STUDY ON RISK-INFORMED, PERFORMANCE-BASED, DESIGN-SPECIFIC REGULATORY FRAMEWORKS TO SUPPORT LICENSING OF MASS-MANUFACTURED FUSION MACHINES

A Report for the
U.S. Senate Committee on Environment and Public Works and the
U.S. House of Representatives Committee on Energy and Commerce

U.S. Nuclear Regulatory Commission
July 2025

TABLE OF CONTENTS

INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) developed this report as required by Section 205(c)(2) of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act) (Ref. 1). Specifically, Section 205(c)(2) of the ADVANCE Act requires the following:

> (2) REQUIREMENT.—Not later than 1 year after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress a report on—
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> (A) the results of a study, conducted in consultation with Agreement States and the private fusion sector, on risk- and performance-based, design-specific licensing frameworks for mass-manufactured fusion machines, including an evaluation of the design, manufacturing, and operations certification process used by the Federal Aviation Administration for aircraft as a potential model for mass-manufactured fusion machine regulations; and
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> (B) the estimated timeline for the Commission to issue consolidated guidance or regulations for licensing mass-manufactured fusion machines, taking into account—
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> (i) the results of that study; and
>
> (ii) the anticipated need for such guidance or regulations.

The NRC is taking a variety of actions to ensure readiness to license fusion machines. This includes ongoing efforts to augment the existing byproduct material framework to establish a regulatory framework appropriate for and specific to fusion machines (Ref. 2). This rulemaking will provide regulatory clarity and support efficient licensing of fusion machines consistent with the changes to the Atomic Energy Act of 1954 (AEA) (Ref. 3) made by Section 205(a) of the ADVANCE Act. Development of efficient regulatory frameworks for new technologies is a priority for the NRC staff as it implements Executive Order (EO) 14300, "Ordering the Reform of the Nuclear Regulatory Commission" (Ref. 4), which directed the NRC to take actions to reform the NRC, including revising its regulations and guidance documents to facilitate nuclear technology deployment.

This report contains the results of the NRC's study on potential regulatory frameworks for licensing mass-manufactured fusion machines, conducted in response to Section 205(c)(2) of the ADVANCE Act. In conducting the study, the NRC gathered insights from Agreement States[1] and other external stakeholders regarding regulatory frameworks that could be used as a model for licensing mass-manufactured fusion machines. The NRC staff is monitoring the fusion industry's progress by tracking various milestones that will indicate readiness for mass production (Enclosure 1, Table 2). The NRC will use these indicators to inform decisions regarding the optimal timeline for the potential development of additional guidance or regulations.

This study resulted in the following key findings that will be considered as the NRC prepares to license mass-manufactured fusion machines:

[1] Agreement States are States that have entered into agreements in accordance with Section 274b. of the AEA where the NRC discontinues, and the State assumes, the authority to license and inspect byproduct materials, source materials, or less than critical mass quantities of special nuclear materials used or possessed within their borders.

- The depth and complexity of a design review can be risk-informed through development of a framework that categorizes standard designs in accordance with their hazard profiles or adopts a substantial equivalence type review. These processes could be used to efficiently approve fusion machine designs for mass manufacturing and prevent redundant review activities.

- The use of production certificates can yield efficiencies in mass manufacturing. Specifically, the review and certification of manufacturing processes and quality assurance programs could be used to provide high confidence that manufacturers can produce identical fusion machines in accordance with their approved design specifications. Production certificates could provide manufacturers with approval on a permanent or long-term basis to produce a device that has an approved design.

- Codes and standards for design and construction can increase regulatory predictability and promote consistency in approaches across the industry. For example, codes and standards can be used to ensure the safety and integrity of pressure-retaining and safety-related fusion machine components.

- The study highlighted how any regulatory framework for mass-manufactured fusion machines will need to be developed for consistent implementation across the National Materials Program while also considering the differences in Agreement State programs. This is important for fusion machine developers and manufacturers given that fusion machine manufacturing will likely occur in Agreement States and fusion machines may be deployed in several of the 40 jurisdictions (39 Agreement States and the NRC) that make up the National Materials Program.

The NRC values public input and feedback. As such, the NRC held public meetings and Government-to-Government meetings to gather perspectives from a diverse range of stakeholders. In addition, the NRC received written and verbal feedback from the fusion industry. The NRC tailored the study and report to address the feedback received. For example, this report includes a discussion of regulatory considerations applicable to environmental reviews as a result of feedback received from the private fusion sector. Enclosure 2 describes these engagements including incoming correspondence.

EXAMINATION OF REGULATORY FRAMEWORKS USED BY EXTERNAL REGULATORY AUTHORITIES

To support this study, the NRC staff consulted with external regulatory authorities, including other Federal agencies and Agreement States, to gain insight into their regulatory processes and assess their potential applicability to mass-manufactured fusion machines. This section provides an overview of each of the studied frameworks, the lessons learned, and the concepts that the NRC will consider leveraging for a risk-informed, performance-based, design-specific regulatory framework for licensing mass-manufactured fusion machines.

DESIGN, MANUFACTURING, AND OPERATIONS CERTIFICATION OF AIRCRAFT

The NRC examined the aircraft design, manufacturing, and operations certification process used by the Federal Aviation Administration (FAA), as specifically required by Section 205(c)(2) of the ADVANCE Act. The FAA implements a series of certification processes that validate the design, production, airworthiness, and operations aspects of civil aviation products.

An entity seeking to design an aircraft, aircraft engine, or propeller must have its design approved by the FAA through issuance of a type certificate. In this process, the FAA evaluates an application to verify that a proposed design satisfies the applicable airworthiness standards and requirements associated with the category of aircraft being developed. Applicants must conduct appropriate flight, structural, propulsion, and systems tests to demonstrate the aircraft can perform its intended use safely and reliably. The processes and plan to demonstrate compliance must be accepted by the FAA before testing may begin. Additionally, applicants must show how their design meets applicable noise, emissions, and fuel venting requirements. FAA safety engineers, or their designees, will review the submittals of compliance data to determine if the testing complies with the applicable airworthiness requirements. Upon satisfactory review of all required data submittals and testing information, the FAA issues a type certificate to the applicant approving the design for production.

Production certificates allow manufacturers to produce aviation products in accordance with an FAA-approved type design. In this process, the FAA evaluates manufacturers' production facilities, FAA-approved quality system, and technical design data to ensure compliance with applicable requirements. The FAA will issue a production certificate authorizing the production of duplicate aviation products when an applicant demonstrates that it is able to repeatedly produce FAA-approved designs that conform to all applicable requirements under an approved quality system.

An airworthiness certificate authorizes the operation of an aircraft in flight and is required for individual aircraft manufactured in, or imported to, the United States. To receive an airworthiness certificate, the registered owner of an aircraft must submit an application to the FAA. The FAA, or a designee authorized by the FAA, reviews the application and may inspect the aircraft to ensure conformity with the approved type design and applicable requirements and will issue an airworthiness certificate if the aircraft is determined to be in a condition for safe operation. This process is generally more efficient for new aircraft produced under an FAA-approved production certificate because the FAA may rely on the approved quality system to demonstrate conformity with the type design.

An entity seeking to conduct domestic or overseas air transportation must be approved by the FAA through an Air Carrier or Operating Certificate. This is a five-phase review process that ensures the applicant can design, document, and implement processes that demonstrate that it will operate approved aircraft in compliance with regulations and safety standards while managing hazards and risks in its intended operating environment.

The NRC learned valuable lessons from the study of these FAA processes. A key consideration gleaned is that the NRC could develop type categories for fusion machines to delineate standards applicable to different types of fusion machines. Given that the hazard profiles of fusion machines may vary significantly based on different containments and reactions, adoption of standards based on type category in guidance or regulations could create efficiencies in certifying different classes of fusion machines for mass production and distribution. For example, the radiological risks associated with a fusion machine using radioactive fuel like

tritium or producing many activation products may pose a higher radiological risk than a machine using non-radioactive fuels or a reaction that produces fewer activation products. In addition, using a type category concept similar to the FAA could provide regulatory predictability for external entities and efficiency in the licensing process by clarifying how regulatory requirements apply to fusion machines with differing hazard profiles.

The NRC will consider leveraging a production certificate process similar to the FAA. Specifically, the NRC will consider adoption of a production certificate review process in which the NRC reviews and certifies fusion machine manufacturing processes and quality assurance programs to provide confidence that manufacturers can produce duplicate fusion machines in accordance with their approved design specifications. The implementation of such a process could alleviate inspection burden on manufacturers and create efficiencies in the licensing of the operator since both the fusion machine design and its production process will have been certified by the NRC.

REGULATION OF RADIATION THERAPY MEDICAL DEVICES

The NRC explored the regulatory framework used by the Food and Drug Administration (FDA) for radiation therapy medical devices, which involves evaluation of the safety and effectiveness of devices before they go to market and continued monitoring after reaching the market. The extent of regulatory control over a proposed radiation therapy medical device correlates to its safety risk. The devices are categorized as class I, II, or III devices, based on a device's description, intended use, and target patient population, and technological characteristics. The device classification will generally indicate the regulatory pathway required to have the medical device authorized for marketing and will determine the types of regulatory controls that are applied to mitigate the risk of the device.

Class I devices pose the lowest risk to patients. Thus, most class I devices are exempt from premarket notification[2] to the FDA. These devices are still subject to general regulatory controls established by the FDA, such as labeling.

Class II devices present an increased level of risk and may require additional controls to provide reasonable assurance of safety. These devices may also be exempt from premarket approval, but most require the developer to submit a premarket notification submission to the FDA During this premarket review, the FDA will review the submission to verify that (1) a new device has the same intended use and technological characteristics as its predicate or the same intended use and different technological characteristics that do not raise different questions of safety and effectiveness as compared to the predicate; and (2) the device is as safe and effective as its predicate. A new class II device may not be marketed in the United States until the applicant receives a determination from the FDA finding the device to be substantially equivalent to a predicate device. Class II devices are subject to general controls and special controls, including those identified in classification regulations, to mitigate identified risks.

Class III devices present the highest risk and require a premarket approval application to the FDA prior to marketing. Unlike the process for class II devices, the premarket approval is not an equivalence review, and the applicant must provide scientific evidence that stands on its own to

[2] A premarket notification is a streamlined process that allows the FDA to determine if a new medical device is as safe and effective, or substantially equivalent, to a legally marketed, or predicate, device. Submitters must compare their device to one or more predicates and support their substantial equivalence claims.

provide reasonable assurance of safety and effectiveness. Novel devices of a new type that the FDA has not previously classified based on applicable statutory criteria are classified into class III, regardless of the level of risk they pose. Developers of new devices may be eligible to submit a De Novo request to the FDA to create a new device classification for a novel device for which general controls alone or general and special controls provide reasonable assurance of safety and effectiveness. If the FDA grants a De Novo request, the device will be reclassified as class I or class II and may be marketed and used as a predicate for future class II submissions of similar devices.

The NRC will consider leveraging several concepts from the FDA's regulatory framework for mass-manufactured fusion machines. For example, the NRC will consider developing a substantial equivalence review process to gain efficiency in the review of applications for mass-manufactured fusion machines. As applications for novel designs are submitted to the NRC, the NRC staff could identify similarities to other approved designs that may be used as a technical basis to approve the application without duplicating effort. This efficiency could be further leveraged by sharing the technical bases for approved applications across the National Materials Program. In addition, similar to the FDA, the NRC will consider establishing general risk profiles for different types of fusion machines to inform the level of review required to provide reasonable assurance of adequate protection. This approach would facilitate more efficient risk-informed application reviews.

REGULATION OF SAFETY-RELATED COMPONENTS FOR VEHICLES

The NRC examined the regulatory framework used by the National Highway Traffic Safety Administration (NHTSA) within the U.S. Department of Transportation for motor vehicle and highway safety. NHTSA's Federal Motor Vehicle Safety Standards specify performance requirements for vehicles and equipment to ensure that they meet safety criteria and cover a range of areas, such as crashworthiness, vehicle construction, airbag systems, seat belts, lighting, and tire pressure. Automakers must comply with these standards when designing and manufacturing vehicles. NHTSA does not pre-approve new motor vehicles or new vehicle technologies. Instead, it implements a self-certification system of compliance where vehicle and equipment manufacturers certify that their products meet the applicable standards. NHTSA may test vehicles and equipment that are available for sale to consumers to ensure that they meet the applicable standards.

The NRC could incorporate standards similar to NHTSA in developing a regulatory framework for mass-manufactured fusion machines. In particular, the NRC will consider the use of codes and standards to promote safety and consistency in the design and construction of mass-manufactured fusion machines. The NRC is currently monitoring the development of third-party codes and standards that could be used for mass-manufactured fusion devices and will consider adopting them as progress proceeds (Enclosure 1, Table 2). While the primary focus for a regulatory framework for mass-manufactured fusion machines is the radiological hazards associated with the device, developing and adopting such standards could be an efficient means to provide reasonable assurance of effectiveness for components serving a safety function. This could lead to more streamlined license or certificate application reviews for fusion machines.

AGREEMENT STATE LICENSING OF FUSION MACHINES

Agreement States are States that have entered into agreements in accordance with Section 274b. of the AEA where the NRC discontinues, and the States assume, the authority to license and inspect byproduct materials, source materials, or less than critical mass quantities of special nuclear materials used or possessed within their borders. The NRC assessed lessons learned from Agreement States that could support the development of a risk-informed, performance-based, design-specific regulatory framework for mass-manufactured fusion machines. The NRC and Agreement States share the responsibility of regulating the civilian use of radioactive materials across the United States, referred to as the National Materials Program.

Agreement States have already faced challenges with licensing proof-of-concept fusion machines, specifically regarding the evaluation of offsite dose consequences and neutron shielding. These areas will continue to present challenges for the evaluation of commercial designs, but the development of appropriate computing codes would assist reviewers during the evaluation of commercial fusion machine design applications. Based on this lesson learned from the Agreement States' operating experience, the NRC identified, as a potential future action, an evaluation of upgrades to its current suite of codes or new tools to address these areas and enhance preparedness for licensing these technologies (Enclosure 1, Table 3). Use of a common set of codes specific to fusion machines would facilitate the efficient independent validation of an application's shielding and safety designs during the licensing process.

Agreement States have also developed innovative approaches to licensing unique, novel uses of byproduct material. As an example, the Wisconsin Department of Health Services licensed the NorthStar RadioGenix Molybdenum-99/Technetium-99m generator system. Like fusion machines, this was a novel device that had not been licensed elsewhere in the National Materials Program and did not fully fit into an established framework. A joint NRC/Agreement State working group initially developed a safety evaluation of the device based on the analysis techniques outlined in the guidance for applications of sealed source and device (SSD) evaluation and regulation.[3] While this safety analysis is unique to the RadioGenix device, it demonstrated that the existing National Sealed Source and Device Registry (SSDR) framework, which is summarized in detail later in this report, can be used to evaluate novel devices beyond its intended use. Using the SSDR regulatory framework for approving fusion machine designs would leverage an established system familiar to licensing staff and inspectors across the National Materials Program.

The framework that NRC pursues for the design-specific licensing of mass-manufactured fusion machines could have varying impacts on the Agreement States. For this reason, the NRC will continue to consider the impact to Agreement States as part of the development of a regulatory framework for mass-manufactured fusion machines. For example, as discussed previously and in detail below, the adoption of a framework similar to the SSDR approach could require Agreement States to develop and maintain expertise in the certification of fusion machine technology. Alternatively, adoption of a framework similar to transportation packages and spent fuel casks described below could create a paradigm where the NRC reviews all commercial fusion machine certification applications within the National Materials Program and disseminates information on the approval of each design for Agreement States to streamline specific licensing actions associated with approved designs within their State.

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[3] The State of Wisconsin assumed the authority over the safety evaluation report for the RadioGenix device starting with safety evaluation report SER-2020-01 issued on January 13, 2020.

Considerations Unique to the National Materials Program

Under the National Materials Program, Agreement States exercise regulatory authority over their licensees and lands within their boundaries under the terms of their Agreement with the NRC. The NRC exercises regulatory authority in non-Agreement States and maintains regulatory authority over certain categories of radioactive materials, activities, and categories of Federal lands within Agreement States.

The NRC received stakeholder feedback that the NRC should consider the implementation of a nationwide license for approved entities (manufacturer, distributor, or end user) that would enable deployment of multiple, identical fusion machines without additional authorization requirements for individual units to be built and sited in compliance with the license. The jurisdictional considerations associated with Section 274 of the AEA preclude any Agreement State or the NRC from issuing a single license recognized across the United States (i.e., nationwide license) to a non-Federal entity for the possession and use of byproduct material. However, adoption of a certification framework similar to those discussed in this report could streamline the licensing process across jurisdictions. For example, the SSDR process, which is based on a national registry system, could allow for one agency (Agreement State or the NRC) in the National Materials Program to approve a standard fusion machine design that could be used by another agency. Although this approach would not address the need for specific licenses that authorize the possession, production, and use of byproduct material, it would significantly simplify the review process for the use of fusion machines by the end user and would improve regulatory efficiency. All Agreement States and the NRC are required to recognize another agency's license or, in the case of an SSDR, the registration.

In addition, the NRC has processes in place to ensure consistent regulatory standards for possession, production, and use of byproduct material across the National Materials Program. For example, for every regulation, the NRC establishes compatibility requirements that dictate the level of consistency with which each Agreement State must adopt the regulation into their program, which the NRC periodically reviews as part of its oversight of Agreement State programs. The adoption of a certification process for mass-manufactured fusion machines, with appropriate compatibility requirements, could facilitate uniform regulation of these machines across the United States.

The NRC also received stakeholder feedback that the NRC should consider environmental reviews as part of this study. However, the requirements for environmental reviews differ across the National Materials Program. The National Environmental Policy Act (NEPA) applies to Federal agencies and does not apply to States. Agreement States are not required to adopt the NRC's NEPA implementing regulations under their Agreement with the NRC. Agreement States may have their own laws requiring an environmental review, and specific permitting and siting requirements that a fusion machine applicant or licensee would need to follow.

Nonetheless, some of the frameworks discussed in this report have the potential to provide efficiencies in the environmental review process. For example, adoption of a standardized design certification process that incorporates specific engineering and radiological control standards for fusion machines may provide insight into the machine's potential impact on the environment, and comprehensive environmental impacts could then be evaluated once the siting of a fusion machine is considered. Additionally, repeated licensing actions for commercial fusion machines that involve environmental assessments that determine no significant impacts could potentially lead to a more streamlined environmental review process for other applicants

requesting to use similar or identical fusion machines since the previously approved actions could be used as a basis for future reviews.

Further, the NRC is taking additional actions to enhance its NEPA reviews. For example, Section 5(c) of EO 14300 (Ref. 4) directs the NRC to revise its NEPA implementing regulations in consultation with the Council on Environmental Quality. The NRC staff provided options to the Commission in SECY-24-0046 (Ref. 5) in May 2024 to revise the NRC's NEPA implementing regulations and update relevant NRC guidance and policies. If approved, these changes would include revisions to implement the Fiscal Responsibility Act (FRA) NEPA amendments and would reduce burden and streamline subsequent environmental reviews. External stakeholders, including the fusion industry, would have the opportunity to provide comments as part of the rulemaking process.

EXAMINATION OF EXISTING NRC REGULATORY FRAMEWORKS

The NRC implements established frameworks and certification processes to regulate the use, storage, and transportation of radioactive material. Adoption or modification of existing NRC frameworks could provide an efficient pathway for the establishment of a regulatory framework for licensing mass-manufactured fusion machines. In support of this study and in response to stakeholder feedback, the NRC evaluated several NRC frameworks to assess how they could be leveraged to develop a regulatory framework for licensing mass-manufactured fusion machines. Many aspects of these regulatory frameworks share commonalities with the external frameworks previously discussed in this report.

SEALED SOURCE AND DEVICE REGISTRY

Within the NRC's regulatory framework for byproduct material, the regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210, "Registration of product information," provide a pathway for any manufacturer or initial distributor of a sealed radioactive source or a device containing radioactive sources to request registration of their product with the NRC or applicable Agreement State. Some examples include industrial gauging devices, devices used for therapeutic medical treatment, smoke detectors, and blood irradiators.

In this process, the NRC or Agreement State will review the applicant's design, testing, quality control program, labeling, proposed uses, installation information, recommended maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property during normal and likely accident conditions. After completion of the evaluation, the NRC or Agreement State issues a certificate of registration to the requestor, and the registration is incorporated into the SSDR, which is maintained by the NRC and accessible for use by licensing staff and inspectors across the National Materials Program.

Under this framework, the manufacturer or distributor of the source or device is required to hold a specific license to manufacture or distribute its source or device containing byproduct material. Depending on the category of the device registration, the end user of the product may be required to hold a specific license. An end user requesting a specific license may use the registration to develop a safety program and procedures for safe use of the device. Further, NRC and Agreement State staff reviewing applications may use the information in the certificate of registration to streamline the application review process.

The NRC will consider the development of a certification process for mass-manufactured fusion machines similar to the SSDR framework. For example, the NRC will consider establishment of a standard review process for fusion machine designs and issuance of certifications in a registry that may be used to streamline the licensing process for end users. The NRC received stakeholder feedback that a registration process for fusion machines would promote efficient licensing of designs intended for mass production. To use the current SSDR framework in this manner, some changes would be required to account for the characterization of tritium and unsealed activation products generated in fusion machines since this framework is used for sealed sources and devices with known quantities and forms of byproduct material.

TRANSPORTATION PACKAGES

The NRC establishes requirements for the design and manufacture of transportation packages for radioactive materials. The transportation package certification process is set forth in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." This regulatory framework applies to spent nuclear fuel packages, special packaging for solid and liquid materials, and unirradiated fissile material packages.

The design certification process for packaging involves the applicant providing safety characteristics of the design and demonstrating that the design of the packaging meets the criteria in 10 CFR Part 71. The criteria include tests to demonstrate that the package can withstand normal and accident conditions during transport. Once all applicable requirements have been met, the NRC issues the certificate of compliance (CoC), and licensees[4] are authorized to transport materials within the approved package, subject to applicable NRC and Department of Transportation requirements. The validity of a CoC for packaging is conditioned on adherence to specified operating controls and procedure requirements, quality assurance requirements, and the general provisions of 10 CFR Part 71, including referenced Department of Transportation regulations. Licensees do not need to apply or request to use approved transportation packages under their NRC license; however, regulations require each licensee to notify the NRC, in writing, before the first use of the package.

Aspects of the NRC's certification process for transportation packages could be leveraged in developing a regulatory framework for licensing mass-manufactured fusion machines. For example, the NRC does not limit the number of transportation packages that may be fabricated once a design is approved, making mass manufacturing possible. Additionally, the development of design standards for fusion machines may support an efficient certification process for scaled production and deployment of such machines.

INDEPENDENT SPENT FUEL STORAGE CASKS

Two regulatory pathways for independent spent fuel storage are provided in 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste": the site-specific license and the general license. This study focused on the general license as it is most applicable to a framework for mass-manufactured fusion machines. The general license allows for the storage of spent nuclear fuel at power reactor sites.

[4] "Licensees" here refers to parties that already possess a license issued by the NRC or an Agreement State, as the regulatory scheme set forth in 10 CFR Part 71 is a package certification scheme and the general and specific licenses addressed therein are for transportation only (i.e., packages are not licensed and the only license offered under 10 CFR Part 71 is for transporting a package).

The general license is limited to storage of spent fuel in NRC-certified casks, which require a CoC. The safety review conducted for a cask design is primarily based on the information the applicant provides in a safety analysis report to show that the design and operation of the cask meets the requirements in 10 CFR Part 72. Several considerations may affect the depth of review that is needed for a reasonable assurance determination. For example, these considerations include the uniqueness of the design (as compared to existing designs), safety margins, operational experience, defense-in-depth, and the relative risks that have been identified for normal operations and potential off-normal conditions (or anticipated occurrences) and accident conditions.

If the cask design meets the requirements in 10 CFR Part 72, the NRC approval takes the form of a direct final rule, and a companion proposed rule. The rulemaking process allows external stakeholders to review and comment on the draft CoC, technical specifications, and safety evaluation report. If there are no significant adverse comments, the NRC publishes a notice of confirmation in the *Federal Register* establishing the effective date of the rulemaking, which, when completed, leads to an update of 10 CFR Part 72 to add the new or amended CoC to the list of approved cask designs. If the NRC receives a significant adverse comment, the NRC withdraws the direct final rule and addresses the public comment in the companion proposed rule. After addressing the comment, the NRC staff either modify the proposed CoC, technical specifications, and/or safety evaluation report, as necessary, and publishes the final rule in the *Federal Register*, or withdraws the rulemaking.

Aspects of this framework, such as establishing a flexible, consistent, and effective technical review process to certify each design, could be leveraged for a regulatory framework for licensing mass-manufactured fusion machines. Unlike evaluations of transportation packages and SSDs, which only require independent staff reviews, this framework includes the opportunity for external stakeholders to participate in the notice and comment process. This approach would thus provide increased transparency in the regulatory process.

NTH-OF-A-KIND MICROREACTOR REVIEWS

There is growing interest in developing and deploying microreactors, which are anticipated to be small scale fission reactors with thermal power levels on the order of several megawatts to a few tens of megawatts and compact site footprints compared to traditional large light-water fission reactors. The NRC is exploring regulatory approaches to license "nth-of-a-kind" (NOAK) mass-manufactured microreactors of a common design, allowing for a more efficient and predictable licensing and regulatory strategy. Under the current framework, these facilities will be licensed and regulated under Section 103 of the AEA and the NRC's regulations associated with utilization facilities in 10 CFR Parts 50 and 52.

On June 18, 2025, the staff provided a paper to the Commission describing the strategy for licensing NOAK microreactors and seeking approval of a proposed approach to afford finality to standard operational programs or requirements reviewed and approved by the NRC staff in connection with a design certification or manufacturing license (Ref. 7). The NOAK microreactor licensing strategy leverages a maximally standardized design that has been previously approved by the NRC through a whole plant design certification, manufacturing license, or other appropriate approach. Following approval of a standard design, the deployment licensing phase includes evaluating a variety of site suitability activities; verifying completion of inspections, tests, analyses, and acceptance criteria; and using tools to streamline the licensing process (such as design-specific templates for content of applications, an online system for application submission and processing, and automated licensing document templates). The staff is also

using the advanced reactor construction oversight program inspection scoping methodologies to identify a risk-informed, performance-based inspection footprint for NOAK microreactor construction and deployment. These approaches will provide reasonable assurance that microreactors of a particular design will be built and operated in accordance with the design's licensing basis.

Some of the concepts being explored for NOAK licensing could be employed for licensing mass-manufactured fusion machines. In particular, the design certification and manufacturing license approaches provide for streamlined review of a maximally standardized design that could be appropriate for mass-manufactured fusion machines. Additionally, the use of tools similar to those discussed above could yield efficiencies for both applicants and the NRC staff if applied to licensing mass-manufactured fusion machines. Some concepts that are appropriate for utilization facilities, such as those focusing on elements developed for facility-wide measures, may not apply to licensing mass-manufactured fusion machines because fusion machines will be licensed and regulated under 10 CFR Part 30, which focuses on the safety and security associated with the possession and use of the radioactive material itself.

OTHER NRC FRAMEWORKS

The NRC received stakeholder feedback to consider several other NRC frameworks that may have applicability to mass-manufactured fusion machines, which are described below. Given the complexity of novel fusion machine development, the absence of commercial fusion machine operating experience, and the lack of established hazard profiles, these frameworks may be less suitable as initial regulatory framework models for mass-manufactured fusion machines. The NRC will further consider, as appropriate, the applicability of these frameworks, or aspects thereof, as fusion technology develops and operating experience is gained by both the NRC and industry.

Generally Licensed Devices

Under the regulations in 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," the NRC and Agreement States establish general licenses for possession and use of certain devices containing low levels of radioactive material that pose a limited health and safety risk to users and the public. Some examples include fixed gauges used to measure level and density and emergency exit signs that produce light. To qualify as a generally licensed device, the manufacturer must show that the device, among other criteria, can be safely operated by persons not trained in radiological protection and poses low radiation exposure risk under normal and accident conditions. These devices are reviewed and certified through the SSDR framework described earlier in the report. No specific NRC or Agreement State license is required to obtain a device under this framework. Instead, the general license is granted to users upon obtaining the device. As explained above for independent spent fuel casks, the NRC may consider aspects of a general license for a regulatory framework for licensing mass-manufactured fusion machines.

Master Materials & Broad Scope Licenses

Federal agencies holding a license with the NRC to use and possess radioactive material have the option to seek a Master Materials License (MML), which authorizes the Federal licensee to issue permits for the possession and use of licensed material at multiple sites anywhere in the United States. An MML is available only to Federal licensees, such as the Department of Veterans Affairs, Department of the Air Force, and the Department of the Navy. Similar to 10

CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," an MML is a single broad scope license where the Federal licensee maintains a radiation safety committee and an inspection program that provides oversight over the various permitted locations under the MML and authorizes the licensee to perform certain administrative functions that would otherwise require approval by the NRC. As discussed previously, the issuance of a single nationwide license for a commercial entity is not feasible due to the jurisdictional considerations associated with Section 274 of the AEA.

Novel Medical Technologies

The NRC regulations for medical uses of radioactive material under 10 CFR Part 35, "Medical Use of Byproduct Material," include requirements for the use of novel medical applications of byproduct material that do not fit the categories in specific subparts of 10 CFR Part 35. Each application for an emerging technology is evaluated on a case-by-case basis. The NRC and Agreement States evaluate each application in conjunction with the Advisory Committee on the Medical Uses of Isotopes, the medical community, and developers of the new technology, as appropriate, to determine the risks associated with the technology and the appropriate regulatory requirements. The requirements established for a new modality often leverage existing 10 CFR Part 35 requirements, as appropriate. This approach for novel medical technologies has the advantage of a robust and established regulatory framework for a range of medical uses. Without a similar established framework for a range of fusion machines to use as a foundation to license, register, or otherwise approve a new machine design, the regulatory model for novel medical technologies established by 10 CFR Part 35 would be challenging to implement for mass-manufactured fusion machines at this time. As the fusion industry evolves, the NRC will consider adopting a similar administrative process to review novel approaches to fusion.

INSPECTION AND OVERSIGHT

In support of this study and based on stakeholder feedback, the NRC also evaluated the implementation of oversight frameworks for components and devices to complement the licensing and certification concepts discussed previously in the report. Many aspects of the external frameworks studied have commonalities with the NRC's oversight program, including inspections, reporting, and registration of certain devices. The NRC inspection program specified in Inspection Manual Chapter 2800, "Materials Inspection Program" (Ref. 8), is an adaptable framework that can be adjusted to reflect risk and licensee performance-based on the operating experience gained as commercial fusion machines are developed and deployed. Thus, the NRC will consider best practices from both external and internal oversight frameworks as it incorporates mass-manufactured fusion machines into its byproduct material inspection program.

EXTERNAL OVERSIGHT FRAMEWORKS

FAA

The FAA maintains oversight of aircraft following initial certification by establishing the regulations and requirements for inspections and the qualifications for personnel who conduct inspections. While the FAA maintains the ability to inspect any aircraft, certificate holder, or quality program, most aircraft inspections are performed by authorized maintenance personnel in accordance with an operator's continuous airworthiness maintenance program. These maintenance programs are approved by the FAA.

NHTSA

NHTSA does not inspect but may test vehicles and equipment that are available for sale to consumers to ensure that they meet applicable standards. Additionally, automakers are required to assign a unique Vehicle Identification Number to each vehicle they produce, which helps NHTSA track vehicles for recall purposes to ensure proper registration and compliance with safety standards. Further, automakers must report accident data, including information on the causes of crashes, airbag deployment, injuries, and fatalities. NHTSA uses this data to monitor safety trends and to make informed decisions about future regulations. Finally, NHTSA has the authority to impose penalties on automakers for non-compliance with safety standards, including fines for failures in reporting, recalls, or defects. The agency can also order changes to vehicle designs if it determines that safety standards are being violated.

FDA

The FDA conducts post market surveillance of medical devices through a combination of inspections, Medical Device Reports (MDRs), recalls, post market surveillance studies, and the firm's responsibility to comply with Quality System Regulation requirements. These methods are used to gather information on devices and better characterize real-world performance. Inspections are conducted based on a risk-based assessment to maximize inspection resource utilization. Manufacturers, importers, and device user facilities are required to submit MDRs for certain device-related adverse events. Voluntary reporters, such as patients, health care professionals, and caregivers, may also submit MDRs if they have concerns about a marketed device. A recall is the removal or correction of a device that would otherwise be considered in violation of applicable laws or FDA regulations. The FDA evaluates MDRs and other post market information to ensure the continued safety and effectiveness of devices and determine possible follow-up actions, such as an inspection of the manufacturer, device recall, or safety communication to the public.

NRC OVERSIGHT FRAMEWORKS

SSD and Materials Operations

Following issuance of a specific license for manufacturing, distribution, or use of a device containing radioactive material, the NRC implements oversight through the inspection program outlined in Inspection Manual Chapter 2800. This oversight process includes procedures for both routine and non-routine inspections, such as responding to a reported event or instances where a licensee significantly expands their program. The level of inspection periodicity and effort is informed by the safety risk involved with the licensee's program and the licensee's performance implementing their safety program.

Spent Nuclear Fuel Casks and Transportation Packages

For spent nuclear fuel casks, the NRC has established a risk-informed, performance-based inspection program to perform oversight of cask CoC holders and cask fabricators to ensure that the design, fabrication, and testing is in accordance with the CoC. Fabricator inspections are performed at the beginning and end of the initial fabrication and then at 3-year intervals. The NRC also performs inspections of the generally licensed cask users at multiple stages in the process, including construction of the pad and pre-operational testing, loading and unloading of the spent fuel, and routine storage operations. Supplemental or reactive inspections may also be performed if warranted due to licensee performance or occurrence of an event. NRC-

approved transportation casks are used across the National Materials Program and both the NRC and Agreement States conduct performance and safety inspections of package users as a part of routine inspections, in accordance with NRC regional and Agreement State specific guidance documents.

ESTIMATED TIMELINE (SECTION 205(c)(2)(B) OF THE ADVANCE ACT)

The NRC is conducting a rulemaking to amend its byproduct material regulations to provide clarity on the regulation of near-term fusion machines within its existing regulatory framework, consistent with Section 205(a) of the ADVANCE Act. Specifically, the NRC staff provided a draft proposed rule to the Commission recommending a limited-scope modification to NRC regulations to codify new definitions and content of application requirements for fusion machines (Ref. 2) with associated consolidated draft guidance (Ref. 9) (Enclosure 1, Table 2). In addition, in March 2025, the NRC issued "Vision and Strategy: Regulating Fusion Machines Across the National Materials Program" (Ref. 10), which outlines the NRC's strategic focus areas for development and implementation of reliable licensing and oversight processes for fusion machines (Enclosure 1, Table 1).

The NRC is further seeking to support efficient licensing of mass-manufactured fusion machines, beginning with this study. Specifically, this study identified concepts from several models, both internal and external, that the NRC will consider leveraging for a risk-informed, performance-based, design-specific regulatory framework that could be implemented consistently and effectively across the National Materials Program. The NRC staff, in consultation with external stakeholders, developed milestone indicators for industry readiness to monitor the development of fusion technology across the United States to inform both the technical details of the technology and its anticipated deployment (Enclosure 1, Table 2). Some examples include technical achievements, demonstration of novel components, mass production of critical fusion machine components, submission of applications for first-of-a-kind commercial designs, development of engineering standards, application for siting permits, and funding availability. The NRC will incorporate the milestone indicators and associated NRC actions into a revision of the NRC's Vision and Strategy document for fusion regulation (Enclosure 1, Table 2).

Based on input received from the private fusion sector, some developers are projecting that first-of-a-kind commercial fusion machines will deliver energy to the grid or private consumers as early as 2028.[5] Given these near-term delivery goals, it is critical that the NRC continue to pursue a framework that will enable scaled deployment following a successful initial design. The NRC will consider accelerating the development of additional guidance or regulations for mass-manufactured fusion machines if warranted as it monitors the industry's progress. Given the wide array of approaches being pursued by the industry to achieve fusion, a comprehensive standardized design review process would benefit from operational experience in licensing first-of-a-kind fusion machines and technical details from potential applicants regarding the quantity and form of radioactive materials, activation product analyses, potential release pathways, radiation exposure profiles, and shielding for commercial fusion machine designs.

[5] See Helion Energy press release: https://www.helionenergy.com/articles/announcing-helion-fusion-ppa-with-microsoft-constellation/.

The NRC will continue to consult with the private fusion sector and monitor current developments and technical considerations for fusion machines. The NRC has also identified, as a potential future action, assessment of the need for potential updates to or issuance of new guidance for fusion machines following the licensing and initial operation of the first commercial U.S. fusion machine (Enclosure 1, Table 3). Consolidating lessons learned into guidance would provide additional regulatory clarity to both applicants and regulators across the National Materials Program on the criteria used for evaluating commercial fusion machine license applications using the operating experience of the first fusion machine. From there, the staff will continue to identify necessary changes to current NRC regulations, if any, and additional guidance that may be required to implement a regulatory framework for licensing mass-manufactured fusion machines.

As part of its efforts to enhance the licensing process for fusion machines, the NRC is also taking action to incorporate fusion technology into its existing technical training program for both NRC and Agreement State staff (Enclosure 1, Table 2). In the near-term, the NRC staff is developing a self-guided training course that will provide an introduction into the basic science, physics, and technology associated with fusion machines. Additionally, following the publication of the proposed rule and associated guidance discussed earlier in this section, the staff will develop and provide training on its implementation for NRC and Agreement State licensing and inspection staff. Looking forward, as the fusion industry matures and the first commercial fusion machines are successfully deployed, the staff will work to develop an instructor-led fusion technology course similar to other technology courses designed for various byproduct material operations licensed under the 10 CFR Part 30 framework (e.g., radiography, irradiators, and well-logging). Further, the staff will incorporate the lessons learned from the licensing, inspection, and operation of the first U.S. commercial fusion machines into the NRC's established instructor-led byproduct material licensing and inspection courses. These training efforts will support an efficient licensing process for fusion machines.

CONCLUSION

This study provides a critical foundation for establishing a risk-informed, performance-based, design-specific regulatory framework for licensing mass-manufactured fusion machines. This study identified several existing internal and external frameworks that the NRC will consider leveraging for a regulatory framework to safely and efficiently license mass-manufactured fusion machines, while monitoring the industry's advancements on fusion technology. The NRC will continue to identify potential improvements to its byproduct material framework to support efficient licensing of mass-manufactured fusion machines on a time scale that meets the needs of the industry.

ACRONYMS

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
ADVANCE Act	Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024
AEA	Atomic Energy Act of 1954
CFR	*Code of Federal Regulations*
CoC	Certificate of Compliance
EO	Executive Order
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
MDR	Medical Device Report
MML	Master Materials License
NHTSA	National Highway Traffic Safety Administration
NEPA	National Environmental Policy Act
NOAK	Nth-of-a-Kind
NRC	U.S. Nuclear Regulatory Commission
SSD	Sealed Source and Device
SSDR	Sealed Source and Device Registry

REFERENCES

1. Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024, Pub. L. No. 118-67, div. B, § 205, 138 Stat. 1447 (2024).
2. SECY-24-0085, "Proposed Rule: Regulatory Framework for Fusion Machines (3150-AL00; NRC-2023-0071," December 11, 2024 (Agencywide Documents Access and Management System Accession No. ML24019A060 (package)).
3. Atomic Energy Act of 1954, 42 U.S.C. § 2011 et seq.
4. Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," 90 FR 22587 (May 29, 2025).
5. SECY-24-0046, "Implementation of the Fiscal Responsibility Act of 2023 National Environmental Policy Act Amendments," May 30, 2024 (ML24078A013 (package)).
6. SRM-SECY-24-0008, "Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory," June 17, 2025 (ML25168A133).
7. SECY-25-0052, "Nth-of-a-Kind Microreactor Licensing and Deployment Considerations," June 18, 2025 (ML24309A266 (package)).
8. NRC Inspection Manual Chapter 2800, "Materials Inspection Program," June 30, 2023 (ML23102A025).
9. NUREG-1556, Volume 22, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Fusion Machines," Preliminary Draft, March 12, 2025 (ML24295A002).
10. "Vision and Strategy: Regulating Fusion Machines Across the National Materials Program," March 11, 2025 (ML25069A706).

ENCLOSURE 1

SUMMARY OF ACTIONS RELATED TO THE ACCELERATING DEPLOYMENT OF VERSATILE, ADVANCED NUCLEAR FOR CLEAN ENERGY ACT OF 2024 (ADVANCE ACT) SECTION 205

Actions described in this Enclosure include completed, ongoing, and potential new actions related to Section 205 of the ADVANCE Act. These tables are not exhaustive but highlight actions of particular relevance to this report.

Table 1 – Completed NRC Program Actions Related to ADVANCE Act Section 205

Action	Primary ADVANCE Act Section 205 Provision	Impact	Status/Timeframe
Issued "Vision and Strategy: Regulating Fusion Machines Across the National Materials Program" (ML25069A706)	205(c)	This document outlines the NRC's strategic focus areas and will have a substantial impact on the development and implementation of reliable licensing and oversight processes for fusion machines.	Completed

Table 2 – Ongoing NRC Program Actions Responsive to ADVANCE Act Section 205

Action	Primary ADVANCE Act Section 205 Provision	Commission Action Needed?	Impact	Status/ Timeframe
Developing self-guided fusion fundamentals training course	205(c)	No	A self-guided training course to provide NRC and Agreement State staff with foundational technical knowledge on fusion machines in preparation for licensing and inspection activities is expected to yield substantial benefits to the NRC and external entities.	Ongoing; 2026
Publishing final rule on fusion machines, including conforming changes to NRC regulations to comport with the ADVANCE Act	205(a)	Yes	Improvements in application quality, established content of application criteria, and consistency of review are expected to yield moderate efficiency gains to the NRC and external entities.	Draft proposed rule provided to the Commission
Incorporating industry milestone indicators and associated NRC actions into a revision of the NRC's Vision and Strategy document for fusion regulation (ML25069A706)	205(c)	No	Integrating the monitoring and evaluation of industry milestones into the NRC's strategy document for fusion regulation will provide an action plan to ensure regulatory readiness for fusion machines as technology is developed.	Ongoing 2026
Issuing NUREG-1556, Volume 22: "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Possession Licenses for Fusion Machines"	205(c)	No	Improvements in application quality, established review criteria, and consistency of review are expected to yield moderate efficiency gains to the NRC and external entities.	Ongoing; 2027

Action	Primary ADVANCE Act Section 205 Provision	Commission Action Needed?	Impact	Status/ Timeframe
Conducting implementation training for NRC and Agreement State licensing and inspection staff following publication of a final fusion rule	205(c)	No	Training on implementation of the new regulations for fusion machines and the associated guidance is expected to yield moderate efficiency gains to the NRC and external entities.	Ongoing; 2028
Monitoring the development and assessing the potential adoption or endorsement of third-party codes and standards for fusion machines (e.g., American Society of Mechanical Engineers)	205(c)	No	Specific standards for the safe design and construction are expected to have a substantial impact to ensure the safety and integrity of pressure-retaining and safety-related fusion machine components.	Ongoing; 2029
Monitoring industry milestones and technical developments to inform the NRC regarding whether and when to develop additional guidance or regulations for mass-manufactured fusion machines	205(c)	No	Understanding the progress of fusion technology development and operating experience will provide the NRC staff with an indication of readiness for issuance of additional guidance or regulations that will further support efficient licensing of mass-manufactured fusion machines.	Ongoing; 2030+

Table 3 – Potential New NRC Program Actions Related to ADVANCE Act Section 205[6]

Action	Primary ADVANCE Act Section 205 Provision	Commission Action Needed?	Impact
Assess lessons learned for potential updates to or issuance of new guidance for fusion machines following initial licensing, deployment, and operation of the first commercial fusion machine in the United States	205(c)	No	Improvements in application quality, established review criteria, and consistency of review are expected to yield moderate efficiency gains to the NRC and external entities.
Evaluate existing suite of NRC health physics computer codes to identify and implement necessary updates or new tools to support independent analyses of fusion machine designs	205(c)	No	NRC staff access to high fidelity computing tools is expected to yield substantial efficiency gains to the NRC and external entities by enabling efficient review of fusion machine designs.

[6] These potential future actions will be undertaken depending on NRC regulatory needs, technology development, and stakeholder interest, and subject to resource availability and prioritization.

ENCLOSURE 2

STAKEHOLDER ENGAGEMENT

Public Meetings

To prepare this report, the U.S. Nuclear Regulatory Commission (NRC) solicited input from a broad range of external stakeholders, consistent with the requirements in Section 205(c) of the ADVANCE Act. Specifically, the NRC sought input from the private fusion sector; Agreement States; other Federal agencies, including the Federal Aviation Administration; and other external stakeholders. The NRC held the following meetings to seek input from external stakeholders on commercial deployment of fusion technology following enactment of the ADVANCE Act:

- The ADVANCE Act: Mass-manufacturing of Fusion Machines (October 23, 2024)

  The NRC held a public meeting to gather feedback from external stakeholders related to the study on regulatory frameworks for licensing mass-manufactured fusion machines pursuant to Section 205(c) of the ADVANCE Act (ML24330A022).

- ADVANCE Act Section 205(c): Study on Regulatory Frameworks for Mass-Manufactured Fusion Machines (March 5, 2025)

  The NRC held a second public meeting to gather additional feedback from external stakeholders related to the study on regulatory frameworks for licensing mass-manufactured fusion machines pursuant to Section 205(c) of the ADVANCE Act (ML25091A143).

- Government-to-Government Meeting (March 26, 2025)

  The NRC hosted a Government-to-Government meeting with the Agreement States and Tribal Governments to gather their feedback related to the study on regulatory frameworks for licensing mass-manufactured fusion machines pursuant to Section 205(c) of the ADVANCE Act.

Industry Consultation

The NRC conducted extensive outreach with the private fusion sector related to this report. Specifically, the NRC staff visited seven fusion company sites to observe and discuss the development of fusion technology across the United States to inform regulatory readiness. Further, representatives from the fusion industry were active participants in the public meetings discussed in this Enclosure and further engaged with the NRC through drop-in meetings and written correspondence.

Correspondence

The NRC received written input related to Section 205(c) of the ADVANCE Act from the following entity:

Incoming Correspondence	ADAMS Accession No.
March 19, 2025, email from Helion Energy to the NRC staff—"Preparing for At-Scale Deployment of Fusion Energy: Novel Licensing Pathways"	ML25104A037