

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 0. 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 Document (DCD) 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 DCD 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 NP-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 topical report 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 DCD 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

Section 17.4 of the FSAR describes the applicant's 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

DCD Tier 1: N/A.

DCD 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 phases 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 FSAR for COL applicants referencing the certified NuScale power plant design.

The applicant described the following key elements of the RAP in the FSAR:

- programmatic controls of the RAP in the areas of organization, design control, procedural controls, records controls, audit controls, and corrective action program;
- process for classifying the functions of SSCs in the design as risk significant or not, including evaluations of risk significance based on a consideration of probabilistic, deterministic, and other methods of analysis, including industry operating experience, expert panel reviews, and severe accident evaluations;
- the expert panel process, including subject matter disciplines represented, experience and qualification requirements for subject matter experts, and roles and responsibilities of the expert panel members;
- output from the classification processes, which includes the list of SSCs included in the scope of the RAP;
- process for determining dominant failure modes of SSCs; and
- QA applicable to RAP activities.

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

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 Revision 1 of the NuScale DCD Tier 2, Section 17.4, and NuScale 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. ML18143B333). The staff based its evaluation on the guidance in SRP Section 17.4, Revision 1, 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 described the details of the RAP that will be implemented during the DC and COL design and construction activities preceding initial fuel load. This description discusses the scope, purpose, objectives, framework, and activities that will occur in the two phases of the RAP (i.e., DC and detailed plant design following issuance of a COL). The staff confirmed that the scope, purpose, and objectives 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 describe the RAP conducted during the operations phases of the plant's life. Based on its review as described above, the staff finds the description of the RAP to be acceptable.

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, Revision 1, 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, Revision 1, which the staff considers adequate.

The applicant has established 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

The application describes the NuScale methodology for identifying SSCs within the scope of the RAP. The NuScale letters of August 28, 2017, and September 18, 2017, further clarify the processes used for assessment and decisionmaking. The methodology is based on a combination of probabilistic, deterministic, and other methods of analysis listed in the application. NuScale Licensing Topical Report TR-0515-13952-A, "Risk Significance Determination," issued July 2015 (ADAMS Accession No. ML15211A470) gives the probabilistic acceptance criteria included in the methodology. In a letter dated July 13, 2016 (ADAMS Accession No. ML16181A215), the NRC approved this topical report for reference in licensing applications for the NuScale small modular reactor design to the extent specified and under the conditions and limitations delineated in the SER approving the topical report. The staff confirmed that the applicant met the conditions and limitations stipulated in the topical report, and therefore, its application for this methodology is acceptable. The expert panel applied deterministic considerations qualitatively as discussed below, and the staff considered the report appropriate and complete. This applicant's methodology is consistent with the staff's expectations as described in SRP Section 17.4, Revision 1, and is therefore acceptable.

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 this range and level of expertise 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, Revision 1, and are therefore acceptable.

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

The staff reviewed the list of risk-significant SSCs selected by the NuScale expert panel, identified in Section 17.4 of the FSAR, and determined that the applicant did not include the chemical and volume control system (CVCS) functions for reactivity control and reactor coolant system makeup in the scope of the RAP. The applicant's process for determining the risk significance of SSCs, as depicted in Figure 17.4-1 in the FSAR, 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. However, it did not appear to the staff that the applicant had considered the following important insights:

- The CVCS provides an alternative means of 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 in Figures 19.1-2 through 19.1-11 in the FSAR indicate core damage in approximately half of the event sequences from the internal events, at-power PRA could be avoided if injection to the reactor coolant system with the CVCS is successful. This result reflects the importance of the CVCS as a contributor to defense in depth in the design.

The staff discussed this point with members of the NuScale expert panel during the audit conducted between March 6, 2018, and April 26, 2018. During this discussion, one of the members stated that the panel considered a number of 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 for the following reasons:

- Quantitative analysis of the risk significance of the CVCS showed that the system did not satisfy the numerical criteria established in Licensing Topical Report TR-0515-13952-NP, Revision 0, which the NRC had approved for referencing in the NuScale application for DC.
- Additional defense in depth had been included in the design in the form of the containment flood and drain system, which can be used to flood the containment to successfully remove decay heat and avoid core damage following a loss-of-coolant accident with both the emergency core cooling system and CVCS unavailable.

- The following give reasonable assurance of adequate capability to satisfy system availability and reliability missions:
 - In accordance with FSAR Table 14.2-38 (ITAAC), Test #38-1 (system level test) is intended to verify that the CVCS can support the reactor system by providing a primary coolant makeup rate of at least 20 gallons per minute. This is consistent with assumptions in the PRA, data in FSAR Table 9.3.4.1, and data in SD-B010-1374, “Chemical and Volume Control System Design Description.”
 - Periodic operation of the CVCS makeup pumps to adjust boron concentration and reactor coolant system inventory during power operation is an adequate means of indicating the unavailability of one or more components in the system.
 - The CVCS will be subject to the requirements in 10 CFR 50.65, based on its being referenced in NuScale emergency operating guidelines (i.e., NuScale Licensing Topical Report TR-1117-57216-P, Revision 0, “NuScale Generic Technical Guidelines,” dated November 30, 2017 (ADAMS Accession No. ML17334B822)).

The staff reviewed the information provided by the applicant and finds that the expert panel adequately considered the CVCS for inclusion into the D-RAP list. 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 included in the scope of the D-RAP in light of the applicant’s criteria for including SSCs in the scope of the RAP and considered the acceptability of excluding the CVCS from the scope of the RAP as discussed above. The staff finds that the application of the criteria to select SSCs for the D-RAP is appropriate.

On July 11, 2018, the staff held a public teleconference with the applicant to discuss the removal of the CVCS function to support RCS by isolating dilution sources from the FSAR Rev.1, Table 17.4-1 (ADAMS Accession No. ML18204A035). The applicant removed the function because neither the demineralized water system supply isolation valves nor the general transient initiating event was risk significant after finalizing the PRA. The staff found that the applicant adequately considered the system function within the RAP scoping process that included an expert panel review. Therefore, the staff found the removal of the system function 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, Revision 1, 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 Section 17.4.7 of the FSAR:

- The QAPD in Section 17.5 of the FSAR 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 FSAR 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, Revision 1, and are therefore acceptable.

17.4.4.8 ITAAC for Design Reliability Assurance Program

The applicant did not propose an ITAAC for the RAP. This is not consistent with the NRC's expectations as documented in SRP Section 17.4, Revision 1, "Reliability Assurance Program." However, the NRC is currently reconsidering whether an ITAAC for RAP is necessary. The NRC staff has submitted a paper to the Commission proposing that DC and COL applicants no longer be expected to submit an ITAAC for the RAP (ADAMS Accession No. ML18192B471). The Commission has not yet taken a position on the staff's proposal. If the Commission rejects the staff's proposal, the staff will ask NuScale to amend its application with an ITAAC for RAP. If the Commission accepts the staff's proposal, then the applicant will not need to take any further action. **This is currently Open Item 17.4-1.**

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, DCD Tier 2.

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

Item No.	Description	DCD 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, procurement, fabrication, construction, and preoperational testing activities.	17.4.7

17.4.6 Conclusion

The staff finds that NuScale has fully addressed the required information relating to the RAP at the DC phase except that of the D-RAP ITAAC. Therefore, because of the Open Item 17.4-1 that remains to be resolved for this section, the staff is unable to finalize its conclusions as to acceptability.

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

17.5.1 Introduction

NuScale Topical Report NP-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

DCD 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."

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 Part 50, Appendix B, specifies 18 quality criteria that the QAPD must address.
- 10 CFR 52.47(a)(19) requires that a standard DC applicant include a QAPD that satisfies applicable portions 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 NP-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 DCD Tier 2, Revision 0, Section 17.5, incorporates NP-TR-1010-859-NP-A, Revision 3, without exception, for control of activities affecting quality during the DC of the NuScale plant 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(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 2017 (ADAMS Accession No. ML17201J382). The inspectors identified no findings of significance. The NRC staff will perform a follow-up inspection to verify continued effective implementation of the QAP. This follow-up inspection is being tracked as **Open Item 17.5.1**.

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 DCD Tier 2 (see Table 17.5-1). COL applicants must provide this information.

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

Item No.	Description	DCD 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 DCD Tier 2, Section 17.5, and completed a preliminary QA implementation inspection. 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 NRC staff will perform a follow-up QA implementation inspection to verify the continued effective implementation of the QAP. This inspection is being tracked as **Open Item 17.5.1**.

17.6 Maintenance Rule

17.6.1 Introduction

Section 17.4 of the FSAR addresses the NuScale Maintenance Rule (MR) program.

17.6.2 Summary of Application

DCD Tier 1: N/A.

DCD 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 Revision 1 of DCD 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 DCD 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 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 DCD Tier 2.

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

Item No.	Description	DCD 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 DCD Tier 2, Section 17.6, is acceptable.