NRC Responses to Public Comments
Final Rule: NuScale Small Modular Reactor Design Certification

NRC-2017-0029; RIN 3150-AJ98

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Office of Nuclear Reactor Regulation

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ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
CFR	*Code of Federal Regulations*
COL	combined license
DCA	design certification application
DCD	design control document
DCR	design certification rule
EA	environmental assessment
ECCS	emergency core cooling system
ER	environmental report
FR	*Federal Register*
FSER	final safety evaluation report
GDC	general design criterion/criteria
ITAAC	inspections, tests, analyses, and acceptance criteria
NRC	U.S. Nuclear Regulatory Commission
NuScale	NuScale small modular reactor
PRA	probabilistic risk assessment
SAMDA	severe accident mitigation design alternative
TMI	Three Mile Island

U.S. NUCLEAR REGULATORY COMMISSION
RESPONSE TO PUBLIC COMMENTS RECEIVED ON THE PROPOSED RULE
"NUSCALE SMALL MODULAR REACTOR DESIGN CERTIFICATION"

Introduction

This document presents the U.S. Nuclear Regulatory Commission's (NRC's) responses to written public comments received on the proposed rule, "NuScale Small Modular Reactor Design Certification" (NuScale). The NRC published the proposed rule and notice of the proposed rule in the *Federal Register* on July 1, 2021 (86 FR 34999), for public comment with a 60-day public comment period. On August 24, 2021 (86 FR 47251), the NRC extended the public comment period by 45 days, resulting in a total comment period of 105 days.

The proposed rule on NuScale is available from the Federal e-Rulemaking Web site at https://www.regulations.gov/ (Docket ID No. NRC-2017-0029) and through the NRC's Agencywide Documents Access and Management System (ADAMS) (Accession No. ML21147A432).

In developing the final rule, the NRC considered all the comments provided in response to the proposed rule. If, as a result of its review of a public comment, the NRC changed the rule text, the final rule preamble (also referred to as the statements of consideration), or the supporting documents, the NRC's response to the comment indicates where the change occurred.

Overview of Public Comments

The NRC received comments from nine individuals and organizations, as shown in Table 1. Of those comments, six were in favor of the design certification rule (DCR), one was opposed, and the other two comments stated no preference for the outcome of the rule but included questions. One of the submissions was received after the close of the public comment period. As stated in the proposed rule, comments received after the comment close date are considered by the NRC when it is practical to do so; the NRC determined it was practical to consider the late-filed comment submission.

The NRC reviewed and annotated the comment submissions to identify separate comments within each submission. Accordingly, a single submission may have several individual comments associated with it. The NRC gave each individual comment within a submission a unique identifier. The NRC's summaries include this unique identifier to indicate which individual comments are addressed by each response. Public comment submissions are available online in the NRC Library at http://www.nrc.gov/reading-rm/adams.html. From this page, the public can access ADAMS, which supplies text and image files of the NRC's public documents. If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC's Public Document Room at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. In addition, public comments and supporting materials related to this final rule can be found at https://www.regulations.gov by searching for Docket ID NRC-2017-0029.

Table 1: Comment Submissions

Comment Submission ID	Commenter	ADAMS Accession Number
1	Private Citizen, Keith Welch	ML21189A248
2	Private Citizen, James A. Hoerner	ML21189A249
3	Private Citizen, Diana Wulf	ML21196A531
4	Nuclear Energy Institute	ML21288A130
5	Union of Concerned Scientists	ML21288A131
6	NuScale Power Inc.	ML21288A189
7	The United Association of Plumbers and Pipe Fitters and The Mechanical Contractors Association of America	ML21288A273
8	The Breakthrough Institute	ML21288A274
9	Private Citizen, Nick Wagner	ML21288A275

Comment Categorization

This comment response document separates the comments into the nine categories identified below. Within each category, the NRC summarizes and responds to the comments. In general, the NRC addresses each individual comment. However, when similar comments can be readily grouped together, the NRC has binned those comments and treated them as a single comment. The agency's response addresses the binned comments. The annotated comment number or numbers appear in parentheses at the end of each comment summary to provide a cross-reference to aid the reader.

The comment summaries are grouped in the following categories:

A. General Comments on the Proposed Rulemaking
B. Severe Accident Mitigation Design Alternatives
C. Unresolved Technical Issues in the Design Certification Application
D. Departures, Changes, or Exemptions
E. Gas Combustion
F. Reference Corrections
G. Inadvertent Actuation Block Valves
H. Definitions
I. Compliance

A. General Comments on the Proposed Rulemaking

Comment A-1: Two comments support the proposed rule. One comment states that "the innovative design will also play an important role in providing relatively clean, safe, reliable, and cost-competitive base-load electricity and ensuring America remains a leader global nuclear technology." The second comment states that NuScale "is designed to provide a safer, more cost-effective clean option for meeting future energy needs and is particularly well suited to replacing aging U.S. coal plants." (2-1, 7-1)

NRC Response: The comments support the proposed rule and suggest no changes. No changes were made in response to these comments.

Comment A-2: The comment states that the review process was clear and well communicated in a manner that provides a high-level of public confidence. In addition, the comment states that lessons learned from the NRC's review of the NuScale design certification application (DCA) should be documented and disseminated for general knowledge and improvement of future DCA submissions and to assist combined license (COL) applicants to proceed more effectively with their applications. (8-1)

NRC Response: The NRC agrees with the comment. The Office of Nuclear Reactor Regulation (NRR) issued a report on lessons learned from NRR's review of the NuScale DCA on March 20, 2022 (ADAMS Accession No. ML22088A160). No changes were made in response to this comment.

Comment A-3: The comment states opposition to the design certification approval. In addition, the commenter requested the NRC to focus on water and abolish the Price-Anderson Act. (3-1)

NRC Response: The NRC licenses and regulates the Nation's civilian use of radioactive materials to provide reasonable assurance of adequate protection of public health and safety and to promote the common defense and security and to protect the environment. The comment is out of scope, and no changes were made in response to this comment.

B. <u>Severe Accident Mitigation Design Alternatives</u>

Comment B-1: The comment states that the NRC failed to consider severe accident mitigation design alternatives (SAMDAs) associated with the potential for boron redistribution/dilution transients that could lead to core damage. Specifically, the comment states that the NRC's environmental assessment (EA) referenced in the proposed rule fails to evaluate potential SAMDAs that could reduce the risk of core damage and radiological release associated with boron redistribution events. The comment further states that "as the result of Chapter 15 deficiencies, the ECCS design is incomplete." In addition, the comment notes that the latest NuScale design changes have improved the boron mixing before the emergency core cooling system (ECCS) actuation, but "additional design modifications are needed for NuScale to mitigate post ECCS actuation boron dilution and demonstrate that the system capabilities to bring the system back to normal with no adverse impacts on the core cooling." (5-1)

NRC Response: The NRC disagrees with this comment. As described in Final Safety Evaluation Report (FSER) Section 19.1.4.6.4, the NRC thoroughly reviewed the possible phenomena and processes that could lead to rapid flow incursions that could lead to core damage. The NRC performed an independent evaluation (ADAMS Accession Nos. ML20191A069 and ML20205L317) into the physical processes affecting the boron dilution and how those processes might impact the likelihood for core damage to occur during postulated events. The NRC found in FSER Section 19.1.4.6.4 that the applicant adequately addressed the impact of the boron redistribution phenomena in the DCA probabilistic risk assessment (PRA), and the PRA adequately reflects the design and operation as described in the DCA. The NRC found reasonable assurance that there are no known significant risk contributors that are unaccounted for and that the identified risk insights are acceptable to support the Commission’s objectives for use of PRA at the design stage. Because boron redistribution is unlikely to lead to core damage and is not a significant risk contributor, the NRC concludes that further consideration of a SAMDA is not warranted. No changes were made in response to this comment.

Comment B-2: The comment states that the NuScale PRA has identified a cask drop during refueling as the internal initiating event with the highest frequency of core damage (on the order of 1×10^{-6}/plant-year for a 12-module plant). Nevertheless, the NRC, despite being unable to “reach a finding” on SAMDAs associated with a cask drop during refueling (Release Category 8 in the NRC EA), approved the NuScale environmental report (ER) on the basis that any SAMDA addressing this risk would be associated only with improvements to the reactor building crane, which “is not considered part of the design certification.” The comment states that this is false because the crane has a critical function in the operation of the plant and plays an outsized role in plant risk, and it is highly likely that other SAMDAs could be identified to help mitigate the risk of a cask drop. (5-2)

NRC Response: The NRC believes the comment is referring to events involving a dropped NuScale power module because Release Category 8 is associated with a dropped NuScale power module during refueling operations. A potential cause of a dropped NuScale power module could be failures associated with the reactor building crane. With that understanding, the NRC disagrees with this comment.

However, based on this comment the NRC clarified in the final EA that the NRC’s environmental evaluation included aspects of the reactor building crane because the crane was considered during the review of the DCA. The staff documented its review of the reactor building crane in the following FSER Sections: 3.2.1, “Seismic Classification”; 3.7.3, “Seismic Subsystem Analysis”; 3.8.4, “Seismic Category I Structures”; 9.1.2, “New and Spent Fuel Storage”; 9.1.4, “Light Load Handling System (Related to Refueling)”; 9.1.5, “Overhead Heavy Load Handling System”; 18.1, “Human Factors Engineering Program Management”; and 19.1.4.6.3, “Reactor Building Crane Failure Resulting in Postulated Module Drop.”

Based on its review, the NRC staff concluded that the reactor building crane is single-failure proof consistent with cranes used in currently operating plants and the guidance for Type I cranes in NUREG-0554, “Single-Failure-Proof Cranes for Nuclear Power Plants,” issued May 1979 (ADAMS Accession No. ML110450636), and American Society of Mechanical Engineers (ASME)-NOG-1, “Rules for Construction of Overhead and Gantry Cranes (Top Running Bridge, Multiple Girder).” The design includes limit switches to protect against the reactor building crane experiencing overtravel, overspeed, overload, and unbalanced load events. The major risks for a dropped module are due to human errors of commission and failures of instrumentation. Two additional inspections, tests, analyses, and acceptance criteria (ITAAC) for the reactor building crane were added to Tier 1 of the design control document (DCD) for rated load tests of the module-lifting fixtures and module-lifting adapter and for inspection of the as-built module-lifting fixtures and module-lifting adapter.

Also, as the staff noted in its FSER, a COL applicant that references the NuScale design will describe the process for the handling and receipt of critical loads, including NuScale Power

Modules, to satisfy COL Item 9.1-5. A licensee that references the NuScale design must satisfy all ITAAC, including those associated with the reactor building crane.

The NRC evaluated three SAMDAs related to the reactor building crane. As discussed in the draft EA, one SAMDA is related to automation of the power module transport process to reduce operator errors of commission, one SAMDA is related to providing a railway system on the reactor pool floor to assist in transporting the power module to the refueling area, and the final SAMDA is related to improving testing and maintenance procedures for the reactor building crane. The SAMDA related to the addition of a railway system was eliminated because the cost exceeded the benefit. The two SAMDAs related to automation of the power module transport process and improving testing and maintenance procedures are dependent on site-specific information provided by a COL applicant referencing the NuScale design.

The final EA clarifies that the two SAMDAs to be analyzed by a COL applicant referencing the NuScale design are related to a design element to reduce human errors of commission. A COL applicant could consider additional design elements addressing human errors of commission in addition to training and procedures. Thus, the dropped module severe accident risks and maximum benefit discussed in Revision 5 of the NuScale DCA ER (ADAMS Accession No. ML20224A512) could change as a result of the COL applicant's closure of the two SAMDAs and COL Item 9.1-5. Any COL applicant referencing the NuScale design would need to close the related COL items, assess the risks according to site-specific conditions regarding dropping a module during any moves, and address SAMDAs for reducing or avoiding adverse environmental effects in the COL application.

Finally, the NRC disagrees with the comment that "the NRC approved the NuScale ER." The NRC does not approve an applicant's ER; rather the agency prepares an independent EA based on the applicant's ER and other sources. The conclusion of the NRC's EA is that the proposed action will not have a significant effect on the quality of the human environment. The proposed action is to certify the NuScale design in Appendix G to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

No change to the rule was made in response to this comment.

Comment B-3: The comment states that "site-specific SAMDAs, multi-unit aspects, procedural and training SAMDAs, and the reactor building crane design would need to be assessed when a specific site is proposed for constructing and operating a NuScale power plant." The term "multi-unit" in the context of a multi-module reactor design is ambiguous, as each reactor module could be considered a unit. The EA considered multi-module aspects; it appears this phrase was meant to instead refer to multi-plant aspects (i.e., more than one 12-module facility at a site). The comment suggests replacing the term "multi-unit" with "multi-plant." (6-10)

NRC Response: The NRC agrees with this comment that the term "multi-unit" could be confusing for the NuScale design. The NRC staff addressed the distinction between multi-module and multi-unit review issues in its response to NuScale Power dated October 25, 2016 (ADAMS Accession No. ML16229A522). In its response, the NRC staff referenced the definitions of "Nuclear Power Unit" and "Modular Design'" found in 10 CFR 52.1, "Definitions," as shown below:

> *Nuclear power unit.* A nuclear power unit means a nuclear power reactor and associated equipment necessary for electric power generation and includes those structures, systems, and components required to provide reasonable assurance the facility can be operated without undue risk to health and safety of the public.
>
> *Modular design* means a nuclear power station that consists of two or more essentially identical nuclear reactors (modules) and each module is a separate nuclear reactor capable of being operated independent of the state of completion or operating condition of any other module co-located on the same site, even though the nuclear power station may have some shared or common systems.

For the purposes of the NuScale design, each nuclear power module is a single "unit," but because the design has been reviewed for up to 12 units in a single reactor building, some multi-unit site issues have been reviewed and resolved for the NuScale design. Footnote 1 in the final EA clarifies that the SAMDA candidates for "multi-unit sites" for NuScale are evaluated in the context of multiple 12 unit plants at the same site.

The NRC added a discussion of these issues to the preamble to the final rule and revised the EA to clarify how multi-unit site considerations were handled. The NRC has also added to the final rule a definition of the term "nuclear power unit" as applied to NuScale.

C. Unresolved Technical Issues in the Design Certification Application

Comment C-1: The comment states that for the plant-specific DCD, "a COL applicant may also have to include considerations for multi-module facilities in the plant-specific DCD that were not previously evaluated as part of the design certification rule." The comment states that it is unclear what the NRC intends by this statement because the NuScale final safety analysis report is based on a 12-module plant. The comment proposes clarification or deletion of the statement that a COL applicant may need to address additional multi-module considerations in the plant-specific DCD. (6-8)

NRC Response: The NRC confirms that it evaluated the NuScale power plant, including up to 12 modules and the associated balance-of-plant support systems and structures. Accordingly, Section V.B of the preamble to the final rule reads, "A COL applicant will also have to include considerations for a multi-unit site in the plant-specific DCD that were not previously evaluated as part of the design certification rule, e.g., construction impacts on operating units." For example, an applicant proposing to add modules to an operating NuScale power plant would need to address the potential impacts on the operating modules from the addition of the new modules that were not reviewed as part of the DCA..

Comment C-2: The comment states that the NRC identified the following issues as unresolved open items in the DCA: shielding wall design, containment leakage from the combustible gas monitoring system, and steam generator stability during density wave oscillations. The comment also states that these unresolved issues create regulatory uncertainty for COL applicants. The comment proposes that the industry make the outstanding issues generic to allow effective resolution by the research community. In addition, the comment states that the NRC should clarify what the potential outstanding multi-module considerations and provide guidance on how they may be resolved. (8-3)

NRC Response: The NRC takes no position on this comment to the extent the comment recommends that the industry consider genericizing the unresolved issues. The NRC disagrees with the comment requesting clarification on how to resolve outstanding issues because this discussion is referring to issues that may arise from site- or application-specific considerations that were not evaluated in the design certification process (e.g., later addition of modules to an operating NuScale power plant), and as such, the NRC cannot determine prospectively what the issues might be. The preamble to the final rule clarifies that the NuScale design is certified for up to 12 modules in a single reactor building (i.e., multi-module considerations for construction and operation of up to 12 modules in a single reactor building), and no changes were made in response to this comment.

D. Departures, Changes, or Exemptions

Comment D-1: The comment states that although 10 CFR 50.109(a) applies to standard design approvals, it does not apply to design certifications. The NRC has addressed this issue in Section VIII.C.1 of the final rule, which provides that the backfitting requirements in 10 CFR 50.109 apply to changes to NuScale design certification generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rules (and do not require a change to a design feature in the generic DCD). The change processes described in Section VIII.C.1 are specific to the NuScale design certification rule. (4-1)

NRC Response: The NRC agrees that Section VIII.C.1 directs the NRC to apply the requirements in 10 CFR 50.109 when making a change to generic technical specifications or other operational requirements that were completely reviewed and approved in the design certification rulemaking and that did not require a change to a design feature in the generic DCD. The NRC further agrees that Section VIII.C.1 of Appendix G applies only to the NuScale design. Each design certification rule has an equivalent provision that applies only to the specific design certification rule of which it is a part. No changes were made as a result of this comment.

Comment D-2: The comment states that an interpretation of Sections VI.C, VIII.C.1, and VIII.C.4 of the final rule that would withhold issue resolution but grant backfit protection and require exemptions for departures from unresolved matters seems inconsistent. The comment cites minimum operator staffing and containment leakage rate testing as examples of operational requirements that were completely reviewed and approved in the NRC staff's FSER. The comment states that the NRC should clarify or revisit, on a generic basis, the portion of Appendix G, Section VI.C, that states "[t]he Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of § 52.63(a)(5).” This statement appears to be in tension with Appendix G, Section VIII.C.1, which applies the requirements of 10 CFR 50.109 to certain operational requirements that were completely reviewed and approved by the design certification rulemaking. The comment states that this is resolved by reading Section VI.C to apply to operational requirements that were not completely reviewed and approved as part of the design certification rulemaking. Issue resolution should be afforded when the NRC has completed its safety review and the public was afforded the opportunity to comment. If the NRC disagrees, it should revisit these provisions for operational requirements on a generic basis and in a manner that does not impact the NuScale design certification rule schedule. (4-2)

NRC Response: The NRC agrees with this comment in part and disagrees in part. Operational requirements and design information are afforded finality by different provisions of the NRC’s regulations. Among other things, an application for design certification may be requested only for “essentially complete” designs (see Sections 10 CFR 52.41, “Scope of subpart,” and 10 CFR 52.47(c)(1)–(2)), which ensures that applicants provide sufficient information to allow the NRC to make comprehensive findings on the design. As Section VI.A of Appendix G states, “[a] conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, and components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for NuScale.” In contrast, operational requirements are generally afforded finality through 10 CFR 50.109, “Backfitting”; for example, changes to the generic minimum staffing requirements in 10 CFR 50.54(m) would be subject to the requirements in 10 CFR 50.109. Therefore, when these provisions for operational requirements were first used, in the Advanced Boiling Water Reactor design certification rule, the Commission determined the following (62 FR 25805; May 12, 1997):

> The Commission does not support extension of … § 52.63 to technical specifications and other operational requirements as requested by NEI, rather the Commission supports the proposal to treat the technical specifications in Chapter 16 of the DCD as a special category of information …. The purpose of design certification is to review and approve design information. There is no provision in Subpart B of 10 CFR Part 52 for review and approval of purely operational matters …. After the COL is issued, the set of technical specifications for the COL (the combination of plant-specific and DCD derived) would be subject to the backfit provisions in § 50.109 (assuming no Tier 1 or Tier 2 changes are involved).

Thus, the generic technical specifications and operational requirements that have been completely reviewed and approved during the design certification rulemaking process are afforded finality by Section VIII.C of Appendix G. However, Section VI.C properly provides that operational requirements, even those completely reviewed and approved in the design certification rulemaking, are not subject to the issue finality requirements in 10 CFR 52.63, “Finality of standard design certifications,” because those requirements are intended for design information, which must be essentially complete, whereas operational requirements do not need to be essentially complete because they are not the primary subject of design certification. However, the NRC recognizes that operational requirements can be affected by aspects of the design and are appropriate for review in the design certification process. The NRC therefore affords completely reviewed and approved operational requirements the finality established through 10 CFR 50.109 by Section VIII.C, as discussed in response to Comment D-1.

The NRC agrees that the design-specific operator staffing requirements in Appendix G are the kind of completely reviewed and approved operational requirements that are the subject of Section VIII.C. However, although NuScale's exemption request for Type A containment leakage rate testing was reviewed in the FSER, the proposed rule did not include an exemption from Type A testing for licensees that reference Appendix G, and therefore, the NRC disagrees with the comment that, as proposed, the containment leakage rate testing matter was a completely reviewed and approved operational requirement. Nevertheless, in the final rule, the NRC has included provisions for both operator staffing and Type A testing, and thus both provisions have been completely reviewed and approved in the course of the design certification rulemaking process and will be subject to the requirements of 10 CFR 50.109 as stated in Section VIII.C.

It is important to note that these are design-specific regulations (i.e., rules that apply only to licensees that reference Appendix G). The NRC can generically address any need for design-specific alternatives to NRC regulations that apply only during operation, but must do so through rulemaking, as has been done in Appendix G for operator staffing and in the final rule for Type A testing provisions. Rulemaking for such matters is necessary because Section VIII.C cannot relieve future licensees that reference Appendix G from complying with applicable regulations. Section VIII.C applies without additional rule provisions only when, for example, the NRC has concluded that an operational method or approach discussed in the DCA does or does not meet an NRC requirement. A conclusion that alternative regulations would be appropriate for a particular design is not, therefore, a completely reviewed and approved "operational requirement" subject to Section VIII.C. Thus, had the NRC not included design-specific regulations in the final rule for minimum staffing and Type A testing, these matters would not be "approved" within the meaning of Section VIII.C.

No changes were made as a result of this comment.

Comment D-3: The comment states that the 10 CFR 50.54(m) exemption is listed among exemptions for "the NuScale design," which is not applicable to the design, but rather to a licensee referencing the design certification. In addition, the comment states that Section V.D may also warrant a brief discussion of this new approach to exemptions from 10 CFR 50.54(m) and 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix J, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors," for licensees referencing the NuScale design certification. The comment proposes the creation of a new Section V.C in the rule to list and clarify the exemptions for licensees referencing the NuScale design certification, such as 10 CFR 50.54(m) and the Appendix J exemption. (6-14)

NRC Response: The NRC agrees that the preamble and rule text should address the design exemptions separately from the design-specific regulations for licensees referencing the NuScale DCR. Therefore, a new section was created under Section IV, "Additional Requirements and Restrictions," to list the exemptions applicable to future applicants and licensees referencing the design certification (i.e., alternative staffing requirements and the Appendix J Type A testing exemption). In addition, the alternative staffing requirements of the proposed rule were removed from paragraph V.B and moved to the new Section IV.C in the rule text.

Comment D-4: The proposed rule states that in proposing a contention on compliance with the Tier 2 departure provisions as part of an ongoing adjudicatory proceeding, the intervenor "must demonstrate that the change stands on an asserted noncompliance with an ITAAC acceptance criterion….” The comment states that it is unclear what it means for a change to “stand on” an asserted ITAAC noncompliance and that previous design certification rules have used the term “bears on,” which appears correct in this context. The comment’s proposed resolution is to replace the term “change” with “departure” to enhance clarity and revise the provision to state, “Further, the petition must demonstrate that the departure bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing….” (6-18)

NRC Response: The NRC agrees with the comment. Previous design certifications have used the term “bears on”; therefore, revising the sentence in paragraph VIII.B.5.g would increase clarity and consistency among 10 CFR Part 52 appendices. The revised sentence in paragraph VIII.B.5.g of the rule generally will read as follows:

> Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the departure bears directly on the amendment request in the case of a hearing on a license amendment.

Comment D-5: The comment states that the preamble and proposed rule do not address the inapplicability of 10 CFR Part 50, Appendix J, to a licensee referencing the NuScale design. NuScale DCA Part 7, Section 7, sought an exemption from 10 CFR Part 50, Appendix A, “General Design Criteria for Nuclear Power Plants,” General Design Criterion (GDC) 52, “Capability for containment leakage rate testing,” for the NuScale design and an exemption from Appendix J Type A testing for licensees referencing the NuScale design. The comment states that the staff’s FSER, Section 6.2.6.4, approved both exemption requests and that neither the preamble nor the “applicable regulations” portion of the proposed rule discusses the exemption for licensees from the Type A testing requirements of Appendix J. The comment proposes the addition of Appendix J Type A testing to the list of exemptions granted by the final rule. (6-7)

NRC Response: The NRC agrees with the comment that the exemption to Appendix J Type A testing should be identified in the rule and preamble to the final rule. FSER Section 6.2.6.4, “Technical Evaluation for Exemption Request No. 7,” issued July 2020 (ADAMS Accession No. ML20205L406), documents the NRC staff’s review of the request to exempt licenses referencing the NuScale design from 10 CFR Part 50, Appendix J, Type A tests. Therefore, the new Section IV.C of the final rule and Section IV.H of the preamble to the final rule will include Appendix J to 10 CFR Part 50 for Type A testing for licenses referencing the NuScale design.

Comment D-6: The comment states that current regulations are written in a specific, prescriptive manner, which is based on large light-water reactor operational experience and incidents. As an example, 10 CFR Part 50 provides control room staffing requirements based on a set of assumptions applicable to large light-water reactors. This will require COL applicants that seek to deploy the NuScale reactor to seek exemptions if they wish to use the number of operators recommended by NuScale.

The comment states that the prescriptive nature of the regulations also required NuScale to seek exemptions from a standard, rather than simply describing how the NuScale design meets safety objectives. The comment recommends allowing use of the Implementation of the Proposed Risk-Informed Technology Inclusive Regulatory Framework Approach for COL

Applicants Referencing the NuScale DCA because it includes elements that would improve regulatory certainty for COL applicants. Specifically, the framework includes provisions for performance-based demonstrations that would enhance the ability of COL applicants to demonstrate that safety objectives have been met, without seeking exemptions. (8-2)

NRC Response: The NRC disagrees with this comment. The final rule provides alternative staffing requirements that will be applicable to any licensee operating a NuScale power plant under Appendix G to 10 CFR Part 52. The NRC is currently developing a rule and guidance for implementing a technology-inclusive regulatory framework. However, work on developing the new framework is ongoing and not available yet for use. No changes were made as a result of this comment.

E. Gas Combustion

Comment E-1: The comment notes that the preamble states that the combustible gas monitoring leakage issue “may be resolved by performing radiation dose calculations and demonstrating that doses would remain within applicable dose limits in 10 CFR part 20….” As the preceding sentence notes, “this issue does not affect normal plant operation or non-core damage accidents.” The dose limits of 10 CFR Part 20, “Standards for Protection against Radiation,” apply to normal plant operations. The comment states that the staff’s FSER, Section 12.3.4.1.3, invokes the control room habitability assessment of 10 CFR 50.34(f)(2)(xxviii) and the “important area” access requirement of 10 CFR 50.34(f)(2)(vii) as relevant to the potential onsite doses associated with this core damage accident-related release; it also cites the accident dose limits of 10 CFR 52.47(a)(2)(iv) as applicable to offsite doses. The comment proposes the deletion of the reference to 10 CFR Part 20 as an applicable requirement for a COL applicant to resolve the combustible gas monitoring leakage issue. (6-5)

NRC Response: The NRC disagrees with the comment. The dose limits of 10 CFR Part 20 apply at all times, not only to normal operating conditions. To resolve the combustible gas monitoring leakage issue, the COL applicant will need to ensure that post-accident leakage from these systems does not result in the total main control room dose exceeding the dose criteria (i.e., 50 millisieverts (5 rem)) for the surrogate event with significant core damage or include design features in accordance with 10 CFR 50.34(f)(2)(xxvi) and (f)(2)(xxviii) to ensure that the dose criteria are not exceeded, or both. To demonstrate that these requirements are met, the COL applicant can submit an analysis showing the 10 CFR Part 20 limits are not exceeded. No changes were made in response to this comment.

Comment E-2: The comment states that the *Federal Register* notice summarizes the NRC’s position that “there was insufficient information available regarding NuScale combustible gas monitoring system and the potential for leakage from this system outside containment.” The NRC was “unable to determine whether this leakage could impact analyses performed to assess main control room dose consequences, offsite dose consequences to members of the public, and whether this system can be safely re-isolated....” The comment states that the NRC conclusions are mistaken because this issue comes down to leakage from a system (combustible gas monitoring), which is addressed in 10 CFR 50.44, “Combustible gas control for nuclear power reactors,” for the express purpose of monitoring combustible gases in a beyond-design-basis core damage event. The comment also states that this type of beyond-design-basis event is not required to meet the offsite dose criteria of 10 CFR 52.47(a)(2)(iv). No design-basis event in the NuScale design damages fuel cladding, let alone causes severe core damage. The NRC seems to be mixing the design-basis offsite dose requirement—which includes a hypothetical major fission product release inside containment postulated only for that purpose—with the functional requirement for combustible gas monitoring under real (although extremely unlikely) core damage scenarios, which are beyond design basis.

In addition, the comment states that the Three Mile Island (TMI) rules do address beyond-design-basis accidents, but they do so by requiring additional functions to help mitigate those events, not by imposing dose limits. NuScale addressed these rules in its "Lessons-Learned from the Design Certification Review of the NuScale Power, LLC Small Modular Reactor," dated February 19, 2021 (ADAMS Accession No. ML21050A431). As noted in that report, 10 CFR 50.34(f)(xxvi) does not apply a dose limit for leakage control, but just requires that leakage be as low as practical. The regulation in 10 CFR 50.34(f)(2)(vii) is explicit (see NUREG-0737, "Clarification of TMI Action Plan Requirements," issued November 1980, ADAMS Accession No. ML051400209) that it does not address leakage from systems outside containment, because those systems already have leakage "as low as practical" under 10 CFR 50.34(f)(2)(xxvi). Lastly, 10 CFR 50.34(f)(2)(xxviii) does not require the control room habitability to address new beyond-design-basis events; instead, it requires licensees to re-verify their control rooms for the DCA Chapter 15 events.

The comment states that the NRC seems to be combining the combustible gas monitoring requirement with other unrelated rules to yield a result that, for the first time, applies dose criteria to beyond-design-basis events. This is akin to requiring a plant to analyze doses for a station blackout or anticipated transient without scram event. The comment states that the NRC's "issue not resolved" position is correct, and this would set a bad precedent for future applicants. (9-1, 9-2, 9-3)

NRC Response: The NRC disagrees with this comment. To perform hydrogen monitoring following a significant accident in the NuScale design, manual actions outside of the control room may be required.

The regulation in 10 CFR 50.34(f)(2)(vii) requires, in part, that licensees perform radiation and shielding design reviews of spaces around systems that may, as a result of an accident, contain accident source term and design as necessary to permit adequate access to important areas. The TMI requirement includes a footnote specifying that the fission product release should be based on a major accident that is hypothesized for purposes of site analysis, or postulated from considerations of possible accidental events, that would result in potential hazards not exceeded by those from any accident considered credible. It also indicates that such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products. In the NuScale design, the site analysis includes an assumed maximum hypothetical accident that includes core damage. NUREG-0737 specifies the 5-rem whole body dose limit for meeting 10 CFR 50.34(f)(2)(vii). Therefore, the NRC's position is that a radiation and shielding design review is required for the actions that may be necessary to perform hydrogen monitoring.

Regarding offsite dose, 10 CFR 52.47(a)(2)(iv) includes a footnote similar to the TMI item, and this requirement is assessed against an assumed core damage accident. Since the hydrogen monitoring system may be in use following a severe accident and since it is uncertain that the system can be safely reisolated, the NRC's position is that leakage from the hydrogen monitoring loop must be shown not to result in doses in excess of the regulatory limits. This is similar to how engineered safety feature system leakage is considered in the offsite dose analysis in other reactor designs.

As a result, no changes were made in response to this comment.

F. Reference Corrections

Comment F-1: Preamble Section IV.F identifies FSER Sections 12.2, 12.3, 3.11, and 15.0.3 as discussing TR-0915-17565, Revision 3, "Accident Source Term Methodology," dated April 2019 (ML19112A172). The staff's FSER Section 15.0.2 also discusses that report. The comment proposes that FSER Section 15.0.2 be added to the list of sections that discuss TR-0915-17565. (6-2)

NRC Response: The NRC agrees with this comment and Section IV.F of the preamble to the final rule generally will read as follows:

> The NRC's review and findings of topical report TR–0915–17565, Revision 3, are documented in the topical report final safety evaluation report issued on October 29, 2019 (ADAMS Accession No. ML19297G520). The approved version TR–0915–17565–NP–A, Revision 4 (ADAMS Accession No. ML20057G132) is discussed in the DCA safety evaluation report Section 12.2, "Radiation Sources," Section 12.3, "Radiation Protection Design Features," Section 3.11 "Environmental Qualification of Mechanical and Electrical Equipment," Section 15.0.2, "Review of Transient and Accident Analysis Methods," and Section 15.0.3, "Radiological Consequences of Design Basis Accidents."

Comment F-2: Preamble Section IV.A identifies FSER Chapter 3 as "Design of Structures, Components, Equipment, and Systems." The title of FSER Chapter 3 is "Design of Structures, Systems, Components, and Equipment." The comment proposes correction of the title of FSER Chapter 3. (6-3)

NRC Response: The NRC agrees with this comment, and the FSER title in Section IV.A of the preamble to the final rule will be changed to FSER Chapter 3, "Design of Structures, Systems, Components and Equipment."

Comment F-3: Preamble Section IV.A states, "With the exception of the steam generator tube and inlet flow restrictor issue discussed previously…." Identifying that previous discussion as Section III.C.3 would increase clarity. The comment proposes replacement of "previously" with "in Section III.C.3." (6-4)

NRC Response: The NRC agrees with this comment and will update the last sentence in Section IV.A in the preamble to the final rule to state, "With the exception of the steam generator tube and inlet flow restrictor issue discussed in Section III.C.3, the NRC found the comprehensive vibration assessment program adequate to ensure the structural integrity of the NuScale power module components."

Comment F-4: Preamble Sections V.B, V.F, and V.H state that the generic technical specifications for the NuScale design are in Chapter 16 of the generic DCD. Chapter 16 of the NuScale final safety analysis report describes the process for developing the technical specifications, but the generic technical specifications are found in Part 4 of the DCA. The comment proposes that references to Chapter 16 of the DCD be changed to instead refer to DCA Part 4. (6-9)

NRC Response: The NRC agrees with the comment and deleted references to Chapter 16. Therefore, Section V.B. and V.H of the preamble to the final rule generally will read as follows:

> Section V.B
> The NRC is treating the technical specifications in Part 4, "Generic Technical Specifications," of the DCA as a special category of information and designating them as generic technical specifications in order to facilitate the special treatment of this information under appendix G to 10 CFR part 52.
>
> Section V.H
> The process in paragraph VIII.C.1 for making generic changes to the generic technical specifications or other operational requirements in the generic DCD is accomplished by rulemaking and governed by the backfit standards in § 50.109.

Comment F-5: The comment states that the proposed 10 CFR Part 52, Appendix G, Section VI.B, list of matters resolved does not include referenced information in public documents. Nuclear safety and safeguards issues associated with referenced information intended as requirements in nonpublic reports are explicitly resolved, but not safety issues in public reports. Several of the reports referenced in the generic DCD are exclusively public reports, with no equivalent nonpublic report that would be within the scope of issue resolution. While issue resolution for the FSER, Tier 2, and the rulemaking record implies resolution of referenced public reports, the design certification for the economic simplified boiling-water reactor, Appendix E (ESBWR DC) to 10 CFR Part 52, includes the 20 documents approved for incorporation by reference by the Director of the Office of the Federal Register (i.e., the public documents) within the scope of Issue Resolution paragraph B.1. A clearer approach for the NuScale design certification may be to revise paragraph B.2 or include a new paragraph. The comment proposes the revision of the issue resolution provisions to include nuclear safety issues associated with referenced information in public documents which, in context, are intended as requirements in the generic DCD for the NuScale design. (6-16)

NRC Response: The NRC disagrees with this comment. The design certification incorporates by reference all documents that are necessary to meet the application content requirements in 10 CFR 52.47(a)–(c) (except for conceptual design information and the ER), and for which either the NRC or the design certification applicant would like to establish finality. Therefore, no additional clarification is warranted, and no changes were made to the rule language in response to this comment.

Comment F-6: The comment states that the proposed rule provides a 15-year duration "from October 29, 2021." Other proposed design certification rules (aside from the direct final rule approach for the Advanced Power Reactor (APR) 1400) have included a placeholder for the final rule effective date; NuScale wants to call attention to this to ensure that the final rule includes the correct duration start date. The comment proposes the revision of the duration provision to begin with the effective date of the final rule. (6-17)

NRC Response: The NRC agrees with the comment, and an effective date of 30 days after publication of the rule in the *Federal Register* will be provided in the preamble to the final rule.

G. Inadvertent Actuation Block Valves

Comment G-1: The comment "strongly agrees with the NRC staff's recommendation in SECY-19-0036 [, "Application of the Single Failure Criterion to NuScale Power LLC's Inadvertent Actuation Block Valves," dated April 11, 2019 (ADAMS Accession No. ML19060A081),] and Commissioner Baran's dissenting vote to reject NuScale's assertion that the critically important inadvertent actuation blocks, which must 'close rapidly and fully seal to prevent premature opening of the main ECCS valve' should be regarded as 'passive' components that are not subject to the single-failure criterion." The comment states the "Commission's majority vote to accept NuScale's illogical contention is irresponsible, dangerous, violates common sense, and should be overturned in the final rule." (5-3)

NRC Response: The Commission's direction to the staff does not regard, redesignate, or reclassify the inadvertent actuation block valves as passive components. Rather, the Commission narrowly directed the staff not to apply the single-failure criterion only to the inadvertent actuation block valve closing function. The decision in the July 2, 2019, staff requirements memorandum to SECY-19-0036 (ADAMS Accession No. ML19183A408) was not changed in response to this comment. No changes were made to the rule text in response to this comment.

Comment G-2: Preamble Section IV.C states that the inadvertent actuation block valve is "safety-significant." In this context, "safety significant" is undefined and creates ambiguity. The comment states that NuScale has not undertaken risk-informed categorization of structures, systems, and components pursuant to 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," which categorizes SSCs by their safety significance. Risk insights indicate that the inadvertent actuation block is not risk significant. The comment proposes that the phrase "safety-significant" be deleted from the preamble. (6-6)

NRC Response: The NRC glossary defines the term "safety-significant" as follows:

> …used to qualify an object, such as a system, structure, component, or accident sequence, this term identifies that object as having an impact on safety, whether determined through risk analysis or other means, that exceeds a predetermined significance criterion.

For the NuScale design, the NRC characterized the inadvertent actuation block valves as "safety-significant" because of the important role they play in ensuring that the fuel integrity and containment barriers remain intact and because they are necessary for satisfying safety requirements such as 10 CFR Part 50, Appendix A, GDC 10, 35, and 38. The use of the term "safety-significant" in the preamble is consistent with its use in the FSER and SECY-19-0036. No changes were made to the rule text in response to this comment.

H. Definitions

Comment H-1: The comment states that the generic DCD is defined as “the document containing” Tier 1 information, Tier 2 information, and generic technical specifications. This definition may cause confusion because the NuScale DCA does not include a discrete document containing that information; the generic technical specifications are in Part 4 of the DCA. The comment proposes revision of the final definition to read “...means the Tier 1 and Tier 2 information (including the technical and topical reports referenced in Chapter 1) and generic technical specifications that are incorporated by reference into this appendix.” (6-11)

NRC Response: The NRC agrees that the DCD is not contained in a single document but disagrees that the term “generic DCD” refers only to a single document containing Tier 1 information, Tier 2 information, and generic technical specifications. The generic DCD as a whole is a singular official record that NuScale Power, LLC, as the design certification applicant, is required to maintain. The NRC notes that the same definition has been used for other design certification rules for which the generic DCD comprises multiple documents but agrees that the definition can be clarified.

In the final rule, the definition of generic DCD reads as follows:

> *Generic design control document (generic DCD)* means the documents containing the Tier 1 and Tier 2 information (including the technical and topical reports referenced in Chapter 1) and generic technical specifications that are incorporated by reference into this appendix.

The NRC does not intend this variation from other design certification rules to indicate a substantive difference from those other design certification rules, but merely clarifies that this DCD comprises multiple documents.

Comment H-2: The comment states that the plant-specific DCD definition is defined to include “plant-specific changes to generic DCD information.” Under design certification rule nomenclature, “changes” are generic, while “departures” are plant-specific. The comment proposes that “changes” be replaced with “departures.” (6-12)

NRC Response: The NRC disagrees with the comment. The qualifier “plant-specific” clarifies that the changes are, indeed, plant specific (i.e., departures). The term “departure” is generally defined as “plant-specific changes,” so the language “plant-specific change” is equivalent to “departure,” but the term “plant-specific change” is clearer in this context because it contrasts with “generic.” No changes were made in response to this comment.

I. Compliance

Comment I-1: The comment states that all nuclear power plants should incorporate onsite backup generators. The comment also states that there is no reason (other than cost) not to equip these reactors with backup generation. Even if the plant itself can withstand the accident conditions, why force operators to deal with an accident in the absence of onsite power? The midst of a serious problem is not the time to be managing basic issues such as power. While utilities could install backup power if they wished, the only way to ensure that they do so is to require it. (1-1)

NRC Response: The NRC agrees with the comment that, generally, nuclear power plants should have onsite backup generators. The NuScale onsite electrical power system includes a backup power supply system consisting of backup diesel generators, as stated in DCD Part 2, Tier 2, Section 8.1, and the NRC's safety evaluation report in Section 8.1.1, "Introduction." No changes were made in response to this comment.

Comment I-2: The comment notes that the proposed rule states that the requirements of 10 CFR Part 20 have not been demonstrated with respect to steam generator tube integrity. The radiation protection standards of 10 CFR Part 20 pertain to doses to plant workers and members of the public as a result of expected plant operations. Failure of steam generator tubes is an accident condition, as noted in the preamble ("The failure of multiple steam generator tubes resulting from failure of an inlet flow restrictor has not been included within the scope of the NuScale accident analyses in DCA Part 2, Tier 2, Chapter 15."). The comment proposes the deletion of references to 10 CFR Part 20 requirements with respect to steam generator integrity. (6-1)

NRC Response: The NRC disagrees in part and agrees in part. The 10 CFR Part 20 dose limits apply at all times, including during beyond-design-basis accidents. However, the comment is correct that demonstration of compliance with 10 CFR Part 20 dose limits is not required for design certification rule applications. Instead, 10 CFR 52.47(a)(2)(iv) requires applicants to show in the safety analysis that the dose will not exceed certain criteria for this accident. The NRC agrees that a license application will need to meet the standard in 10 CFR 52.47(a)(2)(iv), rather than demonstrating that the 10 CFR Part 20 limits will not be exceeded. Therefore, Section III.C.3 of the preamble and final rule paragraph IV.A.2.i do not refer to 10 CFR Part 20, and the applicable dose criteria regulation was added to read as follows:

Preamble, Section III.C.3

> Therefore, the NRC concludes that NuScale Power has not demonstrated compliance with 10 CFR 52.47(a)(2)(iv) and appendix A to 10 CFR part 50, General Design Criterion (GDC) 4 and GDC 31, relative to potential impacts on steam generator tube integrity from inlet flow restrictor failure…

Rule, Paragraph IV.A.2.i

> Information demonstrating that the requirements of 10 CFR 52.47(a)(2)(iv) and General Design Criterion (GDC) 4 and GDC 31 of appendix A to 10 CFR part 50 are met with respect to the structural and leakage integrity of the steam generator tubes that might be compromised by effects from density wave oscillations in the secondary fluid system…

Comment I-3: The comment noted that the proposed 10 CFR Part 52, Appendix G, Section VI.B.1.d, states that GDC 10, "Reactor design," applies to the steam generator integrity issue, implying that the COLA must demonstrate conformance with GDC 10 to resolve the staff's concerns. Two other provisions of the proposed rule addressing steam generator integrity do not cite GDC 10. As GDC 10 concerns the reactor design, it is not relevant to steam generator integrity and is not cited by the FSER in this respect. The comment proposes the deletion of references to GDC 10 with respect to steam generator integrity. (6-15)

NRC Response: The NRC agrees with the comment because GDC 10 was erroneously listed and is not applicable to the steam generator integrity issue. Therefore, Section VI.B.1.d of the final rule reads: "…consistent with the other design information regarding steam generator integrity described in DCA Part 2, Tier 2, Sections 3.9.1, 3.9.2, 5.4.1, and 15.6.3, and in accordance with 10 CFR part 50, GDC 4 and 31…."

Comment I-4: The comment states that the proposed 10 CFR Part 52, Appendix G, Section IV.A.2.g, would require the COL applicant to include shielding design information to meet the radiation zones specified in DCA Part 2, Tier 2, Figure 12.3-1. This requirement effectively controls that Tier 2 radiation zone map equivalently to Tier 1 information, because a COL applicant would have no ability to depart from the radiation zone map without first getting an exemption from this requirement. In other words, if a COL applicant were to depart from the radiation zone map in a manner otherwise acceptable under the Tier 2 departure provisions (because it meets the 10 CFR 50.59-like criteria), the applicant would still need an exemption from this provision because it would not provide shielding satisfying the generic DCD's radiation zone map.

The comment states that this is an unnecessary new control on Tier 2 information. The regulatory history of Tier 1, standardization, and the change control provisions do not support an exemption requirement for this radiation zone map. The comment also notes that the radiation zone map, while supporting the operational dose limits and equipment qualification, does not rise to the level of a fundamental basis for the staff's review and is not essential to standardization of the plant design, and thus departures from the map do not justify an exemption requirement.

The comment states that the COL applicant can adequately address the NRC's expectation to address shielding of major penetrations by providing the shielding details necessary to meet the radiation zones specified in the applicant's plant-specific DCD; the applicant then maintains the ability to depart from the generic DCD radiation zone maps to the same extent they otherwise would be able to if the shielding details were provided in the generic DCD. The comment proposes changing this provision to refer to the plant-specific DCD radiation zone map instead of the DCA radiation zone map. (6-13)

NRC Response: The NRC disagrees with the comment. The radiation shielding between the power module bays and steam gallery areas minimizes radiation streaming from the reactor power modules to the steam galleries and other outside areas. The shielding is important not only for controlling radiation exposure to individuals but is also credited in the environmental qualification analysis. While these shield walls include large penetrations, NuScale did not analyze the radiation streaming through the penetrations and indicated that the penetration shielding design had not been finalized and would be completed in a future phase of the design. NuScale indicated that this would be the responsibility of the COL applicant.

The rule provision requires that a COL applicant provides penetration shielding information demonstrating that shielding is provided to limit dose equivalent to those values specified in the DCA. If the COL applicant's approach is approved and the COL is issued, the COL applicant will not be required to maintain doses to the radiation zone maps after COL issuance. If the penetration shielding is inadequate to limit doses to those specified in DCA Part 2, Tier 2, Figure 12.3-1, then different aspects of the radiation protection design would be unresolved, including findings related to 10 CFR Part 20 and environmental qualification compliance. For these reasons, it is appropriate to reference the DCA radiation zone map in the provision. The NRC did not change the rule language in response to this comment.