



PROPOSED RULE

10 CFR Part 53

“RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS”

January 8, 2025

Meeting Logistics

- Sound/Audio/Video
- Slides
- Raise Hand Functionality
- Teams Chat
- Meeting Transcription

Agenda

<u>Time</u>	<u>Topic</u>
9:00 – 9:10	Welcome / Introductions / Logistics
9:10 – 10:15	• Section VI, “Specific Requests for Comments” – Factory Testing • White Paper - DRAFT Section 53.1480 – COL supporting testing of manufactured reactors
10:15 – 10:30	Break
10:30 – 11:30	Discussion of testing of fueled manufactured reactors (continued)
11:30 12:30	Lunch
12:30– 2:15	• Relationships between 10 CFR Parts 50/52 and the proposed 10 CFR Part 53 • Consensus codes and standards in the proposed 10 CFR Part 53 • Guidance documents and guidance document updates for 10 CFR Part 53 • Section VI, “Specific Requests for Comments” – Recent Legislation (ADVANCE Act)
2:15 – 2:30	Break
2:30 – 5:00	Opportunity for questions on any aspect of the proposed 10 CFR Part 53 rulemaking package including: Subparts A through M, proposed changes to 10 CFR Part 26, proposed changes to 10 CFR Part 73, and Section VI, “Specific Requests for Comments”

Proposed Rule

- [89 FR 86918](#)
- <https://www.regulations.gov/document/NRC-2019-0062-0310>
- [ML24095A161](#)

28 Associated Documents

- [89 FR 86918](#), Section XIX. Availability of Documents
- <https://www.regulations.gov/docket/NRC-2019-0062/document?postedDateFrom=2024-10-31&postedDateTo=2024-10-31>

White Paper

- Subpart H, DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors ([ML24344A037](#))

Comments on the Proposed Rule

- Go to <https://www.regulations.gov/document/NRC-2019-0062-0310> to submit comments (Click on the blue comment button)
- The comment period closes February 28, 2025 ([89 FR 92609](#))
- We are not accepting comments on the proposed rule during this meeting
- There will be no formal responses to discussions during this meeting, but the staff may post additional information on regulations.gov
- No regulatory decisions will be made during this meeting

Factory Testing of Fueled Manufactured Reactors

- Proposed § 53.620(d) would allow and establish requirements for the loading of fuel into a manufactured reactor at the manufacturing facility for transport to a site with a combined license

Staff Requirements Memorandum (SRM)-SECY-23-0021

8. The staff should include factory fuel load provisions in the proposed rule. The staff should work with stakeholders following publication of the proposed rule to develop regulatory text that would also allow a holder of a manufacturing license to accomplish operational testing on a fueled manufactured reactor at the factory prior to delivery to the site where it will ultimately be used.

- Included question in *Federal Register* Notice
- Prepared and released preliminary draft material (i.e., not complete NRC management or legal review) to support discussions
 - ADAMS Accession No. [ML24344A037](#)
- Public meeting
- Consideration of comments received

Questions in *Federal Register* Notice

Please provide rationales, alternatives, and expected practices

- Should Part 53 include provisions for the testing of fueled manufactured reactors in the manufacturing facility
 - What would be both practical and safe
 - What tests are expected to collect data on fuel or other structures, systems, and components (SSCs)
- What would be appropriate limits on operations
 - Power levels
 - Durations (limit creation of byproduct material)
- What requirements could be revised given limitations on operation
 - Licensing-basis events, aircraft impact assessments, external hazards (seismic)

Questions in *Federal Register* Notice

Please provide rationales, alternatives, and expected practices

- What regulations would be appropriate for the manufacturing facility?
 - Construction (proposed § 53.610)
 - Operations (proposed §§ 53.710 and 53.715)
 - Personnel (proposed § 53.730)
- What licensing mechanism(s) should be considered for in-factory testing of manufactured reactors?
 - License for each manufactured reactor
 - License for manufacturing facility/multiple manufactured reactors
 - Inspections, tests, analyses, and acceptance criteria (ITAAC)

White Paper (ML24344A037)

- Provided to support discussions
- Should not be interpreted as official agency positions

- White Paper organized to provide:
 - Description
 - Draft preliminary rule text (§ 53.1480)
 - Combined license for testing manufactured reactors (COL-TMR)
 - Commission findings on operating states*

* See also FRN Question 7. under Part 53, Subparts E and H—Manufacturing Licenses

7. Some stakeholders have suggested that a fueled manufactured reactor with appropriate protections against criticality should not be categorized as a utilization facility under NRC regulations or Section 11cc. of the AEA.

The NRC is seeking comment on possible approaches where the NRC could find that a fueled manufactured reactor would not be a utilization facility, the basis for such a finding, and the potential benefits of and potential issues with such a finding.

White Paper

- Provided to support discussions
- Should not be interpreted as official agency positions

- White Paper basic approach
 - Building from proposed § 53.620(d)
 - Unirradiated fuel loaded (manufacturing license; Part 70)
 - Limit introduction of byproduct material
 - Radioactive inventory, decay heat
 - Assume in-factory conditions for licensing-basis events
 - Limited consequences assumed in categorizing hazards
 - Consideration of various regulations and licenses
 - Part 53 (Manufacturing license, combined license)
 - Part 70 (Special nuclear material)
 - Part 30 (Byproduct material)
 - Parts 71, 73, 74 and others, as needed

White Paper

- Provided to support discussions
- Should not be interpreted as official agency positions

- Selected White Paper examples (technical requirements)
 - Limit power level ($\leq 5\%$ rated thermal power (commercial))
 - Limit inventory (indirectly via defining restrictive safety criteria (Part 20 annual dose))
 - Licensing-basis events
 - Identified for reactor as tested (e.g., fresh fuel)
 - Mitigated without reliance on human actions
 - Consistent with use of generally licensed reactor operators (GLROs)
 - Design features of manufacturing facility and manufactured reactor
 - Holder of manufacturing license ensures testing does not adversely affect downstream activities (storage, transport, deployment)

White Paper

- Provided to support discussions
- Should not be interpreted as official agency positions

- Selected White Paper examples (technical requirements)
 - Possible alternatives mentioned in draft paper:
 - § 53.440(j) (*aircraft impact*) would not apply
 - §§ 53.415, 53.480, and 53.510 (*external hazards*) would not apply
 - Based on limited consequences, commercial codes
 - § 53.610 (*construction*) would apply to portions of manufacturing facility
 - §§ 53.710 and 53.715 (*SSC configuration control*) would apply for testing
 - §§ 53.730(a) through (e) (*human factors*) would apply
 - § 53.730(f) (*staffing plan*) would be supplemented
 - Test Engineer, Reactor Engineer, GLRO
 - §§ 53.870 and 53.880 (*ISI/IST, Integrity assessment*) would not apply
 - Alternate decommissioning funding requirements (such as Parts 70 and 30) might apply

White Paper

- Provided to support discussions
- Should not be interpreted as official agency positions

- Selected White Paper examples (licensing construct)

- COL-TMR

- Applicable to portions of manufacturing facility and each manufactured reactor (1 through n)

	Testing criteria for first reactor	Testing criteria for subsequent reactors	Criteria for final place of operation
Manufacturing facility	ITAAC (COL-TMR)	§§ 53.710 and 53.715	n/a
Manufactured reactor	ITAAC (COL-TMR (incl ML))	ITAAC (COL-TMR (incl ML))	ITAAC (COL (incl ML))

- Updates to the ITAAC schedule under § 53.1449(a) and ITAAC closure notifications under § 53.1449(c) may address multiple manufactured reactors that are under fabrication or planned to be fabricated under the ML and tested under the COL-TMR
 - Conforming changes (e.g., § 53.620(d))

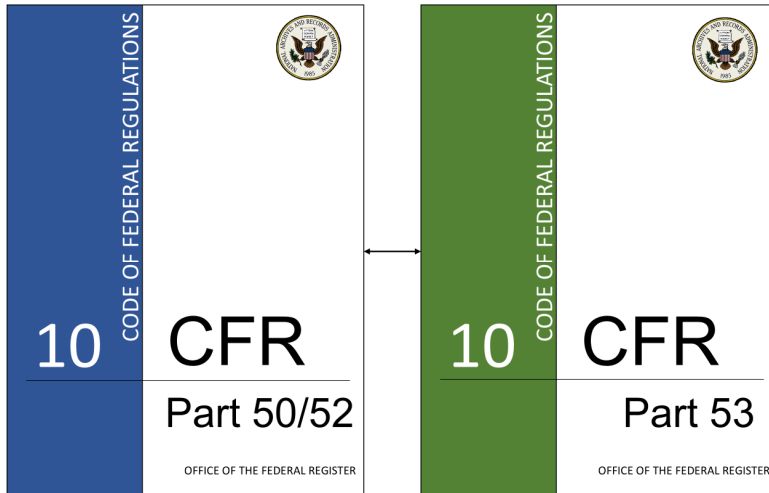
Discussion



Other Selected Topics

- Transitioning from Part 50 or 52 to Part 53
- Consensus codes and standards in proposed Part 53 for NSRST SSCs
- Proposed and planned guidance documents and guidance document updates
- ADVANCE Act and Part 53

Transitioning from Part 50 or 52 to Part 53

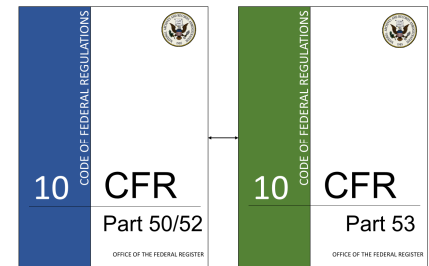


- Part 53 proposed rule language does not currently support starting a licensing path under one part and completing the path under another part.
 - As currently written, all licensing instruments referenced in a Part 53 application must have been issued under Part 53.
 - In other words, a Part 53 OL could not reference a CP issued under Part 50, and a Part 53 COL could not reference an ESP, SDA, DC, or ML issued under Part 52.
- However, an applicant could use technical content from FOAK applications submitted under Part 50 or 52 to form the basis for NOAK applications under Part 53, provided the content meets the requirements in Subpart H of Part 53 for the applicable license, certification, or approval.

Transitioning from Part 50 or 52 to Part 53

Topics to consider when formulating comments:

- Changes to rule language necessary to accommodate approaches beyond what proposed rule would allow
- Differences between Parts 50/52 frameworks (e.g., role of Principal Design Criteria) and Part 53 framework (e.g., §§ 53.210, 53.220, and 53.450)
 - Including how differences in terminology and definitions would be handled
- Need for crosswalk and assessment of gaps to address differences between the frameworks
 - For an application using Advanced Reactor Content of Applications Project (ARCAP) & Technology-Inclusive Content of Applications Project (TICAP), which is based on Licensing Modernization Project (LMP) Methodology
 - For an application using a traditional (LWR) Standard Review Plan (NUREG-0800) structure
- Costs and benefits of allowing cross-part licensing, especially in terms of schedules and resources



Consensus Codes and Standards

(Application to NSRSS SSCs)

Design features needed for §§ 53.210 and 53.220

§ 53.440 Design requirements.

(b) The design features required by § 53.400 must, wherever applicable, be designed using generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the U.S. Nuclear Regulatory Commission (NRC).

... generic endorsement of a code or standard (i.e., through regulatory guidance), including any limitations or conditions, that can be referenced within an application, or through the review of a referenced code or standard as part of the review of a specific application.

*§ 53.020 Definitions
Consensus code or standard means ...*

Consensus Codes and Standards

(Application to NSRSS SSCs)

- Examples of grading requirements via selection of consensus codes and standards:
 - Regulatory Guide 1.26, “Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants”
 - Proposed § 53.480, “Earthquake engineering”
 - Seismic Design Categories (ASCE/SEI 43-19)
- Special Treatment
 - Special treatment (defined in proposed § 53.020) generally refers to measures taken beyond the procurement and installation of commercial grade products to provide confidence that an SSC will comply with the applicable functional design criteria.
 - Should consensus codes and standards applicable to commercial grade SSCs be considered special treatment? If not, how should the use of such standards for NSRSS SSCs be addressed?

Federal Register Notice - Section XVII

Availability of Guidance

... The NRC has issued the following guidance to support licensing reviews of advanced reactors under the existing regulatory framework that will continue to inform applicant development and NRC reviews under parts 50 and 52. Conforming changes to these guidance documents would be needed to ensure they are applicable under part 53. The NRC will issue revisions or part 53-related companions to these guidance documents for public comment after the publication of this proposed rule and then finalize and issue the guidance documents with or after the final part 53 rule.

RG 1.233	Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors
RG 1.247 for trial use	Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities
NUREG-2246	Fuel Qualification for Advanced Reactors
RG 1.87 (Rev 2)	Acceptability of ASME Code, Section III, Division 5, “High Temperature Reactors”
RG 1.246	Acceptability of ASME Code, Section XI, Division 2, “Requirements for Reliability And Integrity Management (RIM) Programs for Nuclear Power Plants,” for Non-Light Water Reactors
TICAP/ARCAP Guidance Documents	RG 1.253, “Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” and DANU-ISG-2022-01 through -09
RG 4.7 (Rev 4)	General Site Suitability Criteria for Nuclear Power Stations

Guidance for Implementing Part 53

Issued for Comment

DG-1413	Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants
DG-5073	Fitness For Duty Programs for Commercial Nuclear Plants And Manufacturing Facilities Licensed Under 10 CFR Part 53
DG-5074	Access Authorization Program for Commercial Nuclear Plants
DG-5075	Establishing Cybersecurity Programs for Commercial Nuclear Plants Licensed Under 10 CFR Part 53
DG-5076	Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants
DG-5078	Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53
DRO-ISG-2023-01	Operator Licensing Programs
DRO-ISG-2023-02	Interim Staff Guidance Augmenting NUREG-1791, 'Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),' for Licensing Commercial Nuclear Plants under 10 CFR Part 53
DRO-ISG-2023-03	Development of Scalable Human Factors Engineering Review Plans

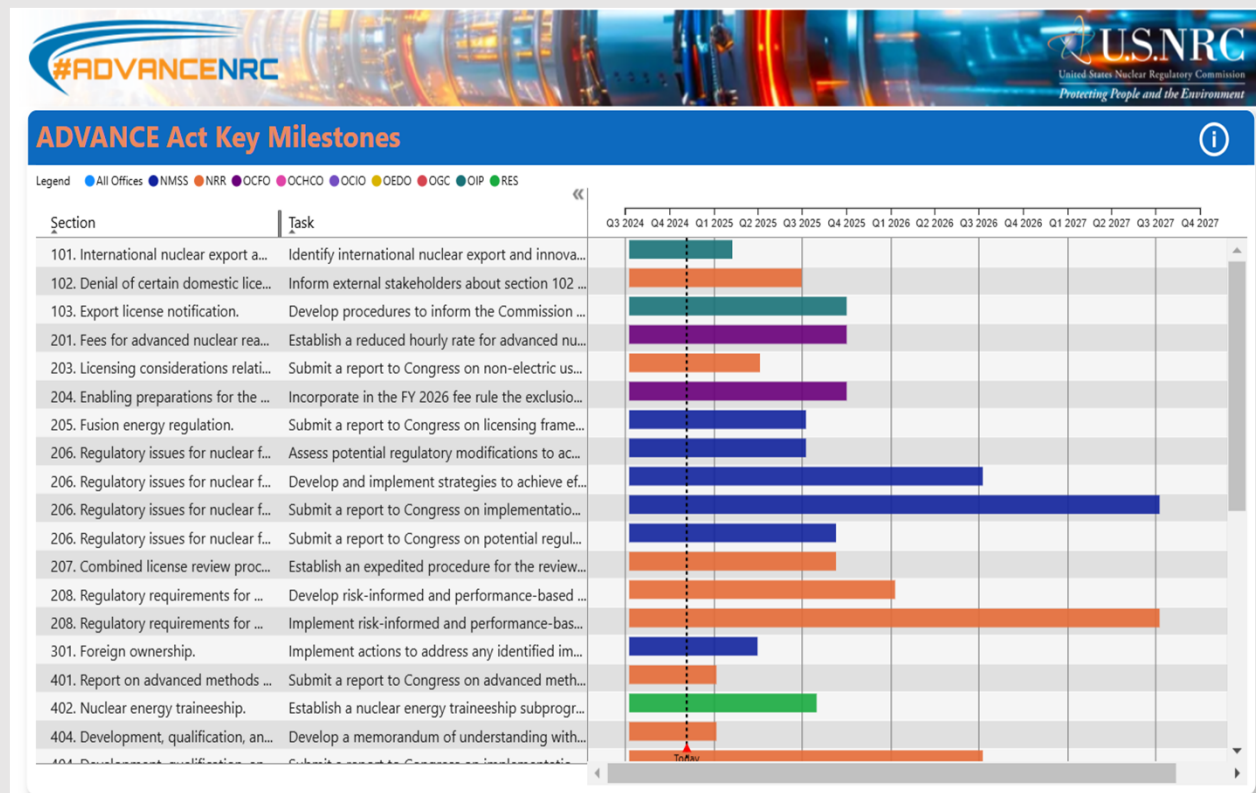
Other Part 53 Guidance Activities

- [Advanced Reactor Application Guidance website](#)
- DG-1443, “Comprehensive Risk Metrics and Associated Risk Performance Objectives for Commercial Nuclear Plants”: under development
- Assessing Public Health Risk Associated with Chemical Hazards of Licensed Material Under 10 CFR Part 53: under development
- Content of application guidance: under development
- NRC has not yet initiated the development of some guidance documents in this category but will engage stakeholders during the development of these documents to ensure common prioritization:
 - Guidance for the implementation of proposed § 53.620(d) to allow for the loading of fuel into a manufactured reactor
 - New consensus codes and standards needed for advanced reactor development

To Stay Informed of Progress



Follow NRC's ADVANCE Act implementation with this Dashboard



For Your Questions and Ideas



Contact us with ADVANCE Act questions, comments and ideas

CAUTION – Please do not confuse with comment process for proposed rule



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Contact Us About the ADVANCE Act of 2024

Please submit your questions or comments on the ADVANCE Act of 2024 below. Submissions received through this form will be considered as part of the NRC's implementation of the ADVANCE Act, and whether the NRC responds to the submission may depend on the nature of the question or comment. Submissions may be used or modified by the NRC in the NRC's implementation of the ADVANCE Act without attribution to the author of the submission.

This form is not for the submission of requests under the Freedom of Information Act (FOIA). You may submit a FOIA request by sending an email to FOIA.Resource@nrc.gov. For more information on how the NRC administers its FOIA program, please visit <https://www.nrc.gov/reading-rm/foia/foia-privacy.html>

NOTE: If you need to report a safety concern, please do not use this page. Instead, please see [Report a Safety or Security Concern](#).

Category: *

---- Select ----

Question or Comment: *

Would you like to remain anonymous?: *

☐ Yes
☒ No

Before sending us contact information, you may wish to review our [Privacy Policy](#).

Specific Request for Comment: ADVANCE Act



- ADVANCE Act specifically mentions the technology-inclusive regulatory framework to be established under Section 103(a)(4) of NEIMA
 - Section 203, “Licensing Considerations Relating to Use of Nuclear Energy for Nonelectric Applications”
 - Section 208, “Regulatory Requirements for Micro-Reactors”
 - Licensing "mobile deployment”
 - Streamlining the review process
 - ADVANCE Act provides the NRC with three implementation options:
 - (1) the existing regulatory framework
 - (2) the Part 53 rulemaking
 - (3) a pending or new rulemaking
- The NRC is seeking comment on how Part 53 could be revised to better enable its potential use to implement the ADVANCE Act



Micro-Reactors (Section 208)



- Given the language included in Section 208, the NRC's specific request for comment under the Part 53 proposed rulemaking on how Part 53 could be revised to better address the ADVANCE Act's requirements includes topics related to micro-reactors
- Next public meeting on micro-reactors focusing on Section 208 of the ADVANCE Act scheduled for early 2025
- NRC response to the NEI Rapid Deployment letter issued December 9, 2024 ([ML24317A174](#))
- NOAK micro-reactor paper expected to go to the Commission in early 2025

Additional Requested Topics

- Change Evaluation Criteria
 - Proposed § 53.1550 vs. NEI 22-05
 - Note that this topic relates to FRN question under “Part 53, Subparts H and I – Probabilistic Risk Assessment Information”
 - Note that NEI 22-05 has at this time not been endorsed by the NRC

Change Evaluation Criteria

Proposed § 53.1550 vs NEI 22-05

Proposed § 53.1550	NEI 22-05
(i) Does not result in an increase to the frequency or consequences of an event sequence such that an event sequence not previously identified as risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e).	Criterion (b)—Change an AOO, DBE or BDBE from non-risk significant to risk significant according to NEI 18-04 LBE risk significance criteria. Criterion (d)—Result in identifying one or more DBAs not previously evaluated in the UFSAR or one or more AOOs, DBEs, or BDBEs that are (i) not previously evaluated in the UFSAR and (ii) classified as risk significant according to NEI 18-04 LBE risk significance criteria.

Change Evaluation Criteria

Proposed § 53.1550 vs NEI 22-05

Proposed § 53.1550	NEI 22-05
(ii) Does not result in an increase to the frequency or consequences of an event sequence such that an event sequence identified as risk significant in accordance with § 53.450(e) exceeds the licensing-basis event evaluation criteria required to be established in accordance with § 53.450(e).	Criterion (a)— Result in a change to the frequency and/or consequences of one or more AOOs, DBEs, or BDBEs documented in the final safety analysis report (as updated) in a manner that would exceed (i) the NEI 18-04 Frequency-Consequence Target; or (ii) an NEI 18-04 Cumulative Risk Target.
(iii) Does not involve either of the following: (A) a change to the NRC-approved comprehensive risk metric(s) or associated risk performance objective under § 53.220(b),	n/a
(B) an increase to the frequency or consequences of one or more event sequences such that there is more than a minimal reduction in the margin between the calculated comprehensive risks posed by the commercial nuclear plant and the safety criteria of § 53.220.	Criterion (a)— Result in a change to the frequency and/or consequences of one or more AOOs, DBEs, or BDBEs documented in the final safety analysis report (as updated) in a manner that would exceed (i) the NEI 18-04 Frequency-Consequence Target; or (ii) an NEI 18-04 Cumulative Risk Target.

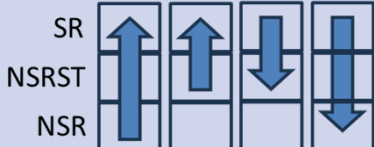
Change Evaluation Criteria

Proposed § 53.1550 vs NEI 22-05

Proposed § 53.1550	NEI 22-05
(iv) Does not involve a departure from a method of evaluation described in the FSAR (as updated) used in assessing licensing-basis events in accordance with § 53.450 unless the results of the analysis under § 53.450 are conservative or essentially the same, the revised method of evaluation has been previously approved by the NRC for the intended application, or the revised method of evaluation can be used under an NRC-endorsed consensus code or standard.	Criterion (i)—Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses. (Note – translates to method of evaluation for design-basis accidents (DBAs))

Change Evaluation Criteria

Proposed § 53.1550 vs NEI 22-05

Proposed § 53.1550	NEI 22-05
(v) Does not result in the escalation in the safety classification of an SSC from non-safety-related to non-safety-related but safety-significant or from non-safety-related but safety-significant to safety-related. 	Criterion (g)—Result in a change of any SSC from (i) No Special Treatment to Safety Related; or (ii) Non-Safety-Related with Special Treatment to Safety Related; or (iii) Safety Related to Non-Safety-Related with Special Treatment; or (iv) Safety Related to No Special Treatment. 
(vi) Does not result in more than a minimal decrease in defense in depth.	Criterion (h)—Result in a change to the performance of a safety-significant SSC that would change the overall evaluation of defense-in-depth adequacy.

Change Evaluation Criteria

Proposed § 53.1550 vs NEI 22-05

Proposed § 53.1550	NEI 22-05
(vii) For commercial nuclear plants licensed under this part for which alternative evaluation criteria are adopted in accordance with § 53.470, does not result in a change to the frequency or consequences of event sequences such that the calculated margins between the results for event sequences evaluated in accordance with § 53.450(e) and the alternative evaluation criteria decreases by 25 percent or more.	n/a
(viii) Does not result in the identification of a new design-basis accident in accordance with § 53.450(f).	Criterion (d)—Result in identifying one or more DBAs not previously evaluated in the UFSAR or one or more AOOs, DBEs, or BDBEs that are (i) not previously evaluated in the UFSAR and (ii) classified as risk significant according to NEI 18-04 LBE risk significance criteria.

Change Evaluation Criteria

Proposed § 53.1550 vs NEI 22-05

Proposed § 53.1550	NEI 22-05
(ix) Does not result in a decrease by 10 percent or more in the margin between the consequence of any design-basis accident and the safety criteria in § 53.210.	Criterion (c)—Result in more than a minimal increase in the consequences of a DBA.
<i>(Note control of SR SSCs by proposed §53.710 (technical specifications))</i>	Criterion (e)—Result in (i) the inability of a Safety Related SSC to meet a Safety Related Design Criterion as described in the FSAR (as updated) or (ii) a change to a Safety Related Design Criterion that reduces the reliability or capability of the SSC in the performance of its RSF as described in the FSAR (as updated).
(x) Does not prevent meeting the design requirements in § 53.440(j) to limit the release of radionuclides from reactor systems, waste stores, or other significant inventories of radioactive materials assuming the impact of a large, commercial aircraft.	n/a

Other Topics

Opportunity for questions on any aspect of the proposed 10 CFR Part 53 rulemaking package including:

- Subparts A through M
- Proposed changes to 10 CFR Part 26
- Proposed changes to 10 CFR Part 73
- Section VI, “Specific Requests for Comments”

Discussion



Additional Information

Additional information on the
10 CFR Part 53 rulemaking is available at
<https://www.nrc.gov/reactors/new-reactors/advanced/modernizing/rulemaking/part-53.html>

Go to
<https://www.regulations.gov/document/NRC-2019-0062-0310> to submit comments (Click on the blue comment button)

Provide meeting feedback for this meeting at
<https://feedback.nrc.gov/pmfs/feedback/for-m?meetingcode=20241511>

Public Comment
Period Closes on
February 28, 2025





Closing

Acronyms & Abbreviations

ADAMS	Agencywide Documents Access and Management System	DC	design certification
ADVANCE Act	The Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024	DG	Draft Regulatory Guide
AEA	Atomic Energy Act of 1954	DRO	Division of Reactor Oversight
ARCAP	Advanced Reactor Content of Application Project	ESP	early site permit
ASCE	American Society of Civil Engineers	FOAK	first-of-a-kind
ASME	American Society of Mechanical Engineers	FR	<i>Federal Register</i>
AOO	anticipated operational occurrences	FSAR	Final Safety Analysis Report
BDBE	beyond-design-basis event	GLRO	generally licensed reactor operator
CFR	<i>Code of Federal Regulations</i>	ISG	Interim Staff Guidance
COL	combined license	ISI	inservice inspection
COL-TMR	combined license for testing of manufactured reactors	IST	inservice testing
CP	construction permit	ITAAC	inspections, tests, analyses, and acceptance criteria
DBE	design-basis event	LBE	licensing-basis event

Acronyms & Abbreviations

LMP	Licensing Modernization Project	RG	Regulatory Guide
LWR	light-water reactor	RIM	Reliability and Integrity Management
		RSF	Required Safety Function
ML	manufacturing license	SDA	Standard Design Approval
NEI	Nuclear Energy Institute	SEI	Structural Engineering Institute
NEIMA	Nuclear Energy Innovation and Modernization Act	SRM	Staff Requirements Memorandum
NOAK	Nth-of-a-kind	SSC	structure, system, or component
NRC	U.S. Nuclear Regulatory Commission	TICAP	Technology-Inclusive Content of Applications Project
NSRSS	non-safety-related but safety-significant	UFSAR	Updated Final Safety Analysis Report
NSRST	non-safety-related with special treatment		
NUREG	U.S. Nuclear Regulatory Commission technical report designation		
OL	operating license		