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POLICY ISSUE
(Notation Vote)

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FOR: The Commissioners

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SUBJECT: OPTIONS FOR LICENSING AND REGULATING FUSION ENERGY SYSTEMS

PURPOSE:

This paper provides the Commission with options for licensing and regulating fusion energy systems. Consistent with the Nuclear Energy Innovation and Modernization Act (NEIMA; Public Law 115-439), the U.S. Nuclear Regulatory Commission (NRC) staff is presenting these options to support the development of a regulatory framework for fusion reactors, which the NRC staff refers to as fusion energy systems, by 2027. The development of a regulatory framework is intended to provide clarity and predictability for developers of fusion technologies.

This paper considers both commercial and research and development fusion energy systems that are currently contemplated for deployment through the 2030s. As used in this paper, a “fusion energy system” refers to the device that induces nuclear fusion reactions, as well as the associated radioactive material and the supporting structures, systems, and components that are used to contain, handle, process, or control radioactive materials.

SUMMARY:

In the United States, fusion research and development activities have been carried out largely under the purview of the U.S. Department of Energy (DOE). Additional research and development have been performed under the jurisdiction of Agreement States using authority under their agreements with the NRC or using their general authority.

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In accordance with NEIMA, the NRC staff is developing the regulatory infrastructure to support the further development and commercialization of fusion energy systems.

The NRC staff has developed three options for the regulation of fusion energy systems: (1) a utilization facility approach, (2) a byproduct material approach, and (3) a hybrid approach, which would introduce decision criteria to license and regulate fusion energy systems under either a byproduct material or utilization facility regulatory approach based on an assessment of potential hazards. The NRC staff recommends the hybrid approach to ensure long-term technology inclusivity while augmenting the NRC's byproduct material framework to address currently proposed fusion energy systems. This approach is consistent with the maturity of fusion technology; the type, quantity, and form of materials expected to be used in the production of fusion energy; and the anticipated hazards associated with the operation of currently proposed fusion energy systems.

If the NRC staff's recommended option is pursued, the NRC's byproduct material framework in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," would serve as a foundation for regulating fusion energy systems in the near term. Under this option, the NRC would develop a limited-scope rulemaking, which would be implemented through either changes to 10 CFR Part 30 or the consolidated inclusion of fusion-specific requirements in a new part to 10 CFR, and the development of supporting regulatory guidance. Such an approach would include technology-specific definitions to establish the scope of regulatory requirements for fusion energy systems and content-of-application requirements supportive of a performance-based approach to regulation. Other changes to regulations and preparation of associated guidance would address the scalability of requirements and the safe and secure use of radioactive materials in the production of fusion energy. Additionally, the NRC staff would develop decision criteria to determine when specific fusion energy systems should be considered utilization facilities. Given the NRC staff's assessment that near-term fusion energy systems are unlikely to meet such criteria, the NRC staff would wait to initiate development of the utilization facility aspects of the hybrid approach until developers propose fusion energy systems with different risk profiles that pose more significant hazards to public health and safety or introduce new common defense and security considerations. To support both near-term and future deployment of fusion energy systems, the NRC staff will establish an agile and responsive regulatory research program that stays current with the evolving technology and how it impacts potential regulatory issues to support efficient licensing and regulation.

BACKGROUND:

In anticipation of future license applications for fusion energy systems, the Commission asserted in 2009, as a general matter, that "the NRC has regulatory jurisdiction over commercial fusion energy devices whenever such devices are of significance to the common defense and security, or could affect the health and safety of the public."[1] However, the Commission directed the NRC staff to wait until the commercial deployment of fusion technology became more predictable before expending significant resources to develop a regulatory framework.

[1] See Staff Requirements Memorandum (SRM)-SECY-09-0064, "Staff Requirements—SECY-09-0064—Regulation of Fusion-Based Power Generation Devices," dated July 16, 2009 (Agencywide Documents Access and Management System Accession No. ML092230198).

In the years following the Commission's direction to the NRC staff, commercial companies[2] worldwide have continued development of fusion technologies using a variety of designs and fuel cycles. Design proof of concept, including exceeding scientific break-even (i.e., Q>1)[3] and even net power production, is now targeted for some commercial fusion energy system concepts as soon as the mid-to-late 2020s, with deployment projected to follow in the 2030s.

In 2019, through NEIMA, Congress directed the NRC to develop the regulatory infrastructure to support the development and commercialization of advanced nuclear reactors, including both nuclear fission reactors and fusion reactors. Section 103 of NEIMA requires the NRC to "complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants" by December 31, 2027.

In response to NEIMA and the continued development of fusion technologies, the Commission directed the NRC staff in 2020 to "consider appropriate treatment of fusion reactor designs in our regulatory structure by developing options for Commission consideration on licensing and regulating fusion energy systems."[4] In its response to this Commission direction, dated November 2, 2020 (ML20288A251), the NRC staff stated that it would assess the potential risks posed by fusion technologies and possible regulatory approaches separate from the ongoing rulemaking for advanced nuclear fission reactors that would create 10 CFR Part 53, "Risk-Informed, Technology-Inclusive Regulatory Frameworks for Commercial Nuclear Plants."

DISCUSSION:

To inform the development of the framework options presented in this paper, the NRC staff engaged stakeholders, as detailed in enclosure 4, and consulted various references related to fusion processes, technologies, components, hazards, and accident analyses. Documents reviewed include, among others, DOE guidance[5] for existing fusion research facilities in the United States, safety reports for the International Thermonuclear Experimental Reactor (ITER), a Gesellschaft für Anlagen-und Reaktorsicherheit (GRS) report[6] that lists the potential hazards for large fusion facilities, a report by the United Kingdom Atomic Energy Authority (UKAEA) on safety and waste aspects of fusion,[7] and information from current developers.

Technical Assessment of Fusion Technologies

Nuclear fusion is a process in which two or more atomic nuclei in a plasma are combined to form a heavier element, releasing energy along with charged particles and neutrons. Fusion

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[2] See the Fusion Industry Association's report "The global fusion industry in 2022," dated July 14, 2022, (https://www.fusionindustryassociation.org/about-fusion-industry).
[3] Q, the fusion energy gain factor, is the ratio of fusion power produced in a nuclear fusion reactor to the power used to heat the plasma.
[4] SRM-SECY-20-0032, "Staff Requirements—SECY-20-0032—Rulemaking Plan on 'Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062),'" dated October 2, 2020 (ML20276A293).
[5] The DOE has developed magnetic fusion safety requirements and guidance (DOE-STD-6002-96, DOE-STD-6003-96, and DOE-HDBK-6004-99) that could be used as a starting template for any NRC fusion regulations or guidance. The NRC could also use the DOE's standard for tritium handling and safe storage (DOE-STD-1129-2015).
[6] See GRS-389, "Review of the safety concept for fusion reactor concepts and transferability of the nuclear fission regulation to potential fusion power plants," issued January 2016 (https://www.grs.de/en/news/publications/grs-389-review-safety-concept-fusion-reactor-concepts-and-transferability-nuclear). The GRS is a technical support organization to German regulatory authorities.
[7] See UKAEA-RE(21)01, "Technology Report—Safety and Waste Aspects for Fusion Power Plants," issued September 2021 (https://scientific-publications.ukaea.uk/wp-content/uploads/UKAEA-RE2101-Fusion-Technology-Report-Issue-1.pdf).

energy systems can produce tritium, neutrons, and neutron activation products that need to be properly contained to protect public health and safety. Three common plasma confinement approaches, further detailed in enclosure 3, are currently contemplated for fusion energy systems: magnetic, inertial, and magneto-inertial. These methods generally seek to create an environment with sufficient density, temperature, and energy confinement time conducive to the fusion process to allow net energy production. Fusion devices will generally do the following:

- Work with charged particles (e.g., free electrons and atomic nuclei in the plasma).
- Work in a vacuum.
- Accelerate particles and impart kinetic energy (i.e., raise plasma temperature).
- Discharge the resultant particulate into a medium (e.g., into the plasma, walls, or breeding blankets, creating radioactive material, such as tritium and other activation products).[8]

The fusion energy systems considered in this paper involve no special nuclear material (i.e., plutonium, uranium-233, or uranium enriched in the isotope uranium-233 or in the isotope uranium-235). Therefore, the self-sustained neutron chain reaction that defines nuclear fission reactors in NRC regulations is not possible in the currently anticipated fusion energy systems, and these systems would not pose an associated fission product hazard. Instead, the operation of fusion energy systems typically involves the use or production of tritium and other radioactive materials normally categorized by the NRC as byproduct material.

While the hazards associated with specific fusion energy systems vary depending on design, key areas of focus for protecting public health and safety are confinement of radioactive materials, shielding of the radiation (e.g., gamma and neutron), consideration of the presence or absence of supporting systems for breeding tritium, and the inventories of tritium or other radionuclides at the site. Potential radiological hazards posed by fusion energy systems include the following:

- Significant quantities of tritium[9] may be located on the site, including within the vacuum vessel, in processing, in storage, and permeated into structural materials.
- During operation, fusion devices represent a large radiation source, including high-energy neutrons and gamma radiation, that requires shielding and can cause radiation damage to structures, systems, and components.
- Neutron bombardment will activate facility components, with quantities of activation products increasing over time.
- Energetic plasma-surface interactions may generate dust containing tritium and activation products.

[8] This is not true for fusion energy systems that use aneutronic fuel since the fusion reaction does not produce neutrons.
[9] The maximum inventory of tritium at ITER is expected to be 4,000 grams. Commercial companies pursuing fusion energy systems for deployment in the United States have communicated to the NRC staff that tritium inventories for their systems are expected to be significantly less.

In addition to radiological hazards, fusion energy systems pose other hazards associated with large industrial energy-producing facilities. These are design dependent and could impact radiation safety during routine operations and accident scenarios. Some of these hazards include high magnetic fields, thermal shock from plasma disruption, loss of coolant and cooling, hydrogen or dust explosions, chemical hazards, cryogenic releases, and the use of high-power lasers. Initiating events and design basis accidents related to the hazards described above will need to be considered during the licensing of fusion energy systems (e.g., potential for confinement boundary breach).

Further explanation of the most significant hazards and accident scenarios for fusion energy systems appears in UKAEA-RE(21)01 referenced above.

Design characteristics that may contribute to the safe operation of fusion energy systems include the following:

- In the event of a vessel breach and loss of vacuum, the plasma in which sustained fusion reactions occur will collapse. This will end the fusion reactions and the corresponding energy and radioactive material production, minimizing the amount of radioactive material available for release and the energy to drive such a release.
- Only a fraction of the total site tritium inventory is present in the plasma within the vacuum vessel during operation. Therefore, the potential source term due to a vacuum vessel breach is limited.[10]
- Unintended large power excursions are limited because new fuel must continue to be actively introduced and burnt fuel removed to sustain the fusion reaction.

Additionally, fusion energy systems may use low-activation materials (e.g., ferritic/martensitic steels, vanadium alloys, and silicon carbide/silicon carbide composites) that do not produce long-lived, highly radioactive waste that requires cooling before being moved to a repository for disposition. It is anticipated that most of the waste output from fusion energy systems will consist of low-level radioactive waste. However, some proposed designs may produce greater-than-Class-C[11] waste and tritiated waste that will need to be assessed as developers of commercial-scale fusion energy systems prepare for licensing.

Fusion Energy Systems Considered for Near-Term Deployment

Near-term fusion energy systems are expected to differ[12] from historically considered facilities. Past conceptual designs and safety studies were based on large deuterium-tritium tokamaks (i.e., facilities that would operate at greater than 1,000 megawatts electric or about 3,000

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[10] There will be tritium absorbed in materials in the vessel and activated materials in the device components. Energetic plasma-surface interactions will also generate dust that could contain tritium and activation products, and this dust may be chemically reactive, which would contribute to a source term. However, the largest dose contributor is expected to be the tritium present in the vacuum vessel at the time of the event.

[11] The list of radioisotopes and specific activities that define Class C waste category limits in tables 1 and 2 of 10 CFR Section 61.55 “Waste classification,” will need to be expanded to include the radioisotopes of importance for fusion energy systems. For more details, see section 7.4 of DOE-STD-6003-96, “DOE Standard, Safety of Magnetic Fusion Facilities: Guidance,” issued May 1996 (https://www.standards.doe.gov/standards-documents/6000/6003-astd-1996).

[12] See EFDA-RP-RE-5.0, Revision 1, “A Conceptual Study of Commercial Fusion Power Plants: Final Report of the European Fusion Power Plant Conceptual Study (PPCS),” dated April 13, 2005 (https://fire.pppl.gov/eu_ppcs_full_2005.pdf).

megawatts thermal). Today, advances in plasma physics, supporting system technologies (e.g., superconducting magnets and high-power lasers), and computing capability are expected to enable the design and operation of fusion energy systems with less fuel (e.g., tritium) and with better control of the plasma compared to systems historically studied. Tritium inventories, particularly the active inventory in the fusion device, are expected to be low, and the development of structural materials with smaller neutron cross-sections is intended to minimize activation products.

For example, during a March 23, 2022, NRC public meeting on "Developing Options for a Regulatory Framework for Fusion Energy Systems," the Fusion Industry Association (FIA) presented[13] the results of a fusion technology survey of its members. The results of the survey revealed that anticipated near-term fusion power plants are expected to vary greatly in size, ranging from devices aiming to produce kilowatts to devices aiming to produce gigawatts of thermal power. Additionally, the expected tritium inventory at commercial fusion power plants is expected to be less than 100 grams, with 0.1 gram or less in the vacuum chamber. The FIA did note that additional quantities of tritium may be stored in other physical locations on the same site. Therefore, while historical references are important to consider, as discussed below, near-term concepts are expected to be of lower radiological risk based on differences in designs, materials, and inventory of radioactive material.

For the purposes of assessing regulatory frameworks for fusion energy systems, the NRC staff focused on the potential near-term concepts under development for deployment in the United States. Based on the NRC staff's understanding of the designs, expected material possession, and hazards of these facilities, currently proposed fusion energy systems are expected to possess the following device, radioactive material, and supporting structures, systems, and components characteristics:

- No fissile material is present, and criticality (a self-sustaining neutron chain reaction) is not possible.
- Energy and radioactive material production from fusion reactions cease without any intervention in off-normal events or accident scenarios.
- Active post shutdown cooling of the fusion device's structures containing radioactive material is not necessary to prevent a loss of radiological confinement (i.e., vessel breach).[14]
- Radionuclides present in the fusion device, in processing or storage, or in activated materials, in any significant mobilizable amount are expected to result in low doses to workers and member of the public during credible accident scenarios (e.g., less than 1 rem effective dose equivalent to a person off site).

[13] See "Developing a Regulatory Framework for Commercial Fusion Energy Systems," dated March 23, 2022 (https://www.nrc.gov/docs/ML2208/ML22081A057.pdf). The presentation also provided a high-level overview of potential accident releases at fusion plants of the size that FIA members are considering in the near term.
[14] See EURFUBRU XII-217/95, "Safety and Environmental Assessment of Fusion Power (SEAFP): Report of the SEAFP Project," European Commission DG XII, Fusion Programme, issued June 1995 (https://www.researchgate.net/publication/303252621_Safety_and_Environmental_Assessment_of_Fusion_Power_SEAFP_Final_Report_of_the_SEAFP_Project).

- Currently contemplated fusion energy systems would need active engineered features (e.g., plasma confinement mechanisms, vacuum maintaining systems, fuel injection, external heating) to achieve a self-sustaining fusion reaction.

Based on these characteristics, the NRC staff expects that for purposes of minimizing dose to workers and members of the public, the safety focus of fusion energy systems will be on the control, confinement, and shielding of radioactive material present at the site rather than on the performance and control of the device.

As the fusion energy industry in the United States matures and evolves, the NRC staff will consider any new information on the characteristics of fusion energy systems that is gained through external or NRC research activities, licensing, and operating experience; updated designs, concepts, and technologies; knowledge of new or heightened hazards; and stakeholder engagement. The NRC staff will provide any new material that informs the categorization of future fusion energy systems to the Commission, as appropriate, in rulemaking or additional policy papers.

As part of its evaluation of potential regulatory frameworks for fusion energy systems, the NRC staff considered the following factors to inform its recommendation:

- Potential differences in near-term vs. future technologies, including associated hazards and potential significance to public health and safety and the common defense and security

- Consistency with the Atomic Energy Act of 1954, as amended (AEA) and Commission regulations and policy

- Framework scalability from current research and development facilities to expected commercial fusion energy systems

- Consistency with the National Materials Program

- Radiological and nonradiological hazards associated with operations and radioactive material inventories for a variety of designs

- Ability to leverage existing requirements that can legally and technically encompass proposed fusion energy systems and associated hazards

- Applicability and flexibility in certain programmatic areas (e.g., financial protection (Price-Anderson), foreign investment, licensing process)

<u>Legislative and Regulatory Considerations</u>

The NRC staff has continued its assessment of the appropriate regulatory and legal framework for fusion energy systems, building on the analysis presented in SECY-09-0064, “Regulation of Fusion-Based Power Generation Devices,” dated April 20, 2009 (ML092230171). The AEA does not mandate a particular licensing pathway for fusion energy systems. Therefore, to develop regulatory options, the NRC staff assessed whether fusion energy systems could meet the relevant material and device definitions in the AEA. Because fusion energy systems within the scope of this paper do not possess, use, or produce special nuclear material or source material, the NRC staff concludes that proposed fusion energy systems do not currently meet the AEA definitions of special nuclear material, production facility, or source material.[15] As such, this paper does not consider the corresponding NRC regulatory frameworks in these areas. The analysis presented below considers how fusion energy systems may be assessed for categorization using the AEA definitions for utilization facility and byproduct material.

Classification of Fusion Devices as Utilization Facilities

Section 11cc. of the AEA defines a utilization facility as follows:

> … (1) any equipment or device, except an atomic weapon, determined by rule of the Commission to be capable of making use of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public, or peculiarly adapted for making use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public; or (2) any important component part especially designed for such equipment or device as determined by the Commission.

The first part of the definition concerns "any equipment or device, except an atomic weapon, determined by rule of the Commission to be capable of making use of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public." Currently proposed designs for fusion energy systems are not expected to possess, use, or produce special nuclear material, and would, therefore, not be subject to this part of the AEA definition of utilization facility. Any design that makes use of hybrid fusion and fission technologies and, thus, possesses special nuclear material may be regulated by the NRC as a utilization facility on a case-by-case basis upon consideration of the operating characteristics and hazards of the device. Such designs are outside of the scope of this paper.

The second part of this AEA definition concerns facilities "peculiarly adapted for making use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public." As used in this section of the AEA, "atomic energy" is defined as "all forms of energy released in the course of nuclear fission or nuclear transformation." Legislative history suggests that nuclear transformation includes nuclear fusion[16]; thus, a fusion device could qualify as a "device…peculiarly adapted for making use of atomic energy" under this portion of the definition. Therefore, fusion devices could logically be categorized as utilization facilities, provided they are found to make "use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public." The staff assesses fusion devices against these criteria under Option 1 of this paper.

If the Commission determines now or in the future that a subset of, or all, fusion energy systems make use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect public health and safety, a rulemaking would be necessary to categorize such systems as utilization facilities.

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[15] AEA Sections 51 and 61 provide processes for determining that additional material is special nuclear material or source material. Each of these sections requires the Commission to make findings related to the material and the President to assent in writing to the determination.

[16] See chapter 2, "Definitions" (page 11), of Senate Report No. 1699, "Amending the Atomic Energy Act of 1946, as amended, and for Other Purposes."

Past Commission Decisions to Classify Nonreactor Technologies as Utilization Facilities

Using its authority granted by the AEA, the Commission has previously determined on a case-by-case basis whether specific equipment or devices should be regulated as utilization facilities. The NRC staff evaluated historical decisions in which the Commission determined by rule that nonreactor equipment or devices should be classified as such.

In the rule adding the SHINE accelerator-driven subcritical operating assemblies (i.e., irradiation units[17]) to the 10 CFR 50.2 definition of "utilization facility" (79 FR 62329; Oct. 17, 2014), the NRC stated that the irradiation units had "many safety considerations similar to those of non-power reactors." The NRC also explained that regulation of the irradiation units solely under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," was not an appropriate alternative because the irradiation units were operated in a manner similar to fission reactors, the routine operating margin of subcriticality was less than what had been previously approved for other 10 CFR Part 70 licensees, and the operating state more closely resembled the effective neutron multiplication factor of fission reactors than fuel cycle facilities. Additionally, accident scenarios, such as loss of coolant, reactivity additions, and release of fission products, would be similar to non-power reactors.

In another determination, the Commission considered a proposal from Isochem, Inc., to construct the Fission Product Conversion and Encapsulation Facility (FPCE), which would have processed megacurie quantities of radioactive waste resulting from the chemical processing of spent fuel (30 FR 10330; August 19, 1965). The Commission stated in its determination that the processing of megacurie quantities of radioactive material at the FPCE would "pose significant safety considerations" and that the "theoretically possible consequences resulting from a release of a portion of this material are of the same order of magnitude as those for some already defined utilization or production facilities." The Commission also stated that licensing would "require many complex analyses of the processes to be performed, of the equipment and materials to be used and of the interrelationships between one part of the system with other parts." Therefore, the Commission determined that the FPCE was "peculiarly adapted for making use of atomic energy in such manner as to affect the health and safety of the public and as such is a utilization facility."

In both decisions, the Commission considered design elements, operating characteristics, and hazards of the proposed systems when making a determination on whether the systems should be classified as utilization facilities. As presented in the regulatory framework options and recommendations below, the NRC staff used a similar approach to compare the characteristics of fusion energy systems against existing utilization facility and byproduct material regulatory frameworks.

Classification of Fusion Devices as Particle Accelerators and Regulation of Byproduct Material

The NRC staff examined whether and when fusion devices could be considered particle accelerators and, therefore, regulated under the NRC's byproduct material framework in 10 CFR Part 30. While the AEA does not define the term "particle accelerator," the Commission has defined it by rule in 10 CFR 30.4, "Definitions," as follows:

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[17] An irradiation unit is an accelerator-driven subcritical operating assembly used for the irradiation of an aqueous uranyl sulfate target solution, resulting in the production of molybdenum-99 and other fission products.

> Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, accelerator is an equivalent term.

The 2005 Energy Policy Act (EPAct, Public Law 109-58) expanded the definition of byproduct material to include, in part, NRC jurisdiction over particle accelerator-produced radioactive material. Section 11e.(3) of the AEA defines byproduct material as follows:

> … (B) any material that—(i) has been made radioactive by use of a particle accelerator; and (ii) is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity….

The 2007 final rule expanding the definition of byproduct material to account for the added jurisdiction provided in the EPAct (72 FR 55864; October 1, 2007) uses the same classification criteria as the AEA definition of byproduct material. While the 2007 final rule did not include fusion devices, such devices operate in a manner consistent with the regulatory definition of particle accelerator. Specifically, fusion devices create conditions conducive to fusion reactions by accelerating charged particles (ions and electrons) through electromagnetic interactions in a vacuum while discharging the resultant particulate or other radiation into a medium at energies in excess of 1 megaelectron volt. Therefore, the NRC's byproduct material framework, which is currently applied to particle accelerators, could be used as a foundation for an approach to the licensing and regulation of fusion energy systems.

Additionally, many planned fusion devices will intentionally produce radioactive material (e.g., tritium) as part of normal operation to sustain fusion reactions (i.e., for a commercial or research activity). Therefore, the radioactive material produced by such fusion devices would be considered byproduct material, including any incidentally produced.[18] Some fusion energy systems (e.g., some aneutronic technologies) may only generate radioactive material incidental to the production of energy. If the device does not produce radioactive material for use for commercial, medical, or research purposes, the radioactive material would not meet the AEA definition of byproduct material.

Therefore, if the Commission selects a byproduct material approach, States could regulate material made radioactive by fusion devices that produce only incidental radioactive material consistent with their general authorities in statutes and regulations, such as those for the oversight of ionizing radiation and machine produced radiation (e.g., x-ray devices and accelerators). Also, a utilization facility approach to fusion devices producing only incidental radioactive material would be more complicated under the status quo because this radioactive material would not meet the AEA byproduct material definition. The NRC would have jurisdiction over construction and operation of the facility (including over these activities as they relate to radioactive material), but to the degree the radioactive material becomes separated from facility oversight, additional consideration may need to be given to resolving the respective oversight responsibilities of the NRC and the States.

[18] The statements of consideration for the 2007 final rule explain that the NRC will regulate the radioactive material both intentionally and incidentally produced by all accelerators that are operated to produce a radioactive material for its radioactive properties.

Therefore, the NRC staff recommends that the Commission directs the NRC staff to undertake a separate assessment and report back with an analysis of whether the Commission should consider requesting potential legislative changes relating to jurisdiction over fusion energy systems discussed above.

Current Regulatory Treatment of Fusion Technologies

In the United States, research and development activities related to advancing the science of fusion technologies and plasma physics have largely been performed by, or for, the DOE in facilities such as the DIII-D National Fusion Facility in San Diego, California; the Tokamak Fusion Test Reactor and National Spherical Torus Experiment in Princeton, New Jersey; and the National Ignition Facility in Livermore, California. Developers have performed additional research and development under the jurisdiction of Agreement States in accordance with their AEA section 274b. agreements with the NRC or their general authority. The States of California, New York, Washington, and Wisconsin have each licensed fusion research and development activities.

Before the establishment of a new regulatory framework for fusion energy systems, the NRC staff would address specific licensing process, safety, security, and environmental considerations for fusion facilities on a case-by-case basis. The NRC staff would use available tools such as preapplication engagement and, as necessary, application-specific exemptions, hearing orders, or license conditions to address any unique considerations for the licensing and regulation of fusion facilities.

Coordination with Agreement States

The NRC staff has held five government-to-government meetings with Agreement State representatives since March 2021 related to the development of options for licensing and regulating fusion energy systems. These meetings served as a forum for the NRC staff to provide the status of fusion-related activities, receive feedback, and obtain insights on the Agreement States' fusion licensing experience. At the most recent government-to-government meetings on August 24, 2022, and November 30, 2022, the NRC staff discussed its proposed options to regulate fusion energy systems. In general, Agreement State representatives expressed support for a byproduct material approach for near-term fusion energy systems that would include a limited rulemaking in order to provide regulatory clarity and consistency[19] across the National Materials Program.

Agreement State representatives highlighted the need for predictability, reliability, and compatibility between Agreement State and NRC regulation of future fusion energy systems. Jurisdictional boundaries, regulatory requirements, and guidance need to be clear and enable applicants to be licensed consistently across the National Materials Program regardless of location, regulatory authority, or licensed activity. Several specific areas identified for the NRC staff to consider during the development of a regulatory framework included the need to avoid unintended consequences on current byproduct material licensees and the need for a well-defined scope of regulatory authority that includes clear definitions of what constitutes a fusion energy system and the technologies covered by the regulatory framework. Agreement

[19] Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," dated April 26, 2018 (ML18081A070), establishes the process the NRC follows to determine when an Agreement State must adopt certain proposed or final NRC program elements (including regulations and guidance). Any regulations based on 10 CFR Part 30 and related guidance will be a matter of compatibility for the Agreement States.

State representatives further commented that any decision criteria established to classify fusion energy systems as utilization facilities should be focused on ensuring public health and safety (e.g., a credible maximum release) rather than physical or programmatic criteria (e.g., material inventory or need for offsite emergency planning). Additionally, if a utilization facility approach is implemented, the NRC staff should make clear how a fusion energy system classified as a utilization facility would be regulated differently than fission reactor utilization facilities.

Agreement State representatives identified the need for additional licensing guidance, oversight procedures, and training for licensing and inspection personnel specific to fusion energy systems. Agreement State representatives expressed interest in the NRC staff addressing emergency planning, accident analysis methodologies, and nonradiological hazards as part of the development of a regulatory framework for fusion energy systems.

While Agreement State representatives agreed that security considerations for tritium would need to be addressed, they had differing opinions as to whether this should be taken up in the near term or closer to commercial deployment of fusion energy systems. Agreement State representatives also expressed support for retaining the ability to license and regulate fusion research and development facilities, while having an option to return their authority to regulate commercial fusion energy systems to the NRC similar to a process to voluntarily return their authority to the NRC for sealed source and device evaluations.[20]

Interactions with the Advisory Committee on Reactor Safeguards

The NRC staff met with the Advisory Committee on Reactor Safeguards (ACRS, the Committee) to discuss the staff's draft white paper on options for licensing and regulating fusion energy systems (ML22252A192) in a subcommittee meeting on September 23, 2022, and in a full committee meeting on October 5, 2022. Feedback received from the ACRS at these meetings and in its letter dated October 21, 2022 (ML22290A177), informed the development of this SECY paper and the options for a fusion energy system regulatory framework. Specifically, the NRC staff agrees that decision criteria are necessary to determine when a fusion device should be considered a utilization facility and that these should be developed through the rulemaking process. The NRC staff provided a response to the ACRS letter on November 7, 2022 (ML22306A260), addressing the Committee's recommendations.

In its response, the NRC staff agreed that ongoing research and development activities and near-term fusion energy system concepts that can be classified as particle accelerators and produce radioactive material consistent with the definition of byproduct material in the AEA can be appropriately licensed using the NRC's byproduct material regulatory framework. The NRC staff also agreed with the ACRS that the NRC's regulatory approach to fusion energy systems needs to be flexible and scalable to address the diverse array of concepts, the broad range of potential radiological hazards, and the uncertainties associated with the operation of such systems.

Regulatory Framework Options for Licensing and Regulating Fusion Energy Systems

Based on the information that has been presented to and reviewed by the NRC staff related to the designs, the type and quantity of expected material, and hazards of proposed near-term

[20] See SECY-95-136, "Options to Improve and Standardize the Evaluation and Approval of Sealed Sources and Devices Manufactured in Agreement States," dated May 30, 1995 (ML12261A623). Since 1996, eight Agreement States have returned their sealed source and device authority back to the NRC.

fusion energy systems, the NRC staff has developed three regulatory framework options for Commission consideration. Each of the following options may be used to effectively license and regulate fusion energy systems to fulfill the NRC's mission of providing reasonable assurance of adequate protection of public health and safety, promoting the common defense and security, and protecting the environment:

Option 1 – Regulate fusion energy systems under a utilization facility framework

Option 2 – Regulate fusion energy systems under a byproduct material framework

Option 3 – Regulate fusion energy systems under a hybrid framework using either a byproduct material or utilization facility approach based on potential hazards

Option 1—Regulate fusion energy systems under a utilization facility framework

Under this option, a fusion energy system would be licensed and regulated as a utilization facility under the provisions of AEA section 11cc. if the Commission determines by rule that the system constitutes "equipment or [a] device" that is "peculiarly adapted for making use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public." The statutory criteria are focused on the significance of the "equipment or device" rather than the mere presence of material within the system.[21] Consistent with this focus, the current regulatory framework for utilization facilities centers on the physical control of nuclear fission reactions, removal of radioactive decay heat energy, and containment of fission products in different physical and chemical forms created through use of the facility.

As part of its consideration of the appropriateness of regulating fusion energy systems as utilization facilities, the NRC staff first evaluated whether near-term fusion devices would make use of atomic energy "in such quantity as to be of significance to the common defense and security." Considerations that impact such a decision could involve the potential for radiological sabotage, risks associated with material control (e.g., theft and diversion of material), or implications for nonproliferation (e.g., material safeguards). Based on the following considerations, the NRC staff concludes that the fusion devices considered in this paper are unlikely to meet the common defense and security criterion in the AEA definition of utilization facility:

- Proposed fusion devices do not use or produce special nuclear material.
- Proposed fusion devices cannot readily be adapted to produce special nuclear material such that they would present significant proliferation risk.
- Fusion devices and tritium are absent from the current trigger list[22] associated with the Treaty on the Non-Proliferation of Nuclear Weapons, which identifies "items of equipment or material especially designed or prepared for the processing, use or production of special fissionable material."

[21] In other sections (e.g., AEA sections 53b., 63b., and 81a.), the AEA addresses public health and safety and common defense and security considerations associated with regulating the radioactive materials themselves.
[22] See International Atomic Energy Agency (IAEA) INFCIRC/209/Rev, 5, "Consolidated Trigger List," dated February 18, 2020 (https://www.iaea.org/sites/default/files/publications/documents/infcircs/1974/infcirc209r5.pdf).

- Tritium sales and exports are controlled by the DOE and the NRC, but tritium is not subject to domestic and international material safeguards programs.

- Sabotage of the fusion device would not be expected to result in significant offsite consequences given the safety characteristics of near-term fusion devices (addressed in this paper) and the expected radioactive materials present in the device and at the site.

Next, the NRC staff assessed whether proposed fusion devices would make use of atomic energy in such a manner as to affect public health and safety. As part of considering this AEA criterion, the NRC staff assessed the risk from off-normal and accident scenarios for near-term fusion energy systems.[23]

The NRC staff's consideration of the risk from off-normal and accident scenarios is based on operating characteristics, potential offsite consequences, and the contribution of the device to the radiological consequences of potential releases. As part of this analysis, the NRC staff considered the following device characteristics for currently proposed fusion energy systems holistically:

- Fusion devices will not use fissionable material and, thus, cannot achieve nuclear criticality, a self-sustaining chain reaction that requires intervention to stop.

- Fusion devices are expected to immediately cease energy and radioactive material production during an accident scenario; only the material and energy present at the initiation of the event are available to contribute to a potential release. As such, implementation of extensive safety systems to prevent significant continued production of energy and radioactive material in off-normal or accident scenarios is not necessary.

- In the case of a total loss of active cooling, low residual heating precludes melting of the device's structures and a resulting potential release.

- Offsite consequences during credible accident scenarios involving the fusion device are expected to result in a dose to a person off site of less than 1 rem effective dose equivalent, without the need for extensive controls on the device.

Given these operating characteristics, potential offsite consequences, and the limited contribution of the device to the radiological consequences of potential releases, the NRC staff concludes that near-term fusion devices are unlikely to meet the public health and safety criterion in the AEA definition of utilization facility and therefore recommends that the Commission not determine that fusion devices be broadly classified as utilization facilities from a public health and safety perspective at this time. This is consistent with the rationale used to support past Commission decisions, discussed above, in classifying nonreactor technologies as utilization facilities.

Should the Commission, by rule, define fusion devices as utilization facilities, the NRC staff would assess the appropriate implementation of certain AEA requirements for utilization facilities, including, but not limited to, public liability insurance and indemnity requirements under

[23] Potential radiation exposure due to routine operation is not a salient factor for defining a utilization facility; it is controlled in the same manner, and equally, for all NRC-licensed activities (e.g., utilization facility, byproduct material, special nuclear material, and source material licensees) through compliance with 10 CFR Part 20, "Standards for Protection Against Radiation."

the Price-Anderson Act[24]; restrictions on foreign ownership, control, or domination[25]; mandatory hearings[26]; conditions for licensed operators[27]; sole regulation by the NRC[28]; and export controls described in AEA sections 126-129.[29]

Future fusion devices may make use of greater quantities of atomic energy that may present new or heightened hazards that would pose new or different common defense and security or public health and safety considerations. As any such considerations are identified, the NRC staff will engage the Commission, as appropriate.

Implementation

If the Commission directs the NRC staff to prepare a regulatory framework for fusion energy systems using a utilization facility approach, the NRC staff would take the following steps to develop a new framework:

(1) The NRC staff would engage stakeholders to inform the development of a rulemaking plan that would be provided to the Commission for the development of a new utilization facility framework tailored to the specific hazards and safety considerations of fusion energy systems.

(2) The NRC staff would develop, in parallel, new guidance in support of fusion energy systems being licensed under a utilization facility framework. This would provide regulatory clarity and predictability to applicants for fusion energy systems.

Taking into consideration the evaluation above, the NRC staff has prepared the following list of advantages and disadvantages to developing a regulatory framework for fusion energy systems based on a utilization facility approach:

Advantages

- The NRC staff could develop a single, new technology-neutral, risk-informed, and performance-based regulatory framework (e.g., new part to 10 CFR) to specifically address the unique hazards and characteristics of fusion energy systems.

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[24] The Price-Anderson Act, AEA section 170, requires a utilization facility licensee to maintain financial protection to cover public liability claims for nuclear incidents but gives the NRC discretion on whether to require byproduct material licensees to maintain such financial protection. Also, the Price-Anderson Act provides that facilities with rated capacities of 100 megawatts electric or more must maintain primary financial protection equal to the maximum amount of liability insurance available from private sources and must participate in a secondary financial protection pool. All facilities within the secondary pool are obligated to pay a “deferred premium” (in amounts limited by AEA section 170b.) to cover claims for nuclear incidents at any facility in the secondary pool if the resulting damages exceed the amount of primary financial protection for that facility.

[25] AEA section 103d. prohibits issuing a license under AEA section 103 to an alien or any corporation or other entity owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. AEA section 104d. has a similar prohibition.

[26] For utilization facilities, AEA section 189a.(1)(A) requires a hearing before issuing a construction permit under AEA sections 103 or 104b. or under AEA section 104c. for testing facilities.

[27] AEA section 107 requires the Commission to prescribe conditions for licensing individuals as operators of utilization facilities.

[28] AEA section 274c. requires the Commission to retain authority and responsibility with respect to regulation of the construction and operation of any utilization facility.

[29] AEA section 126 describes export licensing procedures, including inimicality reviews; AEA section 127 describes criteria governing U.S. nuclear exports, including the adoption of IAEA safeguards; AEA section 128 describes additional export criteria and procedures including the requirement to maintain IAEA safeguards; and AEA section 129 describes conduct resulting in the termination of nuclear exports.

Disadvantages

- AEA requirements and restrictions for utilization facilities, including those related to financial protection (Price-Anderson Act); foreign ownership, control, or domination; mandatory hearings; and operator licensing, would be applied to all fusion energy systems, even those with limited credibly releasable quantities of radioactive material and resulting offsite consequences. Developing a rulemaking tailored to implementing these requirements and restrictions for fusion energy systems could require significant effort, which may extend beyond NEIMA's December 31, 2027, deadline.

- AEA section 274c. requires the Commission to retain authority and responsibility with respect to the regulation of the construction and operation of any utilization facility. By adopting a utilization facility framework, Agreement States would be precluded from regulating fusion energy systems.

- Significant resources would be required to develop administrative, programmatic, technological, material, and hazard requirements and guidance associated with fusion energy systems under a utilization facility framework.

- Until a utilization facility framework is developed, near-term facilities noted above may require application-specific exemptions, license conditions, or hearing orders to appropriately regulate under this approach. Relying on these licensing processes could reduce clarity and reliability for fusion energy system applicants. This could result in licensing inefficiencies, including increased use of applicant and staff resources on pre-application engagement and development of application-specific exemptions, license conditions, or hearing orders.

Option 2—Regulate fusion energy systems under a byproduct material framework

If the Commission decides that fusion energy systems do not make use of atomic energy "in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public," fusion energy systems could be licensed and regulated using a material-focused approach. The NRC's byproduct material framework is contained in 10 CFR Part 30 and associated regulations including, but not limited to, 10 CFR Part 20 and 10 CFR Parts 31 through 37 and Part 39.[30] This contrasts with the device-focused approach for utilization facilities like that in 10 CFR Parts 50 and 52.[31] As discussed above, the safety and security considerations associated with near-term fusion energy systems emphasize the control, confinement, and shielding of the inventory of radioactive material on-site, rather than the operation of the fusion device.

The NRC currently uses a scalable approach to licensing byproduct material, which has been used to regulate the potential hazards from an extensive spectrum of technologies, from low-risk

[30] 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 Part 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."
[31] 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

portable gauges to higher risk panoramic irradiators. Byproduct material regulations, along with the guidance in NUREG-1556, "Consolidated Guidance About Materials Licenses,"[32] provide a comprehensive list of technical and regulatory areas required for licensing. For licensing larger quantities of byproduct material, such as those that may be present at fusion energy systems, NRC regulations include specific programmatic requirements, such as those related to financial assurance, emergency planning, and decommissioning. The NRC's byproduct material framework could provide a basis for the licensing, regulation, and oversight of fusion energy systems currently under development.

For example, panoramic irradiators, which typically contain large quantities of radioactive material (i.e., 1 to 5 million curies of cobalt-60), are regulated under 10 CFR Part 36. This regulatory framework uses a comprehensive approach for licensing these activities that considers both the material and device, ensuring that the public and workers are adequately protected from the radiological hazards present. Fusion energy systems could be regulated in a similar manner under a byproduct material framework since they would operate with radioactive material or produce radiation during operation that is distributed across multiple components.

Under this option, the NRC staff would prepare a limited-scope rulemaking, which would be implemented through either changes to 10 CFR Part 30 or the consolidated inclusion of fusion-specific requirements in a new part to 10 CFR, and develop supporting regulatory guidance. Such a rulemaking would include definitions related to fusion energy systems; content-of-application requirements; and other regulatory revisions for fusion energy systems. This would address near-term needs for continued developer research and development activities, enable regulatory clarity and reliability for early commercial deployment, and lay the foundation for addressing the longer term needs of a commercial fusion energy industry. The rulemaking would allow for appropriate treatment and scaling of existing byproduct material requirements for fusion energy systems, including those for emergency planning, security, financial assurance, waste handling and disposition, transportation, decommissioning, and facility design. Licensing guidance would clearly reference existing and newly developed regulatory requirements that an applicant would need to meet to receive a license and operate its facility.

Implementation

If the Commission directs the NRC staff to prepare a regulatory framework for fusion energy systems under the NRC's byproduct material framework, as augmented by a limited-scope rulemaking and supporting regulatory guidance, the NRC staff would provide to the Commission a plan similar to that provided for Option 3, omitting the development of decision criteria for when fusion energy systems should be considered utilization facilities. As part of the rulemaking process, the NRC staff will assess whether it is more efficient to augment the existing byproduct material requirements in 10 CFR Part 30 to include fusion energy systems or establish a new part in 10 CFR. Creating a new part may limit unintended consequences for current byproduct material licensees from regulatory changes related to fusion energy systems. Housing fusion requirements in a new, dedicated part may also streamline any future rulemakings related to the licensing and regulation of fusion energy systems. However, developing a new part may be more resource intensive than augmenting the existing byproduct material requirements. In its assessment of these options, the NRC staff would apply the Principles of Good Regulation to

[32] See https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html.

engage openly with stakeholders to evaluate the relative efficiency, clarity and reliability provided by each of the alternatives.

The NRC staff has prepared the following list of advantages and disadvantages to developing a regulatory framework for fusion energy systems based on a byproduct material approach:

Advantages

- A limited-scope rulemaking would ensure a systematic and risk-informed licensing approach for near-term fusion energy system concepts that possess, use, and produce material that meets the statutory definition of byproduct material.

- The NRC staff would develop a regulatory framework to encompass all near-term fusion energy systems that are within the NRC's jurisdiction, reducing regulatory uncertainty.

- New fusion-specific definitions and requirements for the content-of-applications would allow for scaling of byproduct material requirements, including those for emergency planning, security, financial assurance, waste handling and disposition, transportation, decommissioning, and facility design.

- Regulations and guidance, along with their associated compatibility designations, would align fusion licensing and oversight across the NRC and the Agreement States and provide regulatory predictability for industry and clarity for public stakeholders.

- Framework development can leverage lessons learned from Agreement State regulation of existing research and development activities under a byproduct material approach.

- This option likely supports establishment of a regulatory framework for near-term fusion energy systems by the 2027 NEIMA deadline.

Disadvantages

- Some devices using aneutronic technologies may fall outside of the AEA byproduct material provisions.

- Larger, higher hazard commercial fusion energy systems that differ from the characteristics of near-term facilities noted above may require application-specific exemptions, license conditions, or hearing orders to appropriately regulate under this approach or may be determined to be utilization facilities by separate rulemaking. Relying on these licensing processes could reduce clarity and reliability for fusion energy system applicants. This could result in licensing inefficiencies, including increased use of applicant and staff resources on pre-application engagement and development of application-specific exemptions, license conditions, hearing orders, or separate rulemaking.

Option 3—Regulate fusion energy systems under a hybrid framework using either a byproduct material or utilization facility approach based on potential hazards

The near-term fusion energy systems considered in this paper are unlikely to meet the common defense and security and public health and safety criteria in the AEA definition of utilization facility, and, therefore, could be regulated appropriately under a byproduct material approach.

However, future concepts could be developed that have different risk profiles and pose more significant hazards to public health and safety or introduce new common defense and security considerations that would warrant a utilization facility approach. Under this option, to create an approach that would be technology inclusive of all potential fusion energy systems, the NRC staff would develop a hybrid framework, as shown in figure 1. This hybrid framework would use decision criteria to determine whether a fusion energy system should be licensed and regulated using a byproduct material approach as described in Option 2 or a utilization facility approach as described in Option 1.

For fusion energy systems, the decision criteria would be grounded in the AEA definition of utilization facility and would consider the design elements, operating characteristics, and hazards of proposed fusion energy systems that could impact public health and safety or the common defense and security.

The NRC staff would develop criteria through the rulemaking process to establish a threshold for categorizing fusion energy systems as utilization facilities. For example, if using dose-based criteria, a fusion energy system could be considered a utilization facility if credible accidents exist that result in radiological consequences exceeding that level (e.g., greater than 1 rem to a person off site). Fusion energy systems that do not exceed the dose criteria would be licensed using a byproduct material approach.

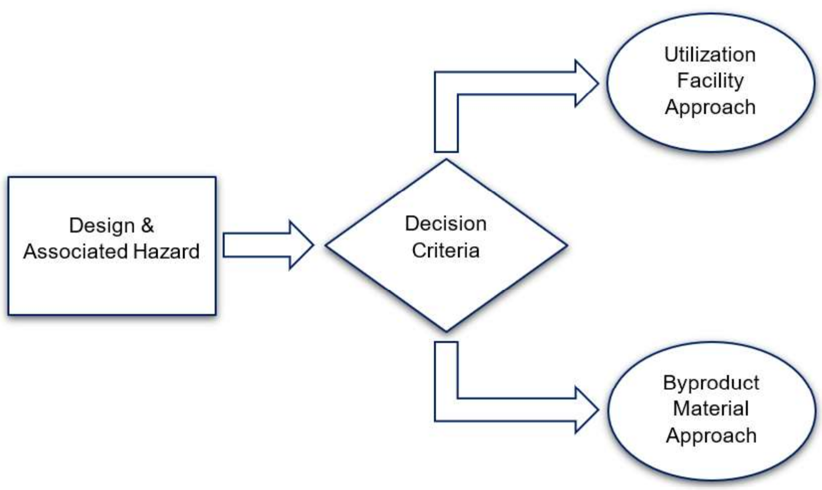

Figure 1: Hybrid approach to fusion licensing and regulation

The decision criteria could also be developed with consideration of tritium inventories and material activation. The NRC staff would evaluate these and other potential approaches for the decision criteria as part of the rulemaking process.

<u>Implementation</u>

If the Commission directs the NRC staff to prepare a hybrid regulatory framework for fusion energy systems, the NRC staff would proceed with the rulemaking plan in enclosure 1 to prepare a limited-scope rulemaking, which would either amend 10 CFR Part 30 or establish a new part in 10 CFR consistent with Option 2. However, in this rulemaking, the NRC staff would also provide criteria for when a fusion energy system should be considered a utilization facility.

As part of a two-phase approach, the NRC staff would postpone the development of the utilization facility aspects of the framework until such time that developers provide detailed information describing the anticipated design and deployment of new fusion energy systems with greater risk profiles or common defense and security concerns than currently contemplated facilities. At the appropriate time, the NRC staff would submit a rulemaking plan to the Commission to initiate the development of the utilization facility approach for such fusion energy systems to support developer needs for regulatory predictability.

Taking into consideration the evaluation above, the NRC staff has prepared the following list of advantages and disadvantages to developing a regulatory framework for fusion energy systems based on a hybrid approach:

Advantages

- This option provides a graded, technology-inclusive approach that could encompass the full range of potential fusion energy systems, including those with different risk profiles from those described in this paper, to address safety and security at facilities with greater hazards.

- New fusion-specific definitions and requirements for the content of applications would allow for risk-informed scaling of byproduct material requirements, including those for emergency planning, security, and facility design.

- Regulations and guidance, along with their associated compatibility designations, would align fusion licensing and oversight across the NRC and the Agreement States and provide regulatory predictability for industry and clarity for public stakeholders.

- Framework development can leverage lessons learned from Agreement State regulation of existing research and development activities under a byproduct material approach.

- This option likely supports the establishment of a regulatory framework for near-term fusion energy systems by the 2027 NEIMA deadline.

Disadvantages

- Under this option, the NRC staff would need to expend more resources than for Option 2 in order to develop the decision criteria and associated technical basis for when a fusion energy system would need to be licensed as a utilization facility.

- Until a utilization facility framework is developed, regulatory uncertainty could be introduced for fusion energy systems that approach the decision criteria, as review of the application would need to be finalized to affirm the assignment of the regulatory approach. This could require application-specific exemptions, license conditions, or hearing orders to appropriately regulate those facilities that approach the decision criteria. Relying on these licensing processes could reduce clarity and reliability for fusion energy system applicants. This could result in licensing inefficiencies, including increased use of applicant and staff resources on pre-application engagement and development of application-specific exemptions, license conditions, and hearing orders. This could also impact the ability of developers to effectively prepare license applications and Agreement States to effectively determine the bounds of their jurisdiction without extensive engagement with the NRC.

COMMITMENT:

If the Commission approves initiation of rulemaking, in accordance with SECY-16-0042, "Recommended Improvements for Rulemaking Tracking and Reporting," dated April 4, 2016 (ML16075A070), the NRC staff will add the rulemaking activity to the agency's rulemaking tracking tool and will add resources for this activity during the next appropriate budget cycle.

RECOMMENDATION:

The NRC staff recommends that the Commission approve Option 3, a hybrid approach, which would introduce decision criteria to appropriately license and regulate fusion energy systems based on their potential hazards. Implementation of this option entails a limited-scope rulemaking (see enclosure 1) to establish a regulatory framework for fusion energy systems that builds upon the NRC's byproduct material framework and develops decision criteria to determine when a fusion energy system should be licensed using a utilization facility approach. This would ensure a systematic and risk-informed approach to the licensing and regulation of fusion energy systems and their associated hazards.

RESOURCES:

Enclosure 2 (nonpublic) includes an estimate of the resources needed to complete the rulemaking plan in enclosure 1.

COORDINATION:

The Office of the General Counsel reviewed this paper and rulemaking plan and has no legal objection.

The Office of the Chief Financial Officer reviewed this paper and has no concerns with the estimated resources in enclosure 2.

Daniel H. Dorman

Digitally signed by Daniel H. Dorman
Date: 2023.01.03 14:20:28 -05'00'

Daniel H. Dorman
Executive Director
for Operations

Enclosures:
1. Rulemaking Plan for Fusion Energy Systems
2. Estimated Resources for the Fusion Energy Systems Rulemaking (nonpublic)
3. Approaches to Producing Energy from Fusion
4. Summary of Engagement on Fusion Energy Systems

SUBJECT: OPTIONS FOR LICENSING AND REGULATING FUSION ENERGY SYSTEMS
DATED: January 3, 2023

ADAMS Accession Nos: Package ML22273A178; Commission Paper: ML22273A163
Enclosure 1: ML22273A175, Enclosure 2: ML22273A177, Enclosure 3: ML22290A236
Enclosure 4: ML22290A237 SECY-012

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