THIS WHITE PAPER IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS) AND REFLECTS INFORMATION PREVIOUSLY SHARED WITH STAKEHOLDERS DURING PUBLIC MEETINGS. THIS LANGUAGE HAS NOT BEEN SUBJECT TO NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS DOCUMENT AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF DEVELOPING OPTIONS FOR COMMISSION CONSIDERATION ON A POSSIBLE REGULATORY FRAMEWORK FOR FUSION ENERGY SYSTEMS.

Introduction

The U.S. Nuclear Regulatory Commission (NRC) is developing a technology-inclusive regulatory framework for advanced nuclear plants. These activities have been undertaken, in part, to address requirements in the Nuclear Energy Innovation and Modernization Act (NEIMA; Public Law 115-439), which directs the NRC to develop a technology-inclusive, regulatory framework for advanced commercial nuclear reactors. NEIMA defines advanced nuclear reactor as including both fission and fusion reactors with significant improvements compared to commercial nuclear reactors under construction as of January 2019. In response to NEIMA and related NRC staff activities associated with the development of a regulatory framework, the Commission directed the staff 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."[1]

The Commission had asserted in 2009 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.[2] The Commission directed the staff at that time to wait until commercial deployment of fusion technology became more predictable before expending significant resources to develop a regulatory framework for fusion technology. Continuing progress in developing fusion technologies and the requirements of NEIMA to provide a technology-inclusive framework for advanced nuclear reactors, including fusion reactors, has moved to the forefront the need to address the licensing and regulation of fusion energy systems.

The staff identified two potential approaches for addressing fusion devices in SECY-09-0064.[3] The two approaches involved either directly licensing and regulating a fusion energy system as a "utilization facility" or extending the NRC's current materials licensing paradigm. In more recent interactions such as the joint Department of Energy (DOE), NRC, and Fusion Industry Association public forum in October 2019, the staff continued to characterize possible regulatory approaches as being ones similar to (1) utilization facilities, (2) materials licenses such as those related to accelerator-produced radionuclides, or (3) a hybrid of the first two approaches or a new approach developed as part of the current activities.

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1 Staff Requirements Memorandum (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 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20276A293)

2 SRM-SECY-09-0064, "Staff Requirements—SECY-09-0064—Regulation of Fusion-Based Power Generation Devices," dated July 16, 2009 (ADAMS Accession No. ML092230198),

3 SECY-09-0064, "Regulation of Fusion-Based Power Generation Devices," dated April 20, 2009 (ADAMS Accession No. ML092230171

Developing Options for Commission Consideration

In response to the Commission direction to the staff in SRM-SECY-20-0032 to develop options for Commission consideration on licensing and regulating fusion energy systems, the NRC staff has initiated interactions with DOE, organizations such as the Fusion Industry Association, individual developers, international organizations, and other public stakeholders. The staff's assessments of the potential risks posed by various fusion technologies and possible regulatory approaches for fusion facilities is being done in parallel with developing the draft proposed rulemaking package for Part 53[4] to support an options paper to the Commission. The draft proposed Part 53 rule is being developed with the aim of accommodating fusion technologies as much as possible to maintain flexibility for future Commission direction on the appropriate approach for licensing and regulating fusion energy systems. While keeping Part 53 open as a possible avenue for regulating fusion energy systems, the staff is also exploring options for Commission consideration that would be similar to materials licenses under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and possible hybrid or new approaches.

Part of the challenge associated with developing possible options for a regulatory framework for fusion energy systems is the wide variety of concepts being considered. Figure 1 provides some examples of technologies and the companies pursuing those technologies and is divided into three general approaches—magnetic fusion energy, magneto-inertial fusion, and inertial fusion energy.

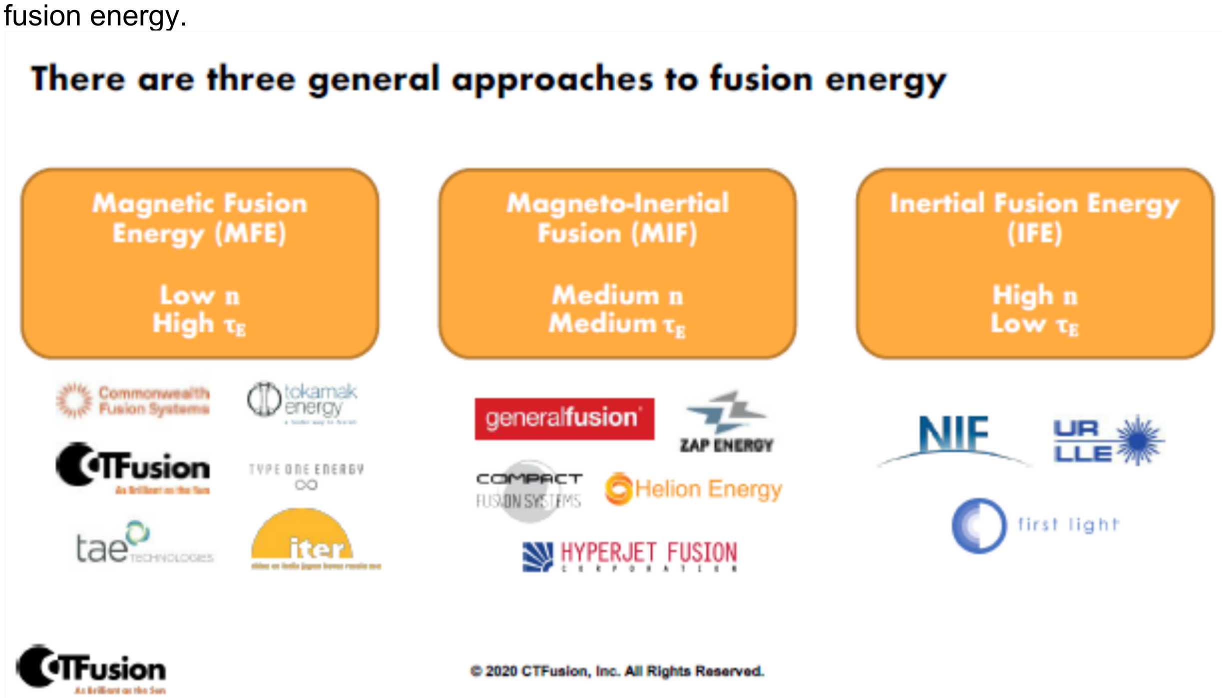

Figure 1: Diversity of Fusion Designs (from slides provided by CTFusion, Inc.)

4 Additional information on Part 53 is provided in SECY-20-0032, "Rulemaking Plan on 'Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)'" dated April 13, 2020 (ADAMS Accession No. ML19340A056) and at the website Regulations.gov under docket number NRC-2019-0062.

A preliminary discussion of three possible options for incorporating fusion energy systems into the NRC's regulatory structure are provided below.

(1) Utilization Facility Approach

Section 11 of the Atomic Energy Act of 1954, as amended (AEA), defines "utilization facility" as follows:

> cc. The term "utilization facility" means (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.

While the history of the NRC has primarily involved utilization facilities making use of special nuclear material, the definition does support the possible treatment of fusion energy systems as utilization facilities provided they are determined in a rulemaking to be of significance to the common defense and security or to affect the health and safety of the public.[5]

The option for addressing fusion energy systems under a utilization facility framework could be implemented by including fusion energy systems within the scope of the proposed Part 53. The existing utilization facility framework is described in documents such as NUREG/BR-0298, "Nuclear Power Plant Licensing Process," (July 2004; ADAMS Accession No. ML042120007) and NUREG/BR-0058, "Reactor Oversight Process" (April 2016; ADAMS Accession No. ML16119A045). The staff is providing versions of preliminary draft rule language for Part 53 to the ACRS and to members of the public in support of that activity. The preliminary rule language addresses areas such as overall safety objectives, design and analysis requirements, operating requirements, and related licensing requirements. The paper providing options for Commission consideration on the licensing and regulation of fusion energy systems is expected to describe how these possible regulations could accommodate commercial fusion facilities and what would then be required for such fusion facilities to be licensed and deployed under a framework developed primarily for fission reactors.

The NRC staff has received some feedback from stakeholders on the possible use of a utilization facility approach for fusion energy systems. Developers and organizations affiliated with the fusion industry generally view this approach to be overly restrictive due to the significant differences in technological attributes of most fusion energy systems, which could result in a low risk to public health and safety from radiological releases. Several examples of feedback related to handling fusion energy systems under a utilization facility approach are summarized below:

- "The Regulation of Fusion – A Practical and Innovation-Friendly Approach," Amy C. Roma and Sachin S. Desai, Hogan Lovells, February 2020

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5 See related discussion in SECY-09-0064 and inclusion of fusion energy systems within the meaning of "making use of atomic energy."

  - The NRC should only regulate when necessary and not try to lump fusion in with fundamentally different fission-based technologies.

- "Igniting the Fusion Revolution in America," Fusion Industry Association, June 2020
  - The NRC's regulations in 10 C.F.R. Parts 50 and 52 for large commercial fission systems and the new regulatory approach discussed for advanced fission systems (i.e. Part 53) address a different suite of risks compared to risks that fusion facilities could create and therefore are not appropriate for fusion systems.

- "Considerations in the Regulation of Fusion-Based Power Generation Devices," David R. Lewis, Jeffrey S. Merrifield and Sidney L. Fowler, Pillsbury Winthrop Shaw Pittman, LLP, November 19, 2020
  - There are a number of legal issues with adverse ramifications that will arise if the NRC proceeds in establishing a regulatory framework for fusion energy predicated on defining a fusion energy device as a utilization facility. Examples are discussed below:
    - Subject to the provisions of the Price Anderson Act (Section 170 of the Atomic Energy Act, 42 U.S.C. § 2210)
    - Preclude the facility owner or operator from being owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government
    - Would impose the licensing process applicable to fission reactors (e.g., requiring a construction permit, mandatory hearing)
    - Construction and operation of utilization facilities are licensed exclusively by the NRC, and this regulatory authority may not be assumed by a State
    - Would subject the device to export licensing requirements that might significantly impair the ability of U.S. companies to commercialize their technology overseas.

- "Bringing Fusion to the U.S. Grid," Committee on the Key Goals and Innovation Needed for a U.S. Fusion Pilot Plant, A Consensus Study Report of the National Academies of Sciences, Engineering, and Medicine," February 2021
  - **Finding:** A regulatory process that minimizes unnecessary regulatory burden is a critical element of the nation's development of the most cost-effective fusion pilot plant.
  - **Finding:** Because existing nuclear regulatory requirements for utilization facilities (10 CFR Part 50) are tailored to fission power reactors, these requirements are not well suited to fusion technology.

(2) Byproduct Material Approach

Section 11 of the AEA defines two types of byproduct material that could be relevant to fusion energy systems:

> e. The term "byproduct material" means–
> (1) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material [SNM];
> *****
> (3) … (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;
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The definitions for both types of byproduct material have been incorporated into NRC regulations and resulted in guidance, such as NUREG-1556, Volume 21, Revision 1, “Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator” (ADAMS Accession No. ML18143A670).

The definition of the first type of byproduct material (associated with producing or utilizing SNM) could cover some of the initial fuel (e.g., tritium) for those fusion devices using radioactive materials as fuel, but would not capture the radioactive materials produced within the fusion facility (e.g., within tritium breeding blankets). Also, in the longer term, such fusion devices would be expected to use the radioactive materials produced within the fusion facility as fuel. The definition of the second type of byproduct material (associated with particle accelerators) could capture both the radioactive materials used in or produced within the fusion facility. Applying the definition of the first type of byproduct material is straightforward, but, as discussed below, additional study is needed on how the definition of the second type of byproduct material (e.g., tritium produced within breeding blankets) would apply to radioactive materials produced by fusion energy systems.

While some research and development activities related to advancing the science of fusion technologies and plasma physics have been performed under the regulatory regime for byproduct materials, including the licensing and oversight by agreement states, the potential development and deployment of commercial systems warrants further study. A possible question is whether all fusion technologies and designs can be considered accelerators under the provisions of the AEA. Assuming that an argument can be made for treating fusion energy systems as an accelerator and that the other parts of the AEA definition are satisfied, the staff would work with agreement state representatives and public stakeholders to develop regulations and guidance for the production and use of byproduct materials in fusion devices.

Although there are some differences in the regulatory processes associated with utilization facilities and byproduct materials, the technical bases for assessing fusion energy systems are expected to be similar in both approaches. For example, in either approach the design and hazard analysis will determine the scope of requirements needed for a license for the safe use of radioactive materials and similar information will be needed to evaluate the design and radiological hazards associated with a particular commercial fusion facility. The technical basis for the NRC’s licensing decisions would also be similar in either approach and would consider factors such as:

- Design Requirements
  - What is the overall design for the fusion facility?
  - How will the facility be constructed?
  - What codes and standards will be used for critical systems,structures, and components?
  - How will critical systems, structures, and components be environmentally qualified?

    - What acceptance testing will be performed for systems,structures, and components prior to initial operation?

- Hazard considerations
    - What are the hazards associated with this fusion facility?
    - How likely is it that any of these hazardous conditions will occur?
    - What are the consequences if one of these hazardous conditions occurs?
    - What type of defense-in-depth will exist for critical safety systems, structures, and components?
    - What mitigating systems, structures, or components will exist for hazardous conditions identified (e.g., interlocks, shielding (primarily neutron), fire protection, worker and public safety protection)? For example, what are the safety systems required to prevent the accidental release of tritium?

The Part 30 regulations also provide for defining potential requirements based on assessments of possible offsite consequences. A partial list of potential specific license requirements include:

- Radionuclides (maximum possession limits)
    - Tritium
    - Activation Products
- Emergency plans
- Financial Assurance and Decommissioning
- Training
    - Operator training
    - Radiation Safety Officer (RSO) qualifications
- Facility design requirements – construction, acceptance testing, codes and standards, facility modifications, and equipment qualification
- Radiation Safety Program
    - Personnel monitoring
    - Radiation monitoring
        - Routine surveys
        - Contamination control
        - Effluent and Environmental Monitoring
    - Operating and Emergency Procedures
        - Procedures for safe use of radionuclides
        - Security of materials
        - Inspection and Maintenance
        - Equipment Testing Requirements
        - Attendance during operation
        - Reporting Requirements
    - Routine Audits
- Waste management
- Environmental protection regulations – Part 51
- Other Hazards – e.g., ozone, chemicals, lasers

The NRC staff has received some feedback from stakeholders on the possible use of a byproduct material approach for fusion energy systems. Developers and organizations affiliated with the fusion industry generally advocate for this approach. Several examples of feedback related to handling fusion energy systems under a byproduct material approach include:

- “The Regulation of Fusion – A Practical and Innovation-Friendly Approach,” Amy C. Roma and Sachin S. Desai, Hogan Lovells, February 2020
    - Current efforts to develop and demonstrate fusion energy are regulated under the “Part 30” radioactive materials framework. This framework has allowed innovation to proceed while still promoting the public health and safety.
    - If, and only if, the NRC determines that fusion cannot be regulated under a Part 30 framework at commercial scale, the agency should initiate efforts to develop a separate regulatory framework distinct to fusion energy, which recognizes the field’s unique but more limited safety and security concerns.

- “Igniting the Fusion Revolution in America,” Fusion Industry Association, June 2020
    - Rules like the NRC’s Part 20 regulations for general radiation protection and the Part 30 rules for handling byproduct material would be the appropriate scope of regulation for commercial and demonstration fusion energy systems since these regulations would address fusion facilities’ foreseeable risk profiles.

- “Considerations in the Regulation of Fusion-Based Power Generation Devices,” David R. Lewis, Jeffrey S. Merrifield and Sidney L. Fowler, Pillsbury Winthrop Shaw Pittman, LLP, November 19, 2020
    - It has been suggested that fusion facilities should be regulated under the NRC regulations in 10 C.F.R. Parts 30 and 31 which govern byproduct material over which the NRC has jurisdiction pursuant to Section 81 of the Atomic Energy Act. This would avoid the problems created by defining a fusion device as a utilization facility but appears problematic under the current definitions of byproduct material in the Act.

- “Bringing Fusion to the U.S. Grid,” Committee on the Key Goals and Innovation Needed for a U.S. Fusion Pilot Plant, A Consensus Study Report of the National Academies of Sciences, Engineering, and Medicine, February 2021
    - **Finding:** The current regulatory framework used for radiation protection and byproduct material provided under 10 CFR Parts 20 and 30 is well suited to fusion technology.

(3) Hybrid or New Approach

The NRC staff is also assessing the possibility of developing hybrid or new approaches to address the licensing and regulation of fusion energy systems. Such approaches may be able to better address the differences in potential radiological hazards associated with a variety of fusion technologies and designs. The staff has discussed during public meetings two possible ways to develop such a hybrid approach. The first way that a hybrid approach could be developed is to distinguish between different fusion energy systems and address some using a utilization facility model and address others using a byproduct material model. This approach is shown in Figure 2 and was referred to as a fragmented approach during interactions with stakeholders. The decision criteria could involve parameters such as estimated offsite consequences or contributors such as inventories of key radionuclides (e.g., tritium).

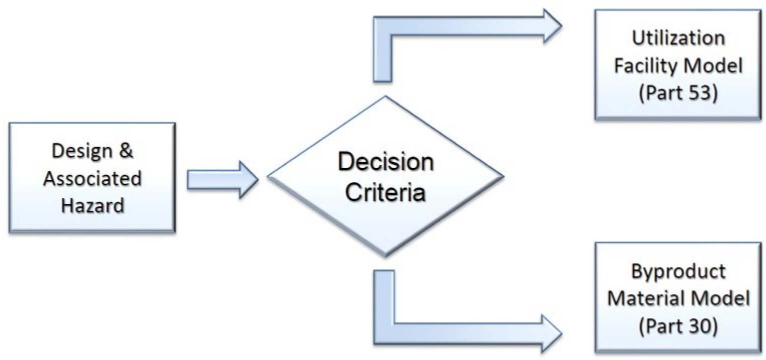

Figure 2: Hybrid Approach within current frameworks (fragmented)

Another way that a hybrid approach could be developed is a graded approach within a single or consolidated framework that would address any fusion energy system. This approach is shown in Figure 3 and was referred to as the consolidated approach during interactions with stakeholders. As with the previous fragmented approach, the decision criteria could involve parameters such as estimated offsite consequences or contributors such as inventories of key radionuclides (e.g., tritium) but distinctions between regulatory requirements for different fusion technologies would be located within the same part of NRC regulations (e.g., a new part for fusion energy systems). Examples of graded approaches to addressing potential hazards are provided in some existing NRC regulations and in DOE requirements and guidance.[6].

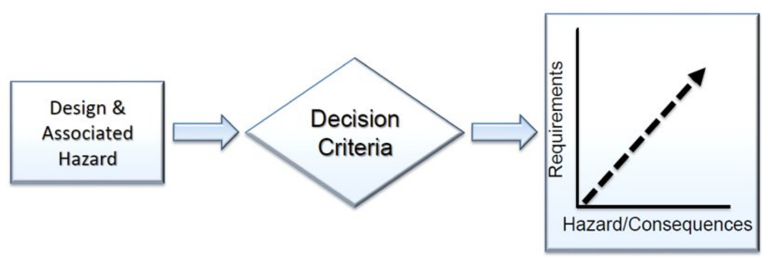

Figure 3: Hybrid Approach within a dedicated fusion framework (consolidated)

The NRC staff has received some feedback from stakeholders on the possible use of a hybrid or new approach for fusion energy systems. Several examples of feedback related to handling fusion energy systems under a hybrid approach include:

- "Considerations in the Regulation of Fusion-Based Power Generation Devices," David R. Lewis, Jeffrey S. Merrifield and Sidney L. Fowler, Pillsbury Winthrop Shaw Pittman, LLP, November 19, 2020
    - Perhaps the cleanest approach, and the one that would provide the most regulatory certainty, would be to amend the Atomic Energy Act to: (1) add a new

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[6] Examples of DOE standards include DOE-STD-1027-2018, "Hazard Cateogorization of DOE Nuclear Facilities," DOE-STD-3009-2014, "Preparation of Nonreactor Nuclear Facility Documented Safety Analysis," and DOE-STD-1020-2016, "Natural Phenomena Hazards Analysis and Design Criteria for DOE Facilities."

Section requiring a license for a fusion energy facility, similar to the provision requiring licensing of materials and without invoking the many restrictions and procedures applicable to utilization facilities; and (2) revise the definition of byproduct material to include material made radioactive in a fusion energy device.

- "Bringing Fusion to the U.S. Grid," Committee on the Key Goals and Innovation Needed for a U.S. Fusion Pilot Plant, A Consensus Study Report of the National Academies of Sciences, Engineering, and Medicine, February 2021
    - In a hybrid approach, the NRC could develop a new regulatory framework through rulemaking that uses aspects of 10 CFR Parts 20 and 30, classifies fusion facilities as "utilization facilities," and uses some aspects of 10 CFR Part 50, such as licensing of operators, if necessary. As such, the regulatory framework would be tailored to the hazards posed by fusion and would only impose regulatory requirements that the Commission deems as necessary to provide reasonable assurance of adequate protection of public health and safety and to promote the common defense and security and to protect the environment.

- "Developing a Graded Approach to Fusion Regulation," Letter dated March 25, 2021, from David Kirtley, Chief Executive Officer, Helion Energy (ADAMS Accession No. ML21085A477).
    - The vast diversity of fusion technologies under development, and applications in industry and power generation, requires a graded approach as a practical matter.
    - The NRC staff could leverage the illustrative tiered approach Helion presented in January in evaluating a potential graded regulatory framework. It should start off recognizing that fusion devices are similar to accelerators rather than fission reactors. It can also leverage performance-based concepts to divide between the different tiers, with different licensing processes within each tier.
    - While there may well be a need to consider different substantive expectations for devices in different tiers in a graded approach, a key difference between the tiers should be the expected level of process required to demonstrate compliance.

Next Steps

The NRC staff is continuing to meet periodically with various stakeholders, agreement states, DOE, and international organizations. These interactions inform the staff's efforts to develop options for Commission consideration on licensing and regulating fusion energy systems. The staff expects to have options developed and a draft paper prepared in late 2021. The staff plans to continue interactions with stakeholders and the ACRS as the paper is finalized and provided to the Commission.