

RULEMAKING PLAN FOR FUSION ENERGY SYSTEMS

Rulemaking Plan

Consistent with Management Directive 6.3, “The Rulemaking Process,” dated July 3, 2019 (Agencywide Documents Access and Management System Accession No. ML19211D136), the U.S. Nuclear Regulatory Commission (NRC) staff is submitting this rulemaking plan. The NRC staff’s proposed rulemaking would be limited in scope, with the objective of developing a regulatory framework for licensing and regulating fusion energy systems that includes definitions, content-of-application requirements, and other targeted augmentations. Additionally, the NRC staff would develop decision criteria to determine when specific fusion energy systems should be licensed as utilization facilities. Consistent with Management Directive 6.3, the NRC staff determined that a supporting regulatory basis is not needed for the rulemaking because, in addition to direction provided in the Nuclear Energy Innovation and Modernization Act (NEIMA; Public Law 115-439), extensive public interactions, literature reviews, and engagements with international regulators, the Agreement States, and the Advisory Committee on Reactor Safeguards (ACRS) have provided the NRC staff with sufficient technical and public policy information to support this limited-scope rulemaking.

Title

Fusion Energy Systems Rulemaking

Regulation

The primarily affected parts and sections of Title 10 of the *Code of Federal Regulations* (10 CFR) include the following:

- Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material”
 - 30.4, “Definitions”
 - 30.32, “Application for specific licenses”
 - 30.33, “General requirements for issuance of specific licenses”
 - 30.34, “Terms and conditions of licenses”
- Part 50, “Domestic Licensing of Production and Utilization Facilities”
 - 50.2, “Definitions”
- Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions”

As part of the rulemaking process, the NRC staff will assess whether it is more efficient to amend the existing byproduct material requirements in 10 CFR Part 30 to include fusion energy systems or to establish a new 10 CFR part. Creating a new part could limit unintended consequences on current byproduct material licensees from regulatory changes related to fusion energy systems. Housing fusion requirements in a new, dedicated part could also streamline any future rulemakings related to the licensing and regulating of fusion energy systems, including the creation of a utilization facility framework.

During the rulemaking process, the NRC staff may determine that it is necessary to make conforming changes to other parts of 10 CFR to support the changes made to the affected parts and sections listed above.

Regulatory Issue

To provide regulatory certainty and predictability for developers of fusion technologies, the NRC's regulations should provide a technology-inclusive regulatory framework for commercial fusion energy systems by 2027, consistent with the direction given in NEIMA.

Existing Regulatory Framework

In 10 CFR Part 30 and associated regulations including, but not limited to, 10 CFR Part 20, "Standards for Protection Against Radiation," and 10 CFR Parts 31 through 37 and Part 39,¹ the NRC provides a framework for licensing a wide variety of uses for byproduct material. The byproduct material regulations, along with the guidance in NUREG-1556, "Consolidated Guidance About Materials Licenses," are scalable, provide a comprehensive list of technical and regulatory areas required for licensing, and have been used to regulate the potential hazards and risks from an extensive spectrum of uses of byproduct material, from low risk (e.g., portable gauges) to higher risk (e.g., panoramic irradiators). The regulations include specific programmatic requirements, such as those related to financial assurance and emergency planning, applicable for licensing larger quantities of byproduct material, as are expected at fusion energy systems. The NRC's byproduct material framework would provide a technology-neutral basis for the licensing and oversight of the broad array of fusion energy systems currently under development.

The requirements for utilization facilities are currently contained within 10 CFR Part 50 and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Both 10 CFR Part 50 and 10 CFR Part 52 use the definition of utilization facility in 10 CFR 50.2, which is focused on facilities utilizing fission processes. Because fusion devices would be regulated differently than fission facilities, the NRC staff may propose a new utilization facility definition that is specific to fusion devices meeting the to-be-developed decision criteria for determining that a fusion energy system is a utilization facility.² The NRC staff would postpone the development of a new utilization facility framework until such time that developers provide reliable information describing the anticipated design and deployment of new fusion energy systems with greater risk profiles than currently contemplated facilities. However, in this rulemaking the NRC staff would provide criteria for when fusion energy systems should be considered utilization facilities.

¹ 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," 10 CFR Part 35, "Medical Use of Byproduct Material," 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," and 10 CFR Part 39, "Licenses and Radiation Safety for Well Logging."

² As part of the rulemaking process, the NRC staff will assess where to locate any potential utilization facility definition for fusion energy systems, including associated decision criteria.

Explanation of Why Rulemaking Is the Preferred Solution

Rulemaking would ensure a systematic, risk-informed approach to the licensing and regulation of fusion energy systems and their associated hazards. In this rulemaking, the NRC staff would develop technology-specific definitions to establish the scope of regulatory requirements for fusion energy systems and technology-inclusive content-of-application requirements supportive of a performance-based approach to regulation. Other targeted augmentations of current regulations and guidance would address the scalability of requirements, applicability of current domestic licensing practices, and other updates necessary for the safe and secure use of radioactive materials used to produce fusion energy.

Rulemaking would allow for the timely alignment of fusion energy system licensing and regulation across the NRC and the Agreement States, as part of the National Materials Program, to provide near-term regulatory predictability for developers, regulators, and the public.

Description of Rulemaking: Scope

The major objective of revising 10 CFR Part 30, which could include the creation of a new 10 CFR part, is to enhance regulatory clarity and predictability by providing definitions of “fusion” and “fusion energy system” and updating the definition of “particle accelerator” to explicitly define radioactive material associated with the operation of a commercial fusion energy device as byproduct material. Additionally, the NRC staff would develop a content-of-application section to lay out the requirements of a licensing application for a fusion energy system referencing the current byproduct material regulatory framework contained in 10 CFR Part 20, 10 CFR Parts 31-37, and 10 CFR Part 39. The NRC staff would determine the appropriate security requirements for large quantities of tritium (hydrogen-3) that could be possessed at commercial fusion energy systems. Finally, the NRC staff would develop decision criteria for determining when specific fusion energy systems should be considered utilization facilities. The established decision criteria would be reflected in a new definition of “utilization facility.” In developing the rule, the NRC staff would consider near-term fusion energy technologies under development for potential deployment in the United States, including their confinement approach, radioactive material inventory, tritium processing strategy, and operational shielding techniques.

This rulemaking would retain the current overall framework for byproduct material but would provide certainty for near-term fusion energy system applicants. The NRC staff would engage stakeholders to develop the definition of fusion energy systems to ensure that it is technology-inclusive and to identify the specific requirements within existing regulations that should be referenced in the content-of-application section.

The development of the utilization facility approach as part of the hybrid framework, tailored to the specific hazards and safety and security considerations of fusion energy systems that meet the established decision criteria, would be addressed in a separate rulemaking when fusion energy system concepts that are reasonably expected to exceed the decision criteria are under consideration for commercial deployment.

Description of Rulemaking: Preliminary Backfitting Analysis

There are no applicable backfit requirements to this rulemaking activity under 10 CFR Part 30 and 10 CFR Part 50. The NRC staff expects that the backfitting regulations would not apply to

this rulemaking because this rulemaking would apply to specific new technologies only and there are currently no licensees or applicants for fusion energy systems. The NRC staff anticipates that the intended rule defining fusion energy systems and the associated content-of-application requirements would be in place before an applicant seeks a license, and the existing regulations, including provisions to propose alternatives or exemptions, would remain available should any applicant wish to use them. The backfitting regulations do not protect future applicants from the imposition of new or different requirements. Therefore, the NRC staff would not be required to prepare a backfit analysis for the proposed rule.

Description of Rulemaking: Estimated Schedule

The staff estimates the following schedule for the rulemaking:

- Initiate development of the proposed rule—upon receipt of the Commission’s staff requirements memorandum.
- Submit the proposed rule to SECY—16 months after receipt of the staff requirements memorandum.
- Submit the final rule to SECY—13 months after the end of the comment period for the proposed rule

Description of Rulemaking: Rulemaking Priority

The NRC staff has preliminarily determined that this activity would be a high priority rulemaking, using the Common Prioritization of Rulemaking ranking methodology, because (1) it would be a significant contributor toward attaining the NRC’s Strategic Plan’s Safety and Security Objective of ensuring regulatory requirements adequately support the safe and secure use of radioactive materials, (2) it would be a significant contributor toward attaining the NRC’s Strategic Plan’s Safety and Security Objective strategy to promote risk-informed decision-making to result in effective and efficient oversight, rulemaking, and licensing, and certification activities, (3) it is required to satisfy Section 103 of NEIMA which directs NRC to “complete a rulemaking to establish a technology-inclusive, regulatory framework” for advanced reactors by December 31, 2027, and (4) there is substantial Agreement State, stakeholder, and public interest in this topic.

Description of Rulemaking: Costs and Benefits

The proposed action is estimated to involve a medium magnitude of costs, including developing the proposed and final rules as well as guidance supporting the definitions for fusion energy systems and the content-of-application section. The proposed action is estimated to provide the following benefits: (1) ensuring 10 CFR Part 30 or a new 10 CFR part is technology-inclusive of anticipated fusion energy systems within the byproduct material regulatory framework, (2) ensuring appropriate security requirements for large quantities of tritium (hydrogen-3), (3) updating content-of-application requirements to allow for appropriate application and scaling of existing requirements (e.g., emergency preparedness, financial assurance, and facility design), (4) adding regulatory certainty for industry and clarity for public stakeholders, (5) aligning fusion energy system licensing, regulation, and oversight requirements across NRC and Agreement State jurisdictions, (6) adding decision criteria to determine whether a specific fusion energy system is a utilization facility, and (7) reducing the potential need for the use of exemptions, license conditions, or orders to apply appropriate regulatory criteria. As part of the proposed rule

stage, the NRC staff would develop a more detailed cost-benefit analysis that would consider the quantitative costs of developing and implementing the rule, as well as benefits in the form of efficiencies and averted costs.

Cumulative Effects of Regulation

This rulemaking would have a net positive impact on the cumulative effects of regulation because (1) it would provide regulatory certainty and predictability for applicants for fusion energy systems, and (2) the NRC staff plans to engage stakeholders through public meetings throughout the process and provide a formal public comment period.

Agreement State Considerations

An Agreement State radiation control program is compatible with the NRC's regulatory program when the State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of agreement material (source, byproduct, and small quantities of special nuclear material as identified by Section 274b. of the Atomic Energy Act, as amended) on a nationwide basis. Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement States," establishes the process the NRC follows to determine when certain proposed or final NRC program elements (including regulations and guidance) must be adopted by an Agreement State. The regulations and guidance proposed by this rulemaking plan will be a matter of compatibility for the Agreement States.

Guidance

The NRC staff anticipates that a new volume of the NUREG-1556 series of consolidated materials licensing guidance would be developed that is specific to fusion energy systems. Conforming revisions or additional guidance documents may also be developed in parallel with this rulemaking. The NRC staff anticipates that a new inspection procedure, to be part of Inspection Manual Chapter 2800, "Materials Inspection Program," dated March 2, 2020, would need to be developed for the oversight of fusion energy systems.

The NRC staff would assess the need for any necessary guidance for a utilization facility approach during subsequent rulemaking efforts.

Advisory Committee on Reactor Safeguards Review

The NRC staff will determine whether this rulemaking falls within the scope of the ACRS charter as the requirements and guidance are developed. The NRC staff may consult with the ACRS on those matters associated with the decision criteria, along with the operational characteristics and accident scenarios of fusion energy systems.

Advisory Committee on the Medical Use of Isotopes (ACMUI) Review

The NRC staff recommends that a review by the ACMUI would not be necessary, as this rulemaking on fusion energy systems would be considered outside the scope of the committee's charter.

Committee to Review Generic Requirements (CRGR) Review

The NRC staff recommends that a review by the CRGR would not be necessary because the backfit regulations do not apply, as described in the “Description of Rulemaking: Preliminary Backfitting Analysis” section of this rulemaking plan.

Analysis of Legal Matters

The Office of the General Counsel (OGC) has reviewed this rulemaking plan for a rulemaking that adds definitions for fusion energy systems within 10 CFR 30.4; and content-of-application requirements in 10 CFR 30.32, 30.33, or 30.34; and decision criteria for when a fusion energy system would be a utilization facility. This rulemaking would provide clarity and regulatory predictability for future applicants for fusion energy systems and reduce the potential need for case-by-case exemptions or license conditions to provide reasonable assurance of adequate protection of public health and safety.

The regulations and associated guidance described in the rulemaking plan would not constitute backfitting because the backfit regulations do not apply, as described in the “Description of Rulemaking: Preliminary Backfitting Analysis” section of this rulemaking plan.

The proposed rule would require preparation of an environmental assessment, as it appears that there are no categorical exclusions in 10 CFR 51.22(c) that would apply to this rulemaking.

The OGC has concluded that there are no known bases for legal objection to the rulemaking.