the technical disciplines, roles and responsibilities, and the qualification requirements of the expert panel.

The applicant stated that the expert panel members must have an accredited 4-year degree in engineering, science, or other related field with a minimum of 5 years of experience in one or more of the following areas:

- PRA or risk and reliability analysis, including 3 years of PRA experience on small modular reactor design;
- safety analysis;
- licensing;
- power plant operations, maintenance, previous commercial senior reactor operator license; and
- design integration or system engineering.

The staff confirmed the range and level of expertise described in the DCA through discussion with expert panel members during the staff’s audit of non-docketed information that took place between March 6, 2018, and April 26, 2018. The range and level of expertise stated in the application are consistent with acceptance criteria in Subsection II of SRP Section 17.4 and are therefore acceptable.

17.4.4.5 Structures, Systems, and Components within the Scope of the Reliability Assurance Program

The staff reviewed the SSCs required to perform risk-significant system functions as listed in DCA Part 2 Tier 2, Table 17.4-1, “D-RAP SSC Functions, Categorization, and Categorization Basis.”

Although the applicant’s process for identifying SSCs within the scope of D-RAP, as depicted in DCA Part 2, Tier 2, Figure 17.4-1, indicates that insights from the PRA and the importance of an SSC as a provision for defense-in-depth are factors considered in selecting SSCs for the RAP, it did not appear to the staff that the applicant considered the following important insights:

- The CVCS provides an alternative means of reactivity control and reactor coolant makeup under accident conditions, which is diverse (active) from the passive emergency core cooling system and therefore is an important contributor to defense in depth in the design.
- Information from the internal events, at-power PRA in DCA Part 2 Tier 2, Figures 19.1-2 through 19.1-11 indicates that core damage in approximately half of the event sequences could be avoided if injection to the reactor coolant system with the CVCS is successful. This insight reflects the importance of the CVCS as a contributor to defense in depth in the design.

Therefore, the staff reviewed the applicant’s response to RAI 8879 (ADAMS Accession No. ML17241A139) and discussed the above CVCS functions during the audit, for a more in-depth understanding of the expert panel’s rationale for not including CVCS in the D-RAP. For reactivity control, the applicant pointed to the large negative moderator temperature coefficient as the primary reason the reactivity control function is not important to risk. For reactor coolant system makeup, the applicant stated that the redundancy of active components in the CVCS ensures its availability. Additionally, the staff gathered from the expert panel that the panel considered several issues, including defense in depth, in its deliberations on the CVCS and decided that the system did not need to be included in the RAP. In making its decision, the expert panel considered that quantitative analysis of the risk significance of the CVCS showed that the system did not satisfy the numerical criteria established in TR-0515-13952-NP-A and additional defense in depth, in the form of the containment flood and drain system, was included in the design and provides an additional means of adding inventory to the RCS.

The staff finds that the applicant followed its process for scoping SSCs into the D-RAP list and documented the expert panel’s rationale for not including the CVCS in the D-RAP list.

The staff reviewed the set of SSCs within the scope of the D-RAP in accordance with the applicant’s criteria and considered the applicant’s rationale for excluding the CVCS from the scope of the RAP as discussed above. The staff finds that the application of the criteria in the selection of SSCs to be included in the D-RAP list is appropriate and reasonable. In addition, the staff finds the applicant’s rationale for excluding the CVCS from the D-RAP acceptable.

The staff reviewed COL Item 17.4-2, which provides assurance that a COL applicant referencing the NuScale power plant DC will identify any site-specific SSCs within the scope of the RAP. The COL item is clear, complete, and therefore acceptable.

17.4.4.6 Process for Determining Dominant Failure Modes

The staff verified that the application describes a proposed process for determining the dominant failure modes of RAP SSCs. The applicant stated that this process incorporates industry experience and analytical methods. Analytical methods for identifying dominant failure modes include PRA importance analysis, root cause analysis, fault trees, and failure modes and effects analysis. The process described by the applicant is consistent with the guidance for an acceptable process given in SRP Section 17.4 and is therefore acceptable.

17.4.4.7 Quality Assurance Associated with Design Activities

The staff verified that the applicant specified the following QA controls in DCA Part 2 Tier Section 17.4.7:

- The QAPD in DCA Part 2 Tier 2, Section 17.5 includes QA controls applicable to the RAP process during the standard plant design phase.
- RAP SSCs that are both safety related and risk significant will be subject to the full 10 CFR Part 50, Appendix B, QAP.
- QA controls for RAP SSCs that are non-safety-related and risk-significant will be consistent with controls described for non-safety-related RAP SSC in DCA Part 2 Tier 2, Section 17.5.
- Established COL Item 17.4-3 requires COL applicants that reference the NuScale certified design to identify the QA controls for the RAP SSCs during site-specific design, procurement, fabrication, construction, and preoperational testing activities.

These controls are consistent with the staff's expectations for QA controls described in SRP Section 17.4 and are therefore acceptable.

17.4.5 Combined License Information Items

Table 17.4-1 lists COL information item numbers and descriptions related to the RAP from Section 17.4, DCA Tier 2. The staff finds the COL information items to be reasonable.

Table 17.4-1: NuScale Combined License Information Items for Section 17.4

| Item No. | Description | DCA Tier 2 Section |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| COL 17.4-1 | A COL applicant that references the NuScale power plant DC will describe the RAP conducted during the operations phases of the plant's life. | 17.4.1 |
| COL 17.4-2 | A COL applicant that references the NuScale power plant DC will identify any site-specific SSCs within the scope of the RAP. | 17.4.1 |
| COL 17.4-3 | A COL applicant that references the NuScale power plant DC will identify the QA controls for the RAP SSCs during site-specific design, | 17.4.7 |

| | | |
|--|--------------------------------------------------------------------------------|--|
| | procurement, fabrication, construction, and preoperational testing activities. | |
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17.4.6 Conclusion

The staff finds that NuScale has fully addressed the required information relating to the RAP at the DC phase and concludes that it is acceptable.

17.5 Quality Assurance Program Description—Design Certification, Early Site Permits, and New License Applicants

17.5.1 Introduction

NuScale Topical Report, TR-1010-859-NP-A, Revision 3, describes the QAP for the NuScale DC. The QAPD incorporates the requirements of ASME NQA-1-2008 and NQA-1a-2009 Addenda, “Quality Assurance Program Requirements for Nuclear Facilities,” as endorsed by NRC Regulatory Guide 1.28, Revision 4, “Quality Assurance Program Criteria (Design and Construction),” issued June 2010.

The QAPD submitted by NuScale addresses the design QA activities in support of the DC. The NuScale QAPD does not address construction and design QA activities that occur once construction begins.

17.5.2 Summary of Application

DCA Tier 1: N/A

DCA Tier 2: Section 17.5 states the following:

The Quality Assurance Program Description (QAPD) for the standard design of the NuScale Power Plant is provided in the topical report, “NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant.”

ITAAC: The applicant did not include any inspections, test analysis, and acceptance criteria (ITAAC) for the QAPD.

Technical Specifications: N/A.

Technical Reports: TR-1010-859-NP, Revision 3, “NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant,” dated March 24, 2016 (ADAMS Accession No. ML16084B004)

17.5.3 Regulatory Basis

The following NRC regulations contain the relevant requirements for this review:

- 10 CFR Part 50, Appendix A, “General Design Criteria for Nuclear Power Plants,” General Design Criteria (GDC 1), “Quality Standards and Records,” requires that a QAP be established and implemented.

- 10 CFR 52.47(a)(19) requires that a standard DC applicant include a QAPD that satisfies applicable requirements of Appendix B to 10 CFR Part 50.

The guidance in SRP Section 17.5 lists the acceptance criteria adequate to meet the above requirements, as well as review interfaces with other SRP sections.

17.5.4 Technical Evaluation

The NRC staff reviewed TR-1010-859-NP, Revision 3, “NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant,” dated March 24, 2016 (ADAMS Accession No. ML16084B004). The staff’s SER dated September 22, 2016, documents the evaluation of the NuScale QAPD (ADAMS Accession No. ML16196A123). Specifically, the NRC staff evaluated the NuScale QAPD and verified that it meets NRC regulations by following the guidance in SRP Section 17.5. The staff verified that DCA Tier 2, Revision 2, Section 17.5, incorporates NP-TR-1010-859-NP-A, Revision 3, without exception, for control of activities affecting quality during the development of the NuScale DCA and is therefore acceptable.

Staff Inspection of NuScale QAPD Implementation

Appendix B to 10 CFR Part 50 sets forth the requirements for quality assurance programs for nuclear power plants. Per 10 CFR 52.47(a)(19), the description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 were satisfied. NRC Inspection Manual Chapter 2508, “Construction Inspection Program: Design Certification,” contains staff guidance to perform a post-docketing QAP inspection. This post-docketing QAP inspection provides the staff with reasonable assurance that the QAP has been adequately implemented. This inspection is consistent with the regulations that govern all stages of the licensing process and allows staff to verify whether activities affecting quality are conducted under the appropriate provisions of Appendix B to 10 CFR Part 50. Effective implementation of the QAP provides reasonable assurance that SSCs will perform their intended safety function. A post-docketing QAP inspection occurred June 6–9, 2017, and is documented in Inspection Report Number 05200048/2017-201, issued July 24, 2017 (ADAMS Accession No. ML17201J382). The inspectors identified no findings of significance. The NRC staff also planned a follow-up inspection to verify continued effective implementation of the QAP. This follow-up inspection was tracked as **Open Item 17.5.1**. The NRC staff performed a follow-up inspection on February 25-28, 2019 and is documented in Inspection Report No. 05200048/2019-201, issued April 5, 2019 (ADAMS Accession No. ML19093A669). No findings of significance were identified during the inspection. Therefore, **Open Item 17.5.1** is now closed.

17.5.5 Combined License Information Items

COL Information Item 17.5-1 addresses the QAP applicable to site-specific design activities and to the construction and operations phases from DCA Tier 2 (see Table 17.5-1). COL applicants must provide this information. The staff finds the COL information items to be reasonable.

Table 17.5-1: NuScale Combined License Information Item for Section 17.5

| Item No. | Description | DCA Tier 2 Section |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| COL 17.5-1 | A COL applicant that references the NuScale power plant DC will describe the QAP applicable to site-specific design activities and to the construction and operation phases. | 17.5 |

17.5.6 Conclusion

As discussed above, the NRC staff completed its review of DCA Tier 2, Section 17.5, and completed post-docketing QA implementation inspections. The staff used the requirements of Appendix B to 10 CFR Part 50, 10 CFR 52.47(a)(19), and the guidance of SRP Section 17.5 as the bases for evaluating the acceptability of NuScale's QAPD. The staff concluded that NuScale's QAPD has established an acceptable QAP in accordance with applicable NRC regulations and industry standards for DC activities. The staff performed two quality assurance implementation inspections to verify effective implementation of the QAP.

17.6 Maintenance Rule

17.6.1 Introduction

DCA Part 2 Tier 2, Section 17.4 addresses the NuScale Maintenance Rule (MR) program.

17.6.2 Summary of Application

DCA Tier 1: N/A.

DCA Tier 2: The applicant provided an action item for COL applicants referencing the NuScale power plant design to describe the program for monitoring the effectiveness of maintenance required by 10 CFR 50.65.

ITAAC: N/A.

Technical Specifications: N/A.

Technical Reports: N/A.

17.6.3 Regulatory Basis

The following NRC regulations contain the relevant requirements for this review:

- 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants."
- 10 CFR 52.79(a)(15), which requires that a COL FSAR describe the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.

The guidance in SRP Section 17.6, "Maintenance Rule," lists the acceptance criteria adequate to meet the above requirements, as well as review interfaces with other SRP sections.

17.6.4 Technical Evaluation

The staff has reviewed DCA Part 2, Tier 2, Section 17.6, in accordance with the guidance in SRP Section 17.6. In accordance with the SRP guidance, the DC applicant is not required to address the requirements of the MR, as this is an operational program not required for DC, and no outstanding information is expected in the DCA related to this program.

The NRC staff agrees that the plan or process for implementing the MR program and describing that plan or process in the COL FSAR are the responsibilities of the COL applicant referencing the NuScale design. The COL applicant shall implement the MR program, at the latest, by fuel load (i.e., by the time the Commission makes the finding required in 10 CFR 52.103(g)). The applicant may implement an acceptable MR program in advance of the Commission's 10 CFR 52.103(g) finding, with components being monitored or tracked as they become available.

17.6.5 Combined License Information Items

Table 17.6-1 lists the COL information item number and description related to the MR from DCA Tier 2. The staff finds the COL information items to be reasonable.

Table 17.6-1: NuScale Combined License Information Item for Section 17.6

| Item No. | Description | DCA Tier 2 Section |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| COL 17.6-1 | A COL applicant that references the NuScale power plant DC will describe the program for monitoring the effectiveness of maintenance required by 10 CFR 50.65. | 17.6 |

17.6.6 Conclusion

The NRC staff confirmed that the applicant has fully addressed the information relevant to the MR program at the DC phase. The NRC staff agrees with the DC application that the COL applicant is responsible for developing and implementing the MR program pursuant to the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65. Thus, the staff concludes that the MR information presented in DCA Tier 2, Section 17.6, is acceptable.