
Draft Regulatory Analysis for the Proposed Rule—Regulatory Framework for Fusion Machines

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ABSTRACT

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to augment the existing byproduct material framework to be inclusive of fusion machines. The NRC is proposing requirements that are technology-inclusive to accommodate the wide variety of anticipated fusion machine designs across the National Materials Program. The NRC is also issuing for comment draft guidance for the implementation of this proposed rule, entitled NUREG-1556, Volume 22, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fusion Machine Licenses." This document presents a draft regulatory analysis of the costs and benefits of the proposed rule requirements, "Regulatory Framework for Fusion Machines," and the draft guidance relative to the baseline case (i.e., the No-Action alternative).

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ABBREVIATIONS AND ACRONYMS

ACRS	Advisory Committee on Reactor Safety
AEA	Atomic Energy Act of 1954, as amended
AP	Additional Protocol
AS	Agreement State
BLS	U.S. Bureau of Labor Statistics
CCGT	combined cycle gas turbine
CFR	<i>Code of Federal Regulations</i>
DOC	U.S. Department of Commerce
DOE	U.S. Department of Energy
EPAct	2005 Energy Policy Act
FR	<i>Federal Register</i>
FTE	full-time equivalent (employee)
IAEA	International Atomic Energy Agency
LLW	low-level waste
NEIMA	Nuclear Energy Innovation and Modernization Act
NMP	National Materials Program
NPT	Treaty on the Non-Proliferation of Nuclear Weapons
NPV	net present value
NRC	U.S. Nuclear Regulatory Commission
NSG	Nuclear Suppliers Group
OEWS	Occupational Employment and Wage Statistics
PERT	program evaluation and review technique
SRM	staff requirements memorandum

EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to augment the existing byproduct material framework to be inclusive of fusion machines. The NRC is proposing requirements that are technology-inclusive to accommodate the wide variety of anticipated fusion machine designs across the National Materials Program. The NRC is also issuing for comment draft guidance for the implementation of this rule, entitled NUREG-1556, Volume 22, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fusion Machine Licenses.” This document presents a draft regulatory analysis of the costs and benefits of the proposed requirements, “Regulatory Framework for Fusion Machines,” and the draft guidance relative to the baseline case (i.e., the No-Action alternative).

The NRC is proposing the revision of its byproduct material framework at Part 30 of Title 10 the *Code of Federal Regulations* (10 CFR), “Rules of General Applicability to Domestic Licensing of Byproduct Material,” for the licensing and oversight of the possession, use, and production of byproduct material associated with fusion machines. The proposed amendments to 10 CFR Part 30 are primarily focused on definitions and the content of an application. Proposed amendments to 10 CFR Part 20, “Standards for Protection Against Radiation,” are focused on definitions and establishing a waste disposal site intruder assessment requirement, and proposed amendments to 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” are focused on a requirement to submit an environmental report. In addition, the draft proposed rule includes changes to the definition of byproduct material in several other parts of the regulations (10 CFR parts 37, 50, 72, 110, 150, 170, and 171) as required by the ADVANCE Act¹.

In 2019, the Nuclear Energy Innovation and Modernization Act (NEIMA) 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 machines². 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 due to the continued development of fusion technologies, the Commission in 2020 directed the NRC staff in SRM-SECY-20-0032 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.”

This proposed rule includes regulatory requirements for the possession, use, and production of byproduct material associated with near-term fusion machines that are consistent with existing requirements, to the extent practicable. The technology-inclusive and performance-based focus of this rulemaking would benefit the wide variety of anticipated fusion machine designs across the National Materials Program. In the context of this proposed rulemaking, the focus of licensing and oversight would be on possession, use, and production of radioactive materials associated with fusion machines, as well as activation products. These regulations are intended to ensure consistency in byproduct material licensing reviews associated with fusion machines; promote an efficient licensing process associated with fusion machines; address the safe and

¹ The Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy (ADVANCE) Act of 2024 was signed into law on July 9, 2024; Public Law No: 118-67 (<https://www.congress.gov/118/plaws/publ67/PLAW-118publ67.pdf>).

² The ADVANCE Act amended NEIMA to replace “fusion reactor” with “fusion machine.”

secure use of radioactive materials associated with fusion machines; and support the principles of good regulation, including openness, clarity, and reliability.

The proposed rule would add technology-inclusive content-of-application requirements supportive of a performance-based approach to regulating the possession, use, and production of byproduct material associated with fusion machines. The major provisions of this proposed rule include the following:

- Development of a regulatory framework for licensing the possession, use, and production of byproduct material associated with fusion machines under the existing 10 CFR Part 30 byproduct material framework. This framework would provide a systematic, risk-informed, performance-based approach to the licensing and oversight of byproduct material associated with fusion machines and its associated radiological hazards.
- Establishment of new proposed definitions, adopted from the Atomic Energy Act (AEA) of 1954, as amended by the ADVANCE Act of 2024, to establish the scope of regulatory requirements for the possession, use, and production of byproduct material associated with fusion machines and technology-inclusive content-of-application requirements supportive of a performance-based approach to regulation.
- Other targeted changes to current regulations that would ensure the applicability of current domestic licensing practices, and other updates necessary for the safe and secure use of radioactive materials associated with fusion machines.

This regulatory analysis discusses three alternatives—Alternative 1, the no-action or status quo alternative, Alternative 2, pursuance of the proposed rule, and Alternative 3, which is to issue new guidance clarifying the application of existing regulations to the possession, use, and production of byproduct material associated with fusion machines without changing the existing regulations. The regulatory analysis evaluates the costs and benefits of Alternative 2—the proposed rule requirements and development of the associated guidance documents relative to Alternative 1—the no-action alternative, and Alternative 3—development of guidance documents relative to Alternative 1—no action alternative. It derives the key findings summarized in Table ES-1. Alternative 2 would result in net averted costs to the industry, Agreement States, and the NRC of approximately \$1.38 million at the 7 percent discount rate (net present value (NPV)) and \$3.25 million at the 3 percent discount rate, making the overall proposed rule cost beneficial.

Table ES-1 Total Benefits (Costs) of Proposed Rule (2023 dollars)*

	7% NPV	3% NPV
Industry Benefit	\$2,027,000	\$4,077,000
Agreement State Benefit	\$177,000	\$356,000
NRC Benefit	\$34,000	\$70,000
Total Benefit	\$2,239,000	\$4,503,000
Agreement State Cost	(\$544,000)	(\$919,000)
NRC Cost	(\$314,000)	(\$338,000)
Total Cost	(\$858,000)	(\$1,257,000)
Net Benefit (Cost)	\$1,381,000	\$3,246,000

*Values rounded to the nearest thousand dollars. Rounded values may not sum to rounded totals.

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1.0 INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to augment the existing byproduct material framework to be inclusive of fusion machines. The NRC is also proposing new guidance, NUREG-1556, Volume 22, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fusion Machine Licenses,” for implementation of this proposed rule. The proposed rule would add technology-inclusive content-of-application requirements supportive of a performance-based approach to regulating the possession, use, and production of byproduct material associated with fusion machines. This document presents a draft regulatory analysis of the costs and benefits of the proposed requirements, “Regulatory Framework for Fusion Machines,” and the draft guidance relative to the baseline case (i.e., the no-action alternative). The document also presents an analysis of an alternative in which a guidance is issued, but no changes are made to the regulations.

2.0 STATEMENT OF THE PROBLEM AND OBJECTIVES

2.1 Background

In 2019, the Nuclear Energy Innovation and Modernization Act (NEIMA) 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 machines. 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 due to the continued development of fusion technologies, the Commission in 2020 directed the NRC staff in SRM-SECY-20-0032 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.”

In Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” and associated regulations, including, but not limited to, 10 CFR Part 20, “Standards for Protection Against Radiation,” and 10 CFR Parts 31 through 37, and 10 CFR Part 39, the NRC provides a framework for licensing a wide variety of uses for byproduct material. The byproduct material regulations, along with the guidance in NUREG--1556, are scalable; provide a comprehensive list of technical and regulatory areas that require licensing; and have been used to regulate the potential radiological hazards and risks from an extensive spectrum of uses of byproduct material, from low risk (e.g., portable gauges) to higher risk (e.g., panoramic irradiators). The regulations include specific programmatic requirements, such as those related to financial assurance and emergency planning, applicable for licensing larger quantities of byproduct material, as are expected for fusion machines. The NRC’s byproduct material framework would provide a technology-inclusive framework for the licensing and oversight of the possession, use, and production of byproduct material associated with the broad array of fusion machines currently under development and anticipated across the National Materials Program (NMP).

2.2 Statement of the Problem

In the absence of any regulation, companies possessing radiological materials would have a strong profit incentive to handle radiological materials and dispose of waste radiological products in manners that pose health hazards, damage property and pose security risks. Costly

methods of sufficiently securing materials would be avoided because companies would not bear the full consequences of the risks, thus a socially inefficient level of security would be provided in the absence of restrictions. The market failure for radiological waste disposal is more severe than for other materials, because the materials often have no value and do not interrupt operations if disposed of improperly at lower cost. The changes in the tort liability process needed for adequate protection would be more onerous than the existing regulatory oversight process. Insufficient financial resources to compensate for damages in the case of a high consequence incident would result in companies facing responsibility for only a portion of highly costly incidents, and thus without incentive to provide the socially optimal level of safety and security. Financial assurance for larger liabilities is onerous to assess and secure and would not be enforced by free market activity. Additional problems with tort liability providing a socially efficient level of security include the deniability of the cause of damages (e.g., long-term health consequences due to undocumented exposures), the uncertain value of national security breaches, and the development path dependence of real property that cannot be economically decontaminated.

This rulemaking would not change the regulatory approach used to correct for these market failures, but rather clarifies how existing regulations that prevent these market failures would apply to fusion machines. The staff anticipates that the quantities of radiological materials associated with fusion machine operation would require a license under existing regulations. However, the regulations were written without specific consideration of fusion machine characteristics and licensing needs. Rulemaking would ensure a transparent, systematic, risk-informed approach to the licensing and regulation of byproduct material associated with fusion machines and its associated radiological hazards.

In the proposed rule, the NRC staff describes definitions to establish the scope of regulatory requirements for the possession, use, and production of byproduct material associated with fusion machines and technology-inclusive content-of-application requirements supportive of a performance-based approach to regulation. Other targeted augmentations of current regulations and guidance would ensure that information required for a license is based on the quantity, form, and use of byproduct material, and address applicability of current domestic licensing practices, and other updates necessary for the safe and secure use of radioactive materials used to produce fusion energy.

Rulemaking and associated guidance would allow for the timely alignment of fusion-machine-related licensing and regulation across the NRC and Agreement States, as part of the NMP, to provide near-term regulatory predictability for developers, regulators, and the public.

The purpose of this draft regulatory analysis is to provide decision-makers with an analysis of costs and benefits to support informed decision-making for the purpose of improved regulation of fusion devices.

2.3 Objectives

The Commission has directed the NRC staff to develop a limited-scope rule to license and regulate the possession, use, and production of byproduct material associated with fusion machines under the NRC's byproduct material framework contained in 10 CFR Part 30 and associated regulations. In developing the rule, the NRC staff should consider the existence of fusion machines that already have been licensed and are being regulated by the Agreement States, as well as those that may be licensed before the completion of the rulemaking.

3.0 IDENTIFICATION AND ANALYSIS OF ALTERNATIVES

The NRC considered the following three approaches to address the regulatory problem identified in section 2.2:

- Alternative 1: No Action
- Alternative 2: Rulemaking and Associated Guidance
- Alternative 3: Issue New Guidance (to clarify existing regulations without rulemaking)

Alternative 1 is the no action alternative. Under this alternative, NRC would not amend regulatory language or issue guidance to clarify the application of the current regulations to fusion machines. Under Alternative 2, NRC would amend the regulatory language for the purposes of fusion machines and to reflect the ADVANCE Act; in addition, regulatory guidance would be issued to clarify the application of the regulations, as amended. Under Alternative 3, the existing regulations are unchanged, and a regulatory guide is issued to clarify the application of the existing regulations to the possession, use, and production of byproduct material associated with fusion machines.

Alternative 2 is the recommended alternative. This approach changes the regulatory language to clarify how current provisions would apply to the possession, use, and production of byproduct material associated with fusion machines. Rulemaking would ensure a systematic, risk-informed performance-based approach to the licensing and regulation of byproduct material associated with fusion machines and its associated radiological hazards. In this rulemaking, the NRC would define terms and develop definitions to establish the scope of regulatory requirements for fusion machines, address waste management, and develop technology-inclusive content-of-application requirements supportive of a risk-informed performance-based approach to regulation. Other targeted augmentations of current regulations and guidance would ensure that information required for a license is based on the quantity, form, and use of byproduct material, address applicability of current domestic licensing practices, and implement other updates necessary for the safe and secure use of radioactive materials to produce fusion energy.

Alternative 3 would impose no new requirements. Under Alternative 3, NRC would only issue new fusion machine guidance. This approach would not provide the same level of clarity and transparency as amending NRC's regulations, and this approach could lead to inconsistent application of the requirements across the NMP. The qualitative impact of reduced clarity under Alternative 3 would raise labor costs in applying the regulations; therefore, Alternative 3 is not recommended.

3.1 Definitions

3.1.1 Regulatory Issue

The proposed rule would add a new definition for "fusion machine" in 10 CFR 20.1003 and 30.4; revise the definition of "particle accelerator" in 10 CFR 20.1003, 30.4, and 110.2; and revise the definition of "byproduct material" in 10 CFR 20.1003, 30.4, 37.5, 50.2, 72.3, 110.2, 150.3, 170.3, and 171.5, which all are titled "Definitions."

The term "fusion machine" was added to section 11 of the AEA and "byproduct material" was amended in section 11e.(3)(B) by the ADVANCE Act of 2024. The amended definition of

“byproduct material” is now “any material that (i) has been made radioactive by use of a particle accelerator, including by use of a fusion machine; and (ii) if made radioactive by use of a particle accelerator that is not a fusion machine, is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity.”

The AEA’s amended definition creates criteria for determining whether radioactive material produced through use of a particle accelerator is byproduct material under AEA Section 11e.(3)(B): one set of criteria for fusion machines, and another set for particle accelerators that are not fusion machines.

The ADVANCE Act also amended NEIMA to change “fusion reactor” to “fusion machine” and points to the fusion machine definition under the ADVANCE Act. Given the diversity of fusion processes and designs currently under consideration, the new definition provides the flexibility to be incorporated into NRC’s 10 CFR Part 30 framework in a technology-inclusive manner. The proposed regulatory framework would provide a risk-informed approach to protecting workers, the public, and the environment from the possession, use, and production of byproduct material associated with fusion machines.

The NRC’s existing regulations and guidance (i.e., NUREG-1556, Volume 21, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator”) provide for the licensing of particle accelerators. Consistent with the distinction in the AEA between byproduct material produced by fusion machines and other particle accelerators, the NRC’s proposed definitions would consider fusion machines as a subset of particle accelerators. This approach would affirmatively establish that existing guidance for particle accelerators would not apply to fusion machines.

3.1.2 Regulatory Alternatives

Alternative 1: No Action

The NRC would regulate the possession, use, and production of byproduct material associated with fusion machines under existing regulations for particle accelerators. In reviewing each fusion machine application on a case-by-case basis, the NRC and Agreement States would need to evaluate the applicability of the current regulatory definitions in conjunction with the amended statute. Based on these evaluations, the NRC or Agreement States may need to develop specific license conditions, exemptions, or orders.

Alternative 2: Rulemaking and Associated Guidance

The proposed new definition of “fusion machine” and updated definitions for “particle accelerator” and “byproduct material” would enhance regulatory clarity and predictability by explicitly defining radioactive material generated by the operation of a fusion machine as byproduct material, to reflect the AEA’s amended definitions of byproduct material. The proposed application requirements and revisions to reporting and inspection requirements would provide regulatory certainty for applicants for the possession, use, and production of byproduct material associated with fusion machines. The proposed revision to waste disposal requirements in 10 CFR Part 20 would ensure consistency and alignment with the disposal of some novel waste types and radionuclides generated by fusion machines.

Alternative 3: Issue New Guidance (to clarify existing regulations without rulemaking)

Guidance would clarify how the existing regulations and definitions apply to fusion machines. Guidance alone would provide less clarity and regulatory consistency compared to Alternative 2. Similar to Alternative 1, in some cases, the NRC and Agreement States would need to evaluate the applicability of the current regulatory definitions in conjunction with the amended statute on a case-by-case basis. Based on those evaluations, in some cases the NRC or Agreement States may need to develop specific license conditions, exemptions, or orders.

3.2 Contents of Application

3.2.1 Regulatory Issue

The proposed rule would add new requirements under 10 CFR 30.32(k), 10 CFR 30.33(a)(6), and 10 CFR 51.60(b)(1)(viii) that are specific to the application requirements for the possession, use, and production of byproduct material associated with a fusion machine. The proposed rule would provide conforming changes to existing byproduct material requirements to address specific attributes of fusion machines under 10 CFR 20.2008, "Disposal of certain byproduct material"; 10 CFR 30.51, "Records," paragraphs (a) and (a)(1); and 10 CFR 30.52, "Inspections," paragraph (a).

The proposed rule would add technology-inclusive content-of-application requirements supportive of a performance-based approach to regulating the possession, use, and production of byproduct material associated with fusion machines. The content of application section would provide the requirements for licensing the possession, use, and production of byproduct material associated with a fusion machine that would be supplemented by the current general regulatory requirements and the terms and conditions of licenses already contained in 10 CFR 30.32, "Application for specific licenses"; 10 CFR 30.33, "General requirements for issuance of specific licenses"; and 10 CFR 30.34, "Terms and conditions of licenses." In addition to the content-of-application section, NRC would make other conforming changes specific to fusion-machine-produced byproduct material.

The proposed content-of-application section in 10 CFR 30.32(k) would require that an applicant for the possession, use, and production of byproduct material associated with a fusion machine provide a general description of the fusion machine, summarize the operating and emergency procedures related to radiation safety, and describe the applicant's radiation safety organizational structure, training program for fusion machines and radiation protection, inspection and maintenance program, and methodology for maintaining a radioactive material inventory. The summary of the procedures important to radiation protection also would require that the applicant describe (1) the radiation protection measures to be employed for byproduct material, including all interlocks, access control systems, shielding, and radiation monitors; (2) the byproduct material handling systems procedures and inventory control procedures; and (3) any other components or systems used to control radiation and radioactive material.

The contents of application discussion for fusion machines would also give an applicant an alternative to describing the fusion machine relative to radiation safety, as required in 10 CFR 30.32(k)(2)(i)–(iii). The alternative pathway would require the applicant to describe the fusion machine relevant to radiation safety and explain how it can ensure that the fusion machine would be operated safely. This technology-inclusive approach to licensing recognizes the diversity of fusion machine designs being considered now and in the near-term future.

A proposed new section would be added to 10 CFR 30.33(a)(6) to specifically provide the general requirement for approving a license application for the possession, use, and production of byproduct material associated with a fusion machine.

A proposed new section would be added to 10 CFR 51.60(b)(1)(iii) to require an environmental report for the construction and operation of a fusion machine unless a categorical exclusion applies. The scope of the environmental report would be expected to be discussed during preapplication discussions described in 10 CFR 30.32(k)(2)(iv)(B).

Licensed material as described in paragraphs (3) and (4) of the definition of byproduct material in 10 CFR 20.1003 is not defined as low-level radioactive waste. Given that accelerators and fusion machines both produce radioactive material, the NRC is proposing to include new language in paragraph (a) to 10 CFR 20.2008 to allow certain waste from fusion machines to be disposed in a low-level waste (LLW) disposal facility. The NRC does not propose any changes to 10 CFR 20.2006 or Appendix G to 10 CFR Part 20 because the language is sufficiently general to apply to fusion machines without modification. The NRC would add 10 CFR 20.2008 to the list of approved information collections in 10 CFR 20.1009.

The NRC is proposing to amend 10 CFR 30.51(a) and (a)(1) and 10 CFR 30.52(a) to include the production of byproduct material. Some fusion machine designs will produce tritium as fuel by the capture of neutrons in lithium in breeding beds adjacent to the vacuum vessel where the fusion reactions take place.

3.2.2 Regulatory Alternatives

Alternative 1: No Action

The application requirements would be less clear without the new and amended sections. Applicants and licensees would expend resources interpreting the existing regulations for application to their new technologies and would increase risk of misinterpreting the requirements. Similarly, Agreement States and the NRC would expend more effort in processing license applications. The additional effort would be due to both lack of clarity in how the regulations apply and due to the added effort in processing applications submitted under less clear requirements.

Alternative 2: Rulemaking and Associated Guidance

The new and amended regulations would clarify the application of existing regulations to the new technology, which would increase clarity and transparency, and reduce resources needed to interpret and apply existing regulations.

Alternative 3: Issue New Guidance (to clarify existing regulations without rulemaking)

Guidance would clarify how the existing regulations apply to fusion machines, but with reduced benefits when compared to the preferred alternative. This is due to the lack of fusion-machine-specific language in the regulations. Guidance alone would provide less clarity and regulatory consistency across the NMP.

3.3 Environmental Report

3.3.1 Regulatory Issue

Under the proposed 10 CFR 51.60(b)(1)(viii) the applicant would be required to include an environmental report unless a categorical exclusion applies. Requiring an applicant to develop an environmental report would enable the NRC to fully assess the environmental impacts of these novel and evolving fusion designs.

The NRC would review the environmental report with each application per the regulations in 10 CFR Part 51. The NRC will prepare an environmental assessment (EA) under 10 CFR 51.21 unless an environmental impact statement (EIS) is required pursuant to 10 CFR 51.20(b) or a categorical exclusion applies. Upon completion of the EA, the NRC will either prepare a finding of no significant impact (FONSI) as permitted by 10 CFR 51.31(a), or an EIS under 10 CFR 51.20.

Although 10 CFR Part 51 is not required as a matter of compatibility for Agreement States, several Agreement States have environmental requirements that are similar to the requirements in the National Environmental Policy Act (NEPA). An applicant for a license to possess, use, and produce byproduct material associated with a fusion machine in an Agreement State would be required to comply with applicable State environmental requirements.

An environmental report would not be required in situations where a categorical exclusion is appropriate as specified by 10 CFR 51.22. Namely, the action belongs to a category of actions which the Commission, by rule or regulation, has declared to be a categorical exclusion from having to prepare an environmental report, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment.

An applicant for a license to possess, use, and produce byproduct material associated with a fusion machine may apply the guidance in NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," in preparing their environmental-related submittals to the NRC whether to support an EIS, EA, or a categorical exclusion. Under 10 CFR 51.40, a prospective applicant to possess, use, and produce byproduct material associated with a fusion machine is encouraged to confer with the NRC staff to discuss the guidance in NUREG-1748 as early as possible in its planning process before submitting environmental information or filing an environmental report.

3.3.2 Regulatory Alternatives

Alternative 1: No Action

This alternative would maintain the current regulatory framework with no rule language or guidance specifying how environmental reports are to be completed for fusion machines.

Alternative 2: Rulemaking and Associated Guidance

This alternative would update the regulatory language and issue guidance to clarify how environmental reports must be completed for fusion machines.

Alternative 3: Issue New Guidance (to clarify existing regulations without rulemaking)

Guidance would clarify how the existing regulations apply to the preparation of environmental reports for fusion machines. Guidance alone would provide less clarity and regulatory consistency across the NMP.

3.4 Waste Management

3.4.1 Regulatory Issue

The NRC's regulations governing waste management requirements under 10 CFR Part 20 are proposed to be amended to apply specifically to fusion machine facilities and their expected associated radioactive waste. The scope of this discussion includes aspects of 10 CFR Part 20 and 10 CFR Part 61 related to the handling and disposal of radioactive waste generated by fusion machines. The NRC determined that fusion machine waste is adequately addressed by the existing regulations related to land disposal of radioactive waste (i.e., 10 CFR Part 61) with a proposed change to 10 CFR Part 20.

The 2005 Energy Policy Act (EPAAct) expanded NRC jurisdiction to include certain materials made radioactive by a particle accelerator. The NRC's 2007 final rule made conforming changes to 10 CFR 20.2008(a), providing disposal requirements for byproduct material as defined in sections 11e.(3) and (4) of the AEA. Further, the definition of waste in 10 CFR 61.2, which excludes material produced by an accelerator, does not prevent disposal of accelerator-produced waste with a LLW disposal facility. The ADVANCE Act of 2024 amended section 11e.(3) of the AEA to ensure all radioactive material generated by fusion machines is defined as byproduct material. Therefore, the NRC determined that the existing NRC regulations under 10 CFR Part 61 for land disposal of radioactive waste could apply to waste generated by fusion machines.

Similarly, 10 CFR 20.2008(b) states that accelerator waste can be disposed of at a Federal or State solid or hazardous waste disposal facility authorized to dispose of such material. In general, the NRC evaluates whether NRC-licensed material can be sent to a solid or hazardous waste disposal facility for disposal on a case-by-case basis under 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures." For either disposal with LLW or disposal under 10 CFR 20.2002, existing NRC regulations allow NRC-licensed, accelerator-produced material to be sent for disposal with other types of waste if additional applicable requirements are met. Those requirements may include approvals from State and other Federal agencies.

Several stakeholders have expressed concern that the 10 CFR 61.55 waste classification tables may fail to address risk significant radionuclides in fusion machine waste because those tables were based on expected waste streams in the early 1980s. The Advisory Committee on Reactor Safety (ACRS) proposed, in its letter dated October 21, 2022 (ADAMS Accession No. ML22290A177), that the NRC consider revising the 10 CFR 61.55 waste classification tables to address radionuclides generated by fusion machines. The NRC understands the concern that fusion machines could create significant inventories of activation products³ that are not included in the waste classification tables (e.g., see SECY-23-0001). However, this rule

³ Many stakeholders, including the ACRS, expect fusion machines to generate significant quantities of tritium-contaminated waste in addition to activation products. Class A tritium is addressed in the existing 10 CFR 61.55 waste classification tables. The NRC addresses tritium disposed with Class B waste in the draft guidance accompanying the proposed rule. There is no concentration limit for tritium in Class C waste because the calculated value exceeds the specific activity of tritium.

does not propose to revise those tables because sufficient information is not yet available to determine which radionuclides will drive the risk significance of fusion machine generated waste. As described by the ACRS, the activation products formed by fusion machines will depend on the structural materials used in the systems and their impurities. Because many of those materials have not yet been selected or developed, the identity, quantities, and concentrations of the potential activation products in those materials are not yet known. In a staff requirements memorandum (SRM) responding to the NRC staff's plan to revise 10 CFR Part 61 (SRM-SECY-08-0147), the Commission directed the NRC staff to consider changing the waste classification tables after the completion of the integrated low-level radioactive waste disposal rulemaking for 10 CFR Part 61. The NRC staff plans to consider the radionuclides in fusion machine waste during that process. In addition, the NRC is proposing a change to 10 CFR Part 20 that would address issues related to the 10 CFR 61.55 waste classification tables with a requirement for site-specific analyses in some circumstances, as described below.

A key safety concern associated with land disposal of waste from fusion machines is the protection of individuals who might inadvertently intrude into LLW. This protection is typically demonstrated by compliance with technical requirements that are based in part on LLW classification. Therefore, to ensure intruder protection at this time, the NRC proposes to require that licensees with novel wastes or radionuclide concentrations from fusion machines use disposal sites that have completed a site-specific intrusion assessment for such waste material. The NRC proposes to allow disposal of novel waste types without a site-specific intrusion assessment for waste with physical, chemical, and radiological characteristics that can be shown to be consistent with an appropriate waste classification description in 10 CFR 61.7, "Concepts."

To establish that requirement, the NRC proposes as part of this rulemaking to amend 10 CFR 20.2008 to add new language to paragraph (a) that is specific to the disposal requirements for waste from a fusion machine. The new text would require that fusion machine waste that would be disposed of as low-level waste under 10 CFR Part 61 either be accompanied by an analysis showing the waste is manifested and labeled for disposal consistent with the description of the applicable waste class in 10 CFR 61.7 or be disposed of at a disposal site that has completed a site-specific intrusion assessment. Draft NUREG-1556, Volume 22, includes guidance on waste types and radionuclide concentrations the NRC staff has previously analyzed under the waste classification descriptions in 10 CFR 61.7. If a site-specific intrusion assessment will be relied on, the assessment should demonstrate the projected dose to an individual who inadvertently intrudes into the waste at the facility will be less than 0.5 rem (5 mSv) per year. That dose limit is consistent with the dose limit used to develop the LLW classification tables in 10 CFR Part 61, which the NRC selected based on safety, costs, disposal efficiency, and the potential for increased disposal of waste containing long-lived radionuclides that could increase the hazard for long time periods (see NUREG-0945).

3.4.2 Regulatory Alternatives

Alternative 1: No Action

This alternative would maintain the current regulatory framework. Due to the potential novelty of the waste produced by fusion machines, this likely would require custom license conditions to ensure appropriate disposal.

Alternative 2: Rulemaking and Associated Guidance

This alternative would issue guidance and amend 10 CFR Part 20 to require either (1) an analysis showing that the waste is manifested and labeled for disposal consistent with the description of the applicable waste classification in 10 CFR 61.7, “Concepts,” based on the physical, chemical, and radiological characteristics of the waste, or (2) that the waste be disposed of in a facility that has completed a site-specific intrusion assessment.

Alternative 3: Issue New Guidance (to clarify existing regulations without rulemaking)

Guidance would provide standard license conditions for disposal of fusion waste under existing regulations, but custom license conditions and exemptions may still be needed for some applications. The guidance would provide some clarity to the complex approach but would not avert the added effort for waste disposal in the absence of a rule change.

3.5 Reporting and Recordkeeping

3.5.1 Regulatory Issue

The NRC is proposing to amend its regulations governing reporting and recordkeeping requirements under 10 CFR 30.51, “Records,” to cover licensees authorized for the possession, use, and production of byproduct material associated with fusion machines by adding “production of” tritium and activation products for the necessary reports, analyses, submittals, inspection documentation, and other required documentation for a fusion machine. A detailed discussion on accountability, including inventory, production, use, decay, and consumption is included in the draft guidance, NUREG-1556, Volume 22.

3.5.2 Regulatory Alternatives

Alternative 1: No Action

This alternative would maintain the current regulatory framework.

Alternative 2: Rulemaking and Associated Guidance

This alternative would amend regulatory language and issue guidance to clarify how radiological materials used and activated by fusion machines must be analyzed, reported, and documented.

Alternative 3: Issue New Guidance (to clarify existing regulations without rulemaking)

Guidance would clarify how, under existing regulations, radiological materials used and activated by fusion machines would be analyzed, reported, and documented. Guidance alone would provide less clarity and regulatory consistency across the NMP.

4.0 EVALUATION OF BENEFIT AND COSTS

This section examines the benefits and costs estimated to result from conducting rulemaking and developing the accompanying guidance (Alternative 2), and developing new guidance alone (Alternative 3), when compared to Alternative 1 (No Action). Section 4.1 identifies attributes expected to be affected by the rulemaking. Section 4.2 describes how the NRC staff analyzed the benefit and costs.

4.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the regulatory alternatives discussed in section 3.0 are expected to affect. These factors are classified as attributes using the list in chapter 5 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." Each of the following attributes is quantified when possible and an uncertainty analysis is performed to report benefit and cost estimate confidence levels and to identify those variables that most affect the differences in the results distribution:

- Industry Operation. This attribute accounts for the projected net economic effect caused by routine and recurring activities required by the proposed guidance or regulation changes. Activities currently performed but that would no longer be required if the alternative is implemented are treated as averted costs.
- NRC Implementation. This attribute accounts for the projected net economic effect on the NRC if the rule is applied. It includes NRC implementation costs and potential savings relative to those expected under the regulatory baseline.
- NRC Operation. This attribute measures the projected net economic effect on the NRC after the proposed action is implemented. The NRC would incur costs for additional inspection, evaluation, or enforcement activities. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive. As with industry operation costs, NRC operation costs generally occur over long periods of time and are sensitive to the assumed discount factor.
- Other Government Entities. This attribute measures the net economic effect of the proposed action on the Federal Government (other than the NRC) and State and local governments resulting from the action's implementation or operation. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive. The government entities may seek to recover costs for services from the licensee; any recovered costs should not be subtracted from the cost to the government units.
- Regulatory Efficiency. This attribute attempts to measure regulatory and compliance improvements resulting from the proposed action. These may include changes in industry reporting requirements and the NRC's review efforts. This attribute is qualitative in nature. Efficiency actions that are quantifiable are addressed under other attributes.
- Increased Public Confidence. This attribute attempts to measure the change in public confidence in the NRC's ability to improve its regulations, adapt to regulatory needs identified by stakeholders, offer opportunities for stakeholders to provide input to the changes to the fusion machine licensing process, and maintain the NRC's role as an effective industry regulator. This attribute is qualitative in nature.

The above attributes are incorporated into the analysis in section 5.0, as shown in Table 1.

Table 1 **2Evaluation by Attribute**

<u>Attribute</u>	<u>Location of Analysis</u>
Industry Operation	Section 5.1
NRC Implementation	Section 5.2
NRC Operation	Section 5.2
Other Government Entities	Section 5.3
Regulatory Efficiency	Section 5.4
Increased Public Confidence	Section 5.5

Additional attributes listed below were considered and found to not be significantly affected by the rulemaking. The main effect of the rulemaking is to clarify requirements that currently apply to fusion machine licensees, thus safety, security, and environmental protection provided by the regulations is expected to remain unchanged. The value of power production innovation and other technological innovations stemming from fusion machine development and deployment could be significant, however the rulemaking is not expected to significantly change the development and deployment of fusion machines. Existing NRC regulations do not pose a barrier to fusion machine development. Any impediment is in the lack of clarity about how existing regulations apply to fusion machines, which would impose the costs quantified as an industry operation effect, which are minor compared to other fusion machine development and deployment costs, thus not constituting a barrier. These additional attributes are not further analyzed:

- Public Health (Accident). This attribute measures expected changes in radiation exposures to the public due to changes in accident frequencies or accident consequences associated with the proposed action. The proposed rule is not expected to change public exposure due to potential accidents because the actions required to obtain needed licenses that avoid accidents are unchanged from the existing regulations.
- Public Health (Routine). This attribute accounts for changes in radiation exposures to the public during normal facility operations (i.e., nonaccident situations). The proposed rule is not expected to change routine public exposure because the actions required to obtain needed licenses that avoid routine exposure are unchanged from the existing regulations.
- Occupational Health (Accident). This attribute accounts for the health effects, both immediate and long-term, associated with site workers (i.e., both plant personnel and external workers assisting at the plant in response to the accident) as a result of changes in accident frequency or accident mitigation. The proposed rule is not expected to change worker exposure due to potential accidents because the actions required to obtain needed licenses that avoid accidents are unchanged from the existing regulations.
- Occupational Health (Routine). This attribute accounts for radiological exposures to workers during normal facility operations (i.e., nonaccident situations). The proposed rule is not expected to change routine worker exposure because the actions required to

obtain needed licenses that avoid routine worker exposure are unchanged from the existing regulations.

- Economic Consequences (Offsite Property). This attribute measures the expected total effects on offsite property resulting from the proposed action. The proposed rule is not expected to change offsite property value because the actions required to obtain needed licenses are unchanged from the existing regulations and thus will not offsite property values differently from existing regulations.
- Onsite Property. This attribute measures all consequences of an accident that arise within the facility's boundaries—an area controlled by the licensee. The proposed rule is not expected to affect the number or severity of accidents that cause onsite property damage because the actions affecting accidents that are required to obtain needed licenses are unchanged from the existing regulations.
- Industry Implementation. This attribute accounts for the projected net economic effect on the affected licensees to install or implement mandated changes. The proposed rule does impose a change on the industry that would require implementation activities. The proposed rule clarifies industry activities that would need to be implemented in the absence of the proposed rule also.
- Improvements in Knowledge. This attribute accounts for the potential value of new information, especially from assessments of the safety of licensee activities. The proposed rule is not expected to change improvement in knowledge because the actions required to obtain needed licenses are unchanged from the existing regulations.

4.2 Analytical Method

This section describes the process used to evaluate benefits and costs associated with the identified alternatives. The benefits include any desirable changes in affected attributes (e.g., monetary savings, improved safety, improved security) while the costs include any undesirable changes in affected attributes (e.g., monetary costs, increased exposures).

Of the affected attributes discussed in section 4.1, the following attributes could be evaluated on a quantitative basis: industry operation, NRC implementation, NRC operation, and Other Government Entities. Quantitative analysis requires a baseline characterization of the affected universe, including the characterization of factors such as the number of affected entities, the nature of the activities being conducted, and the types of machines and procedures that licensees implement or would no longer implement if the final rule alternative is chosen.

The analysis relies on nonquantitative techniques for other considerations (which include regulatory efficiency and increased public confidence). Nonquantitative techniques are used because monetizing the full impact of each attribute is not possible or practical.

To estimate the costs associated with the evaluated alternative, the NRC staff used a work breakdown approach to deconstruct the activities for each requirement. For each required activity, the NRC staff further subdivided the work across labor categories (e.g., manager, worker). To develop cost estimates, the NRC staff determined the necessary level of effort for each required activity and labor rates for personnel performing these activities.

The NRC staff gathered data to develop levels of effort and unit cost estimates. The staff applied several cost estimation methods in this analysis and used professional knowledge and judgment to estimate some of the costs and benefits. Additionally, it used an engineering buildup method, solicitation of input, and extrapolation techniques to estimate costs and benefits. The engineering buildup method used a step-by-step, bottom-up description of task requirements and estimated resources for labor, materials, and other direct costs to arrive at a total cost. The NRC staff also consulted subject matter experts within the agency to develop inputs used in the analysis by, for example, collecting industry wage data, the cost for specimen testing, and other inputs.

The NRC staff uses analogy to estimate some cost activities, relying on past or current costs to estimate the future cost of similar activities. However, for steps for which the staff has no data, the staff estimated the level of effort based on similar steps in the process for which data are available.

To evaluate the effect of uncertainty in the model, the NRC staff employed a Monte Carlo simulation, which is an approach to uncertainty analysis in which input variables are expressed as distributions. The simulation was run 10,000 times, and values were chosen at random from the distributions of the input variables provided in section 5.6 of this document. The result is a distribution of values for the output variable of interest. The Monte Carlo simulation makes it possible to determine the input variables that have the greatest effect on the value of the output variable. Section 5.6 gives a detailed description of the Monte Carlo simulation methods and the results.

4.2.1 Baseline for Analysis

This regulatory analysis measures the incremental impacts of the alternatives for conducting rulemaking and associated guidance (Alternative 2) and issuing new guidance alone (Alternative 3) relative to a baseline that reflects the anticipated behavior if the NRC undertakes no other regulatory action (Alternative 1: No Action). As part of the regulatory baseline used in this analysis, the NRC staff assumes licensee compliance with existing NRC or Agreement State regulations. Section 5.0 presents the estimated incremental costs and benefits of the rule relative to this baseline.

4.2.2 Affected Entities

For use in this analysis, the NRC staff identified licensees, that possess, use, and produce byproduct material associated with a fusion machine, and Agreement State regulators as the two affected entities. No materials licensees are currently operating fusion machines as defined in the proposed rule.⁴ If the proposed rule goes into effect, when a potential licensee anticipates construction and operation of a fusion machine, it would need to comply with the provisions of the revised rules, to receive the required materials handling certifications. The licensees will either comply directly with NRC regulations or with Agreement State regulations. If regulatory language is changed, Agreement States would revise their regulations for consistency with the final rule. Likewise, the Agreement States' implementation of their revised regulations would be expected to be consistent and compatible with the NRC guidance issued with the final rule.

⁴ This is the status at the time this analysis was prepared. The NRC understands that one license has been granted by an Agreement State for a fusion machine that is currently under construction and others may be granted by Agreement States before any rule change is final, or new NRC guidance is issued.

4.2.3 Fusion Machine Projection

The future development of a fusion machine industry is highly speculative beyond the handful of companies with plans of at least moderate levels of certainty to build fusion machines for commercial use. To construct a stochastic projection of fusion machine deployment, the NRC established bounds within which the industry is expected to develop. The research for this technology has been an international effort since the 1940s with solutions to technological issues that have prevented commercial application only recently, potentially within reach. In the U.S. fusion research is largely funded by the Department of Energy (DOE) including the DOE Office of Fusion Energy Sciences. The DOE funding also supports public private partnerships with eight companies building fusion pilot plants.

The lower bound would be a scenario in which no technological approaches become profitable for commercial application, so no fusion machines are licensed beyond those currently announced. Significant technological barriers to sufficiently positive energy gain for commercial fusion machines remain to be proven, primarily related to sufficient confinement of the fusion plasma. After technologies with positive energy gain are demonstrated, questions remain about the costs of building, operating, and the operating life of the machines, which must be known to assess whether the machines can be profitably operated at the wholesale prices for grid power, or in narrower niches. Because it is possible that no fusion machine approach is found to be commercially viable, a lower bound of no machines beyond those currently announced is possible.

The upper bound is one in which the technology is highly profitable as an electrical power generation source. The upper bound scenario is one in which at least one of the technological approaches provides positive energy gain, the marginal cost of producing power is lower than the wholesale price paid to grid power suppliers, and the profitability is high enough to justify investment in fusion machines without subsidies provided to initiate the technology. The upper bound scenario also envisions fusion machines of a scale small enough to be geographically distributed near power consumers. Larger fusion plants of 1 to 1.5 GW size could prove necessary for commercial viability, in which case many fewer machines would be deployed, and the projection would be below the upper bound. However, if smaller fusion machine power plants that are not substantially less cost efficient are possible, then the reduction in transmission costs, the reduction in transmission infrastructure expansion needs, and the ability to replace retired power plants without investing in new grid connections, would make the upper bound plausible. The NRC based the dynamics of the geographic spread of fusion machines for electrical power generation on the construction of natural gas fired combined cycle gas turbine (CCGT) plants, which were quickly adopted when found to be a profitable alternative. CCGT technology adoption, like the rapid adoption of fusion machines scenario, was driven by the efficiency of the technological developments, and demonstrated that a rapid rate of adoption was possible. This rapid fusion adoption scenario will be possible if fusion machines prove to have profitability advantages over competing power grid sources that are comparable to the CCGT power generation profitability advantage over the competing technology, largely coal fired power plants, that CCGT replaced for new generation capacity and retired generation capacity. Any projection of fusion plant deployments is speculative, given the current state of the technology, so this upper bound is intended to provide a plausible projection to assess the range of benefits provided by the proposed rule despite the substantial uncertainty of the future of this technology.

Between these bounds are many scenarios, including larger fusion power plants, of which fewer are required to meet demand at the marginal cost the machines provide power, a conservative best projection was specified for the PERT distribution, which assumed a slower adoption for

electrical generation, due to technologies being more marginally profitable compared to alternatives, and fusion machines that employ other than grid-connected electrical power generation, which the NRC expects would be a smaller volume use. The NRC invites comments about these projection assumptions for use in updating and improving this analysis.

Appendix B lists the parameters of the stochastic model of fusion machine adoption. Each State has an upper bound or high estimate for fusion machines at the end of the period of analysis based on the electrical utility sector CCGT plants operating in the State (EIA, 2023). The lower bound or low estimate is based on the anticipated near-term number of expected fusion machines. The best estimate is biased toward the low estimate because of the risk of failure of a newly emerging technology. The projection grows slowly for the first 5 years of the projection and then increases log-linearly to the cumulative number of machines in each State at the end of the period of analysis. This projection excludes any licenses granted prior to implementation of the rule.

Using this projection, the projected year that the first fusion machine is established in an Agreement State is the year in which the Agreement State would be expected to establish regulations and guidance consistent with the NRC’s revised regulations. As shown in figure 1, the mean estimate for the end of the analysis period in 2045 is 147 fusion machines, but the number could be as few as 5 and as many as 882. The cumulative number of fusion machines is projected to grow slowly at first, from none in 2026 to five in 2031, before increasing exponentially if some of the technologies are found to be commercially competitive. For the low estimate, no more fusion machines are built after the first five are not found to be commercially viable, while in the high estimate, the cumulative number of fusion machines increases to 882, the total number of electrical utility sector CCGT plants operating in the United States currently.

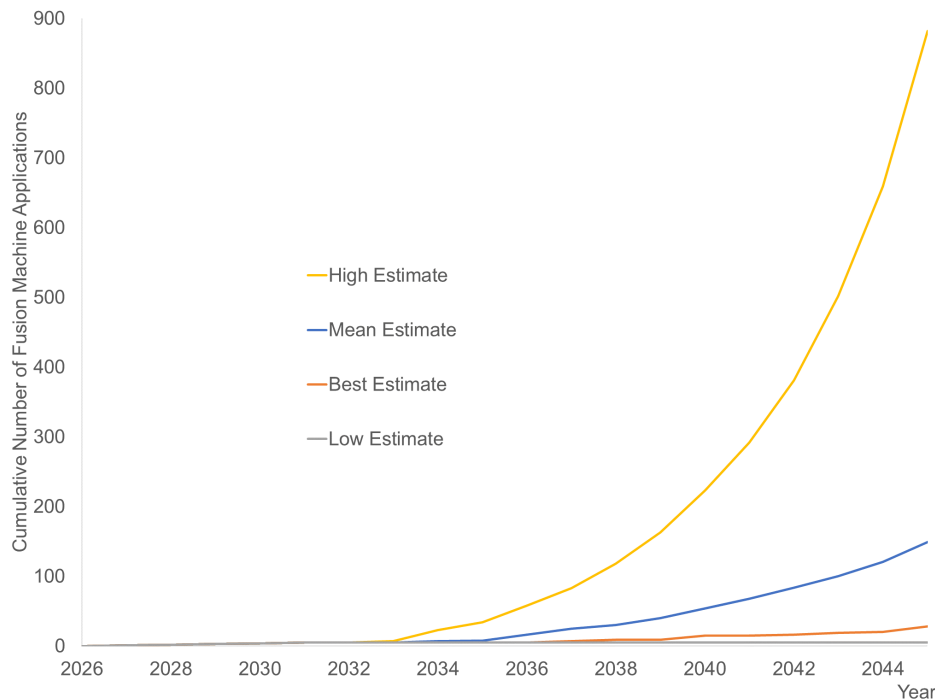


Figure 1 Scenarios for Fusion Machine Applications

These bounding estimates are parameters in the stochastic model of fusion machine adoption that is further described in appendix B. The stochastic model provides the basis for uncertainty

calculations. The point estimate calculations reported in this analysis are based on the mean estimate derived from the State distribution, for which the cumulative number of fusion machines grows to 147 in 2045.

4.3 Cost and Benefit Calculations

This section presents the process for, and results of, evaluating the costs and benefits expected to occur from the proposed rule and associated guidance development (Alternative 2), and development of new guidance alone (Alternative 3), relative to the regulatory baseline (Alternative 1). All costs and benefits are monetized, when possible. The total costs and benefits are then summed to determine whether the difference between the costs and benefits results in a positive benefit. Some benefits are described qualitatively because meaningful quantification is not possible. The values in tables throughout this document may appear to have summation errors, but this is due to rounding within the cost model.

The sign conventions used in this analysis are that all favorable consequences for the alternative are positive and all adverse consequences for the alternative are negative. Negative values are shown using parentheses (e.g., negative \$500 is displayed as (\$500)). The NRC used a 20-year analysis horizon after implementation of the final rule, assumed to be 2026 to 2045 for the purposes of this analysis.

This analysis describes the incremental impacts of each alternative relative to a baseline that reflects anticipated behavior if the NRC does not undertake regulatory or nonregulatory action. The regulatory analysis assumes full compliance with existing NRC requirements, including current regulations and relevant orders. This is consistent with NUREG/BR-0058, draft Revision 5, which states that “in evaluating a new requirement, the staff should assume that all existing NRC and Agreement State requirements have been implemented.”

The staff used best available information regarding the number and type of future fusion machine applicants. The staff considered factors such as trends in new applications (i.e., research and development fusion machines in Agreement States), known potential license applications associated with fusion machine (currently all within Agreement States), and the types of fusion machines involved. The staff used a combination of those factors in determining the future licensees or applicants for each cost estimate. The NRC continues to engage with potential applicants regarding their licensing plans.

Industry labor rates are based on 2023 U.S. Bureau of Labor Statistics (BLS) data. The current NRC labor rate of \$152 per hour was used throughout this analysis. The base year for discounting is 2023, as is the price level for all calculations.

The provisions of the proposed rule would add new requirements and clarify some existing requirements to license and oversee the possession, use, and production of byproduct material associated with fusion machines. For the industry, the proposed rule would provide cost savings due to the reduced likelihood of needing to seek clarification of regulatory requirements. Both the NRC and Agreement States would incur upfront rulemaking costs but would benefit from the lower costs of administering the regulations due to the clarity of the regulations applied to fusion machines.

5.0 RESULTS

As summarized in Table 2, relative to the no action alternative (Alternative 1), the proposed rulemaking (Alternative 2) results in quantifiable net benefits of approximately \$1.38 million assuming a 7 percent discount rate or \$3.25 million assuming a 3 percent discount rate. For the guidance-only alternative (Alternative 3), the quantifiable net benefits are estimated to be \$2.03 million assuming a 7 percent discount rate or \$4.22 million assuming a 3 percent discount rate. These calculations are described further in the following sections. Note that all of the benefits quantified for the proposed rule are due to averted costs, so the positive net benefits quantified are also net cost savings, thus the rule imposes negative costs.

Table 2 3Monetized Benefit/Cost Summary for Alternatives 2 and 3

Description	Net Benefits (Costs) (2023 dollars)*			
	Alternative 2: Rulemaking and Guidance		Alternative 3: Guidance Only	
	7% NPV	3% NPV	7% NPV	3% NPV
Averted Costs				
Industry Benefit	\$2,027,000	\$4,077,000	\$2,027,000	\$4,077,000
Agreement States Benefit	\$177,000	\$356,000	\$177,000	\$356,000
NRC Benefit	\$34,000	\$70,000	\$34,000	\$70,000
Total Benefit	\$2,239,000	\$4,503,000	\$2,239,000	\$4,503,000
Implementation Costs				
Agreement States Cost	(\$544,000)	(\$919,000)	(\$105,000)	(\$178,000)
NRC Cost	(\$314,000)	(\$338,000)	(\$102,000)	(\$110,000)
Total Cost	(\$858,000)	(\$1,257,000)	(\$207,000)	(\$288,000)
Net Benefit (Cost)	\$1,381,000	\$3,246,000	\$2,032,000	\$4,215,000

*Values rounded to the nearest thousand dollars. Rounded values may not sum to rounded totals.

5.1 Cost Impact on NRC and Agreement State Applicants for Fusion Machine Licenses (Industry Operations)

The NRC goal in amending these regulations is to ensure that fusion machine operations with radiological materials do not pose unreasonable risks to public health and safety, the common defense and security, or the environment. The staff found that the provisions in the existing regulations for radiological materials were adequate to accomplish this goal, if augmented by appropriate license conditions (e.g., for disposal of fusion machine waste in a low-level waste disposal facility); however, staff also found that the goal would be better achieved if those existing regulations were clarified to clearly specify applicability to fusion machine operations. For the industry, the clarified regulations have benefits in the form of lower costs and reduced likelihood of needing to seek clarification of regulatory requirements.

Because the existing requirements and proposed regulations have the same fundamental requirements, the cost or benefit of complying with a resulting license would not change. However, because the clarity of the regulations would be improved, the effort of applying for a license is reduced. Because the proposed fusion machine regulations provide a

technology -inclusive regulatory framework, the effort avoided by industry (due to the clarity provided by this rule) will depend on the novelty and complexity of the application.

Uncertainty in both the state of fusion machine technology and the structure of the fusion machine industry affects the estimates of effort avoided. The industrial structure will be related to technology and marketable products of the fusion machines. The range of unknown conditions is the context for estimating the average hours of effort averted for each projected fusion machine licensed during the period of analysis.

The NRC estimates that the average fusion machine applicant will avert 484 hours of effort by increased clarity of requirements for license applications and regulatory compliance with the distribution defined in appendix B (Industry Operations: hours saved for each licensing action due to clarified regulations). The NRC invites comments that can be used to improve this estimate. Due to information limitations, the NRC's monetized estimate of this savings is calculated to be the same for Alternative 2 as for Alternative 3. However, the NRC expects that cost savings would be lower for Alternative 3 by an undetermined amount, due to added effort required for exemptions and license conditions under this alternative. An applicant would expend added effort and may experience licensing delays if exemptions and additional license conditions are needed compared to Alternative 2. To determine the total averted licensing costs, NRC used the total number of expected applications for both NRC and Agreements States as included in Table 3.

Wages for the industry effort (as shown in appendix B) are estimated from the latest BLS Occupational Employment and Wage Statistics (OEWS) survey data (2022). Mean, 25th percentile, and 75th percentile wage data for occupation categories in the Nuclear Electric Power Generation sector are used to calculate a weighted average. The weighted average is deflated to the 2023 price level using the Gross Domestic Product: Implicit Price Deflator from the U.S. Bureau of Economic Analysis for 2024. This wage rate is then loaded with employment costs by dividing by the fraction of employer costs that wages constitute for private industry workers (70.6 percent) from the Employer Costs for Employee Compensation, a dataset derived from the BLS National Compensation Survey for 2023 to calculate an applicant labor rate of \$100.

Table 3 4 Applicant Benefits for Alternatives 2 and 3

Year	Applications**	Averted Licensing Costs*	
		Hours	Net Benefits (Costs)
2026	0	-	\$0
2027	1	484	\$48,452
2028	1	484	\$48,452
2029	1	484	\$48,452
2030	1	484	\$48,452
2031	1	484	\$48,452
2032	0	-	\$0
2033	0	-	\$0
2034	2	968	\$96,905
2035	2	968	\$96,905
2036	8	3,872	\$387,619
2037	5	2,420	\$242,262
2038	7	3,388	\$339,167
2039	12	5,808	\$581,429
2040	12	5,808	\$581,429
2041	13	6,292	\$629,882
2042	16	7,744	\$775,239
2043	19	9,196	\$920,596
2044	23	11,132	\$1,114,406
2045	23	11,132	\$1,114,406
Totals	147	71,148	
	7% NPV		\$2,027,365
	3% NPV		\$4,077,099

* Labor hours and labor rate are rounded from the PERT generated values based on the parameters in table B-1, so benefits may differ from the rounded products.

**Applications prior to 2032 are based on observed activity. From 2032 to 2045, activity is based on a constant growth rate curve on the national level, which implies applications in the States and other jurisdictions modeled. The resulting growth is not smooth because of the truncation of fractional applications modeled for some years that become part of a whole application in a subsequent year. Thus, the zero growth in years 2032 and 2033 is an artifact of the model indicating that no jurisdiction fusion machine deployments have yet grown to a full number.

Both the NRC's recommended rulemaking alternative (Alternative 2) and the guidance only alternative (Alternative 3) in this regulatory analysis result in monetized net benefits to the industry of approximately \$2.03 million using a 7 percent discount rate and \$4.08 million using a 3 percent discount rate. Note that the benefits to industry under Alternative 3 would be lower due to costs that could not be monetized as described above.

5.2 Cost Impact on the NRC

Like licensees, NRC operations would benefit from using the rule, if revised and/or new guidance due to the reduced effort needed to review applications and regulate fusion machines directly regulated by the NRC. The NRC would also incur costs of implementing the proposed rule and/or new guidance.

Implementation Costs

The staff assumed implementation of both Alternative 2 and Alternative 3 would be completed in 2025. For Alternative 2, conducting rulemaking and developing the accompanying guidance would result in a one-time cost to the NRC. The resources to develop the proposed rule and guidance are sunk costs; future rulemaking costs will be those incurred at the final rule phase and costs for the preparation and issuance of final guidance, assuming Alternative 2 is chosen. As shown in Table 4, the labor to “Prepare final rule and supporting documentation” was estimated by staff to be 1,979 hours, so the NRC would expend \$300,862 at the NRC labor rate of \$152 per hour. The labor to “Prepare and issue guidance” is estimated to be 383 hours which amounts \$58,241 at the same labor rate. Thus, the total one-time costs to the NRC would be \$359,103 in 2025.

Table 4 5 NRC Costs and Benefits for Alternative 2

Year	Applications	Implementation Costs					Operational Costs		Net Benefit (Cost) Total
		Prepare final rule and supporting documents		Prepare and issue guidance		Subtotal Implementation	Averted Licensing Costs		
		Hours*	Net Benefits (Costs)	Hours*	Net Benefits (Costs)	Net Benefits (Costs)	Hours*	Net Benefits (Costs)	
2025	0	1979	(\$300,862)	383	(\$58,241)	(\$359,103)	0		
2026	0	0	0	0	0	\$0	0	\$0	\$0
2027	0	0	0	0	0	\$0	0	\$0	\$0
2028	0	0	0	0	0	\$0	0	\$0	\$0
2029	0	0	0	0	0	\$0	0	\$0	\$0
2030	0	0	0	0	0	\$0	0	\$0	\$0
2031	0	0	0	0	0	\$0	0	\$0	\$0
2032	0	0	0	0	0	\$0	0	\$0	\$0
2033	0	0	0	0	0	\$0	0	\$0	\$0
2034	0	0	0	0	0	\$0	0	\$0	\$0
2035	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2036	0	0	0	0	0	\$0	0	\$0	\$0
2037	0	0	0	0	0	\$0	0	\$0	\$0
2038	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2039	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2040	0	0	0	0	0	\$0	0	\$0	\$0
2041	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2042	2	0	0	0	0	\$0	161	\$24,523	\$24,523
2043	1	0	0	0	0	\$0	81	\$12,261	\$12,261

2044	2	0	0	0	0	\$0	161	\$24,523	\$24,523
2045	1	0	0	0	0	\$0	81	\$12,261	\$12,261
Totals	10	1,979		383			726		
	7% NPV		(\$262,785)		(\$50,870)	(\$313,655)		\$33,933	(\$279,722)
	3% NPV		(\$283,592)		(\$54,898)	(\$338,490)		\$69,581	(\$268,909)

* Labor hours are rounded from the PERT generated values based on the parameters in table B-1, so benefits differ from the rounded products.

For Alternative 3, guidance development would result in a one-time cost to the NRC. Future costs for the preparation and issuance of new guidance alone include the additional effort to develop a new document that is consistent with the existing regulations; additional guidance would be needed for items that would have been included in rule provisions. Future costs for the preparation and issuance of new guidance alone would include the additional effort to develop a guidance document that is consistent with the existing rules while using terminology specific to fusion machines. As shown in Table 5, the labor to “Prepare and issue new guidance” was estimated by staff to be 766 hours, so the NRC would expend \$116,483 at the NRC labor rate of \$152. Because this alternative requires no effort to prepare the final rule, the total one-time costs to the NRC in 2025 would be \$116,483.

Table 5 6 NRC Costs and Benefits for Alternative 3

Year	Applications	Implementation Costs					Operational Costs		Net Benefit (Cost) Total
		Prepare final rule and supporting documents		Prepare and issue new guidance		Subtotal Implementation	Averted Licensing Costs		
		Hours	Net Benefits (Costs)	Hours*	Net Benefits (Costs)	Net Benefits (Costs)	Hours*	Net Benefits (Costs)	
2025	0	0	0	766	(\$116,483)	(\$116,483)	0	\$0	(\$116,483)
2026	0	0	0	0	0	\$0	0	\$0	\$0
2027	0	0	0	0	0	\$0	0	\$0	\$0
2028	0	0	0	0	0	\$0	0	\$0	\$0
2029	0	0	0	0	0	\$0	0	\$0	\$0
2030	0	0	0	0	0	\$0	0	\$0	\$0
2031	0	0	0	0	0	\$0	0	\$0	\$0
2032	0	0	0	0	0	\$0	0	\$0	\$0
2033	0	0	0	0	0	\$0	0	\$0	\$0
2034	0	0	0	0	0	\$0	0	\$0	\$0
2035	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2036	0	0	0	0	0	\$0	0	\$0	\$0
2037	0	0	0	0	0	\$0	0	\$0	\$0
2038	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2039	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2040	0	0	0	0	0	\$0	0	\$0	\$0
2041	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2042	2	0	0	0	0	\$0	161	\$24,523	\$24,523
2043	1	0	0	0	0	\$0	81	\$12,261	\$12,261
2044	2	0	0	0	0	\$0	161	\$24,523	\$24,523
2045	1	0	0	0	0	\$0	81	\$12,261	\$12,261

Totals	10	0	766			807			
	7% NPV		\$0		(\$101,740)	(\$101,740)		\$33,933	(\$67,807)
	3% NPV		\$0		(\$109,796)	(\$109,796)		\$69,581	(\$40,215)

*Labor hours are rounded from the PERT generated values based on the parameters in table B-1, so benefits may differ from the rounded products.

Operational Costs

There will be ongoing cost savings to the NRC due to the decreased cost of regulating the possession, use, and production of byproduct material associated with fusion machines that are directly regulated by the NRC. There will be decreased licensing costs to the NRC because of the rule and/or associated guidance. Due to information limitations, the NRC staff monetized these cost savings using the same calculations for Alternative 2 as for Alternative 3, as shown in in Tables 4 and 5 as “Averted licensing costs.” However, the NRC expects that cost savings would be lower for Alternative 3 by an undetermined amount due to the added effort required to process and review exemptions and customized license conditions under this alternative.

NRC staff has estimated that 9 applications would be submitted directly to the NRC. This estimate is based on the projection assumptions (see Table B-1) for fusion machine license applications in States that are not Agreement States. Many of these States have smaller electrical power markets, so few applications are expected to require direct review by the NRC. The NRC invites any comment that can be used to improve these projection assumptions. The effort required to process each application submitted to the NRC is estimated to be reduced by approximately 81 hours because of the increased quality of each application that results from the added clarity to the regulations. This amounts to \$12,300 of savings for each application at the NRC labor rate of \$152 per hour. Because applications are not expected to be submitted directly to the NRC until 2038 and later (see Table A-1, column 5), discounting reduces the present value of the sum of these averted costs substantially to a net present value of \$34,000 (using a 7 percent discount rate) and \$70,000 (using a 3 percent discount rate) as shown in Tables 4 and 5.

Total Costs

Taking rulemaking costs into account, when compared to the no-action alternative, Alternative 2 would result in a net cost to the NRC of approximately \$280,000 (using a 7 percent discount rate) and \$269,000 (using a 3 percent discount rate) as shown in Table 4. When compared to the no-action alternative, Alternative 3 would result in a net cost to the NRC of approximately \$68,000 (using a 7 percent discount rate) and \$40,000 (using a 3 percent discount rate) as shown in Table 5. Neither Alternative 2 nor Alternative 3 is directly cost beneficial to the NRC. All values are in 2023 dollars and discounted to the 2023 base year.

5.3 Cost Impact on the Agreement States

Like licensees, Agreement States would benefit from using the NRC’s revised regulations to develop fusion machine regulation programs. The Agreement States would incur the costs of revising their regulations and guidance to be consistent with NRC revised regulations. After revising their regulations and guidance, the Agreement States would benefit from the reduced effort required for licensing and oversight of new fusion machines built in their State due to the improvements in clarity.

Implementation Costs

The staff assumed that each Agreement State would complete the revision the year that the first license application, for a license authorizing the possession, use, and production of byproduct material associated with a fusion machine, is projected to be received for that Agreement State. The last column in Table A-1 shows the number of Agreement States that the NRC estimates will be added each year of the period of analysis (for example, 6 States in 2036 and 4 States in 2037).

For Alternative 2, the NRC projects the cost for all Agreement States revising their regulations to be \$544,000 at the 7 percent discount rate (\$919,000 at 3 percent) as shown in Table 6. When an Agreement State undertakes the rulemaking and guidance process, the NRC estimates the labor effort for each State to be 895 hours. Thus, at a labor rate of \$56 per hour, each Agreement State would expend \$50,000 for rulemaking and guidance development.

Table 6 7 Agreement State Costs and Benefits for Alternative 2

Year	Agreement State		Implementation Costs		Operational Costs		Net Benefit (Cost) Total
			Prepare Rule and Guidance Consistent with NRC		Averted Licensing Costs		
	Rulemaking	Applications	Hours	Net Benefits (Costs)	Hours	Net Benefits (Costs)	
2026	0	0	-	\$0	-	\$0	\$0
2027	1	1	895	(\$50,393)	81	\$4,540	(\$45,853)
2028	1	1	895	(\$50,393)	81	\$4,540	(\$45,853)
2029	1	1	895	(\$50,393)	81	\$4,540	(\$45,853)
2030	1	1	895	(\$50,393)	81	\$4,540	(\$45,853)
2031	1	1	895	(\$50,393)	81	\$4,540	(\$45,853)
2032	0	0	-	\$0	-	\$0	\$0
2033	0	0	-	\$0	-	\$0	\$0
2034	1	2	895	(\$50,393)	161	\$9,080	(\$41,313)
2035	1	1	895	(\$50,393)	81	\$4,540	(\$45,853)
2036	6	8	5,372	(\$302,358)	645	\$36,319	(\$266,039)
2037	4	5	3,582	(\$201,572)	403	\$22,700	(\$178,872)
2038	1	6	895	(\$50,393)	484	\$27,239	(\$23,154)
2039	1	11	895	(\$50,393)	887	\$49,939	(\$454)
2040	3	12	2,686	(\$151,179)	968	\$54,479	(\$96,700)
2041	2	12	1,791	(\$100,786)	968	\$54,479	(\$46,307)
2042	0	14	-	\$0	1,129	\$63,559	\$63,559
2043	2	18	1,791	(\$100,786)	1,452	\$81,718	(\$19,068)
2044	2	21	1,791	(\$100,786)	1,694	\$95,338	(\$5,448)
2045	0	22	-	\$0	1,775	\$99,878	\$99,878
Totals	28	137	25,071		11,051		
		7% NPV		(\$543,945)		\$177,396	(\$366,548)
		3% NPV		(\$918,932)		\$356,254	(\$562,678)

For Alternative 3, the NRC projects the cost for all Agreement States to be \$105,000 at the 7 percent discount rate (\$178,000 at 3 percent) as shown in Table 7. When an Agreement State undertakes development of new guidance, the NRC estimates the labor effort for each State to be 173 hours. Thus, at a labor rate of \$56 per hour, each Agreement State expends \$9,700 for guidance development.

Table 7 8 Agreement State Costs and Benefits for Alternative 3

Year	Agreement State		Implementation Costs		Operational Costs		Net Benefit (Cost) Total
			Prepare and issue guidance		Averted Licensing Costs		
	Rulemaking	Applications	Hours	Net Benefits (Costs)	Hours	Net Benefits (Costs)	
2026	0	0	-	\$0	-	\$0	\$0
2027	1	1	173	(\$9,755)	81	\$4,540	(\$5,215)
2028	1	1	173	(\$9,755)	81	\$4,540	(\$5,215)
2029	1	1	173	(\$9,755)	81	\$4,540	(\$5,215)
2030	1	1	173	(\$9,755)	81	\$4,540	(\$5,215)
2031	1	1	173	(\$9,755)	81	\$4,540	(\$5,215)
2032	0	0	-	\$0	-	\$0	\$0
2033	0	0	-	\$0	-	\$0	\$0
2034	1	2	173	(\$9,755)	161	\$9,080	(\$675)
2035	1	1	173	(\$9,755)	81	\$4,540	(\$5,215)
2036	6	8	1,040	(\$58,531)	645	\$36,319	(\$22,212)
2037	4	5	693	(\$39,021)	403	\$22,700	(\$16,321)
2038	1	6	173	(\$9,755)	484	\$27,239	\$17,484
2039	1	11	173	(\$9,755)	887	\$49,939	\$40,184
2040	3	12	520	(\$29,265)	968	\$54,479	\$25,213
2041	2	12	347	(\$19,510)	968	\$54,479	\$34,969
2042	0	14	-	\$0	1,129	\$63,559	\$63,559
2043	2	18	347	(\$19,510)	1,452	\$81,718	\$62,208
2044	2	21	347	(\$19,510)	1,694	\$95,338	\$75,828
2045	0	22	-	\$0	1,775	\$99,878	\$99,878
Totals	28	137	4,853		11,051		
		7% NPV		(\$105,298)		\$177,396	\$72,099
		3% NPV		(\$177,888)		\$356,254	\$178,366

Operational Costs

The cost savings for Agreement State regulation are also accrued each time a new fusion machine is built in the State. Table A-1 shows the projected addition of fusion machines in Agreement States.

For Alternative 2, the staff estimates the net benefit of cost savings for Agreement States due to clarified NRC regulations to be \$177,000 at the 7 percent discount rate (\$356,000 at 3 percent) as shown in Table 6. These averted costs are due to labor for license application reviews being reduced by 81 hours for each application, which amounts to \$4,540 for each application at the \$56 per hour labor rate estimated for Agreement States.

For Alternative 3, the NRC does not have information to quantify the expected lower averted labor effort for each application review when compared to Alternative 2. Staff has calculated the labor savings quantified the same for Alternative 3 as for Alternative 2, despite the likelihood of additional labor that would be needed under Alternative 3 for developing and reviewing custom license conditions and exemptions. Thus, the net benefit of cost savings for Agreement States due to clarified regulations is \$177,000 at the 7 percent discount rate (\$356,000 at 3 percent) as shown in Table 7.

Total Costs

Thus, for Alternative 2, the NRC estimates the total net quantified costs (implementation and operational costs) for Agreement States to be \$367,000 at the 7 percent discount rate (\$563,000 at 3 percent). For Alternative 3, NRC estimates a total net benefit of \$72,000 at the 7 percent discount rate (\$178,000 at 3 percent).

An averted cost that could not be quantified when not conducting a rulemaking is the potential necessity of license conditions to address issues related to waste management for fusion machines under the current regulations. The costs averted under Alternative 2 compared to Alternatives 1 and 3 would depend on the frequency and quantity of waste disposal required by the choice of future fusion machine technology, in addition to the number of fusion machines operating. This averted cost could not be accurately quantified.

5.4 Regulatory Efficiency

Alternative 2 would ensure a systematic, risk-informed approach to the licensing and regulation of byproduct material associated with fusion machines and its associated radiological hazards by developing definitions to establish the scope of regulatory requirements for fusion machines and adding technology-inclusive content-of-application requirements supportive of a performance-based approach to regulation. Addressing these changes in rulemaking with associated guidance would improve the licensing process and enhance regulatory stability, predictability, and clarity. The rule and associated guidance would result in a reduction in the time needed for the development and review of case-by-case applications for new fusion machine licenses. Alternative 2 would be a more efficient way to regulate fusion machines compared to using guidance along with other regulatory tools like license conditions, exemptions, or orders. Alternative 2 would also incorporate definitions provided by the ADVANCE Act into regulations, increasing regulatory efficiency. Alternative 2 would facilitate the efficient disposal of fusion waste by creating a process to determine how fusion waste could be disposed of.

Alternative 3 would have regulatory efficiency benefits compared to Alternative 1; however, issuing guidance without updating the regulations would be less efficient than updating the regulations and issuing guidance. Alternative 3 would provide less regulatory efficiency relative to Alternative 2 due to the need for customized license conditions and exemptions.

5.5 Increased Public Confidence

By clarifying the regulations and guidance that apply to fusion machines, Alternative 2 would increase public confidence in the NRC's ability to improve its regulations, adapt to regulatory needs identified by stakeholders, provide opportunities for stakeholders to comment on the changes to the fusion machine licensing process, and maintain the NRC's role as an effective industry regulator. In addition, the rulemaking process provides the greatest opportunity for Commission and public engagement on the issues related to the fusion machine licensing process. Public notice and comment during rulemaking would provide the widest range of viewpoints for Commission consideration before preparation of the final rule. Alternative 3 would be less effective at increasing public confidence because it would not provide the same level of public engagement or clarity compared to Alternative 2.

5.6 Uncertainty Analysis

The NRC completed a Monte Carlo sensitivity analysis for this regulatory analysis using the specialty software @Risk program.⁵ The Monte Carlo approach answers the question, "What distribution of net benefits results from multiple draws of the probability distribution assigned to key variables?"

5.6.1 Uncertainty Analysis Assumptions

Because this regulatory analysis is based on estimates of values that are uncertain, the NRC provides the following analysis of the variables that have the greatest amount of uncertainty, using a Monte Carlo simulation.

Monte Carlo simulations involve introducing uncertainty into the analysis by replacing the point estimates of the variables used to estimate base case costs and benefits with probability distributions. By defining input variables as probability distributions instead of point estimates, the influence of uncertainty on the results of the analysis (i.e., the net benefits) can be effectively modeled.

The probability distributions chosen to represent the different variables in the analysis were bounded by the range-referenced input and the NRC staff's professional judgment. When defining the probability distributions for use in a Monte Carlo simulation, summary statistics are needed to characterize the distributions. These summary statistics include the minimum, most likely, and maximum values of a program evaluation and review technique (PERT) distribution,⁶ and the specified integer values of a discrete population. The NRC used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates.

Appendix B identifies the data elements, the distribution and summary statistics, and the mean value of the distributions that the staff used in the uncertainty analysis.

⁵ Information about the @Risk software is available at <https://lumivero.com/products/at-risk/>.

⁶ A PERT distribution is a special form of the beta distribution with specified minimum and maximum values. The shape parameter is calculated from the defined "most likely" value. The PERT distribution is similar to a triangular distribution in that it has the same set of three parameters.

5.6.2 Uncertainty Analysis Results

The NRC performed a Monte Carlo simulation by repeatedly recalculating the quantifiable results 10,000 times. For each iteration, the program chose the values in the cost model randomly from the probability distributions that define the input variables. The model recorded the values of the output variables for each iteration and used these resulting output variable values to define the resultant probability distribution, in terms of costs and benefits.

Figures 2, 3, 4, and 5 display the histograms of the net incremental costs and benefits compared to the regulatory baseline of the rule's alternatives for affected entities.

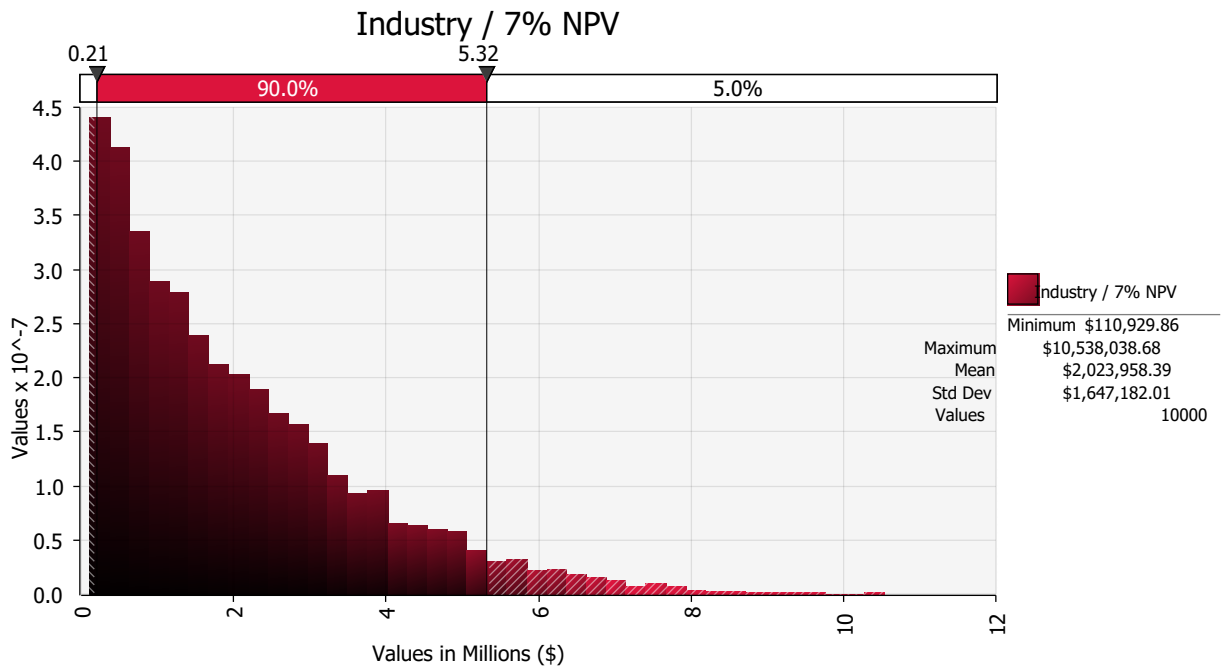


Figure 2 Industry-Averted Licensing Costs (7-percent Net Present Value)

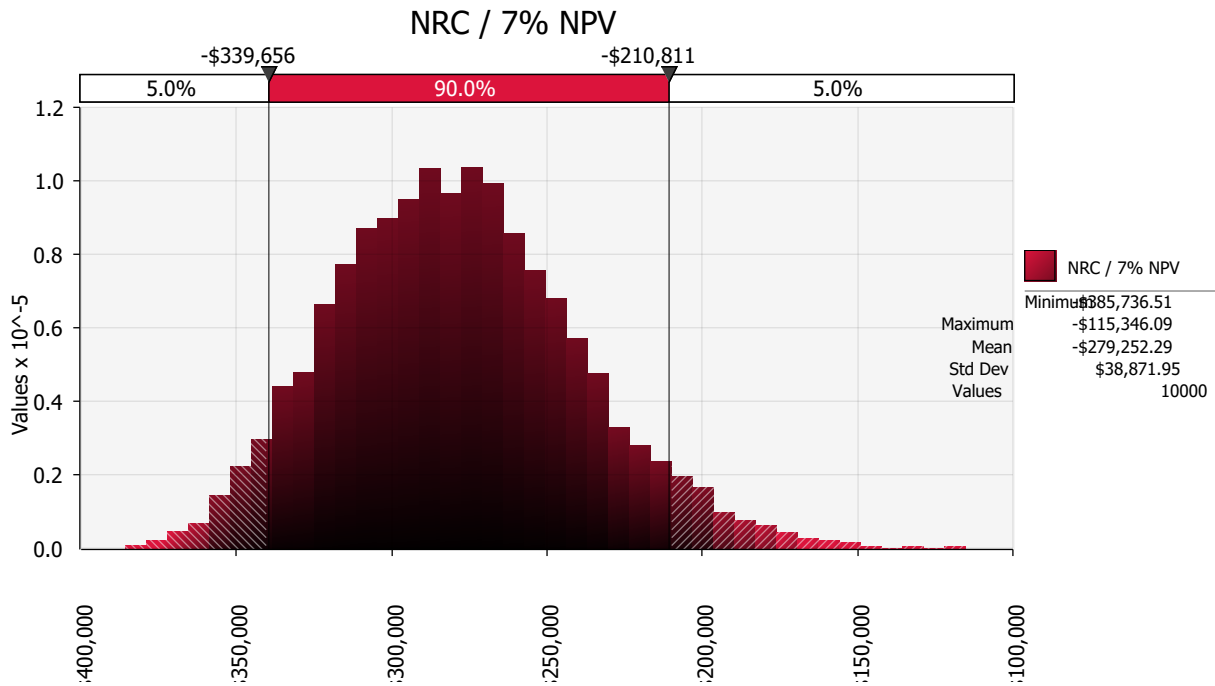


Figure 3 NRC Net Benefit (7-percent Net Present Value)

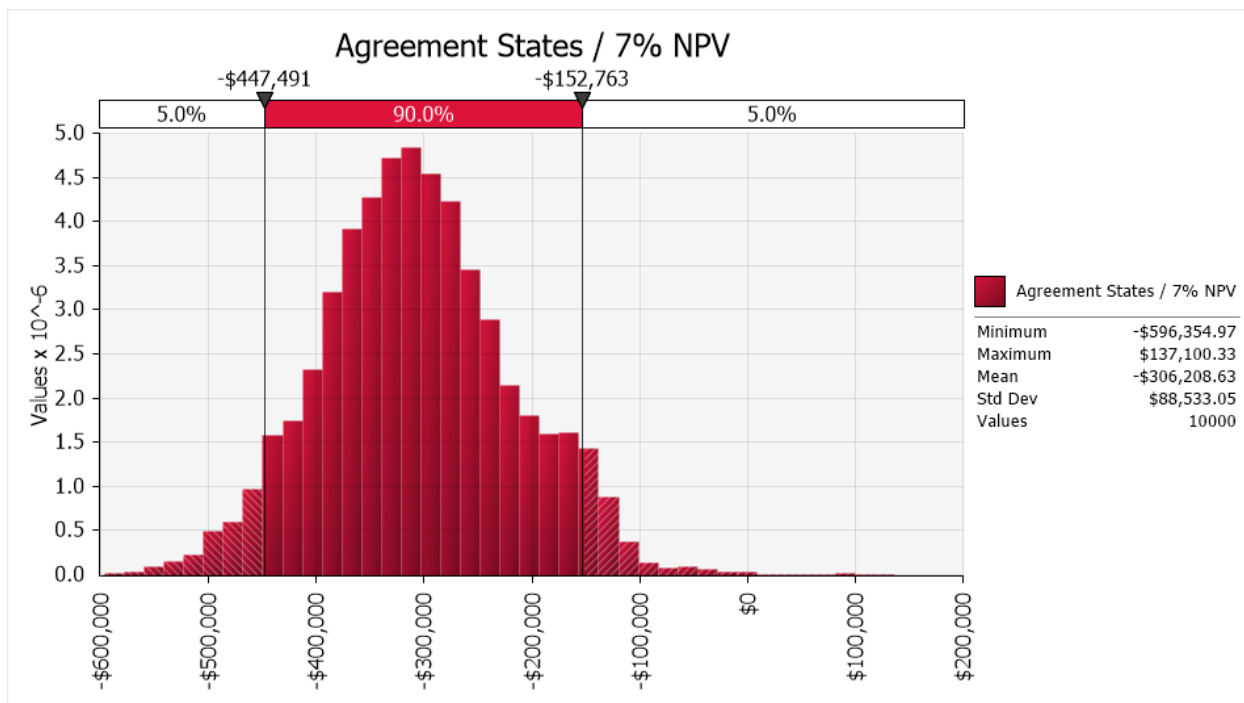


Figure 4 Agreement State Net Benefit (7-percent Net Present Value)

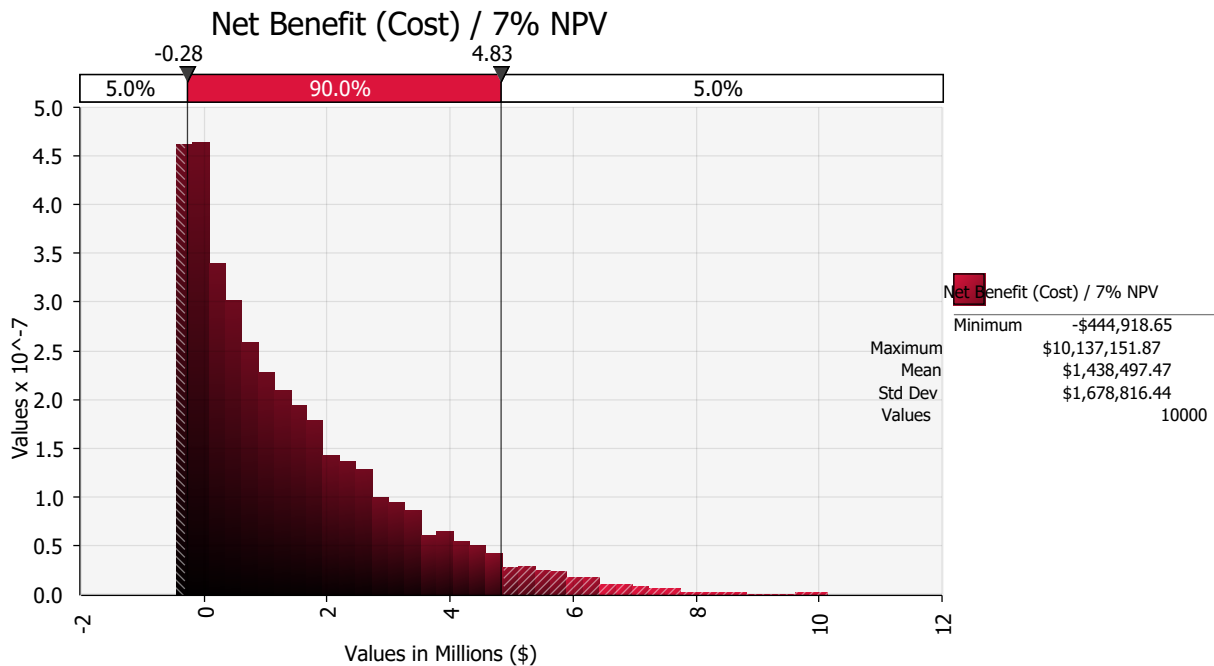


Figure 5 Total Net Benefit (7-percent Net Present Value)

As shown in figure 2, the proposed rule (Alternative 2) would result in mean averted costs to the industry of approximately \$2.0 million using a 7 percent discount rate. The uncertainty analysis indicates that there is a greater than 99 percent chance that this rulemaking alternative would have a positive net benefit to the industry of over \$153,000. Because the proposed rule would only benefit industry, the net benefit for industry could not be negative. However, the benefit skews heavily to the lower net benefit level because our model assumes that rapid growth of fusion machine use is not likely within the time horizon of the analysis. As shown in figure 3, the proposed rule would result in a mean net cost to the NRC of approximately \$279,000, primarily from rulemaking costs with some offset due to the lower cost of licensing the minority of potential license applicants under direct NRC jurisdiction. There is a greater than 99 percent chance that this alternative would cost the NRC more than would be saved with so few direct applications to the NRC providing averted costs for the NRC to offset rulemaking costs. As shown in figure 4, Agreement States would net \$306,000 in costs, with a greater than 99 percent chance that costs will exceed benefits for the Agreement States collectively. As shown in figure 5, the proposed rule would result in a total net benefit of approximately \$1.4 million. These net benefits will be negative if adoption of the technology is very low, as the costs of completing the rulemaking would not be exceeded by savings, due to the more efficient process, for a small number of applications. Because the application projections are skewed to the low adoption scenarios, the probability of negative total net benefits is greater than 20%. The upper tail of the distribution is long indicating that very high positive values are possible at low probabilities. The probability that the total net benefit could exceed \$6.7 million is 1%.

5.6.3 Sensitivity Analysis

In addition to estimating the probability distributions for the net benefits of the proposed rule, the NRC used a Monte Carlo simulation to conduct a sensitivity analysis to determine the variables

that have the greatest impact on the resulting net benefits. Variables shown to have a large effect on the resulting net benefits may deserve more attention and scrutiny than variables shown to have a small or minimal effect. The results are compiled into a “tornado diagram,” which presents, in vertical order, the variables that have the greatest influence on net benefits.

Figure 6 presents the tornado diagram for the benefits of the proposed rule and ranks the variables based on their contribution to cost uncertainty. The estimate that causes by far the greatest variation in the overall results is the estimate of fusion machine applications, which is estimated from State-level data. This variation is due to the uncertainty about the future of this new technology with scenarios ranging from nothing beyond the fusion machines now anticipated to widespread adoption of the technology as a major source of electrical power. The number of applications affects the amount saved due to the increased efficiency of licensing in the proposed rule. The uncertainty in the cumulative number of applications causes the net benefits to range from a cost of \$271,000 to a benefit of \$5.08 million with a 90 percent confidence level.

The estimate that has the second greatest variation in the overall results is the estimate of the average averted cost for each applicant’s licensing effort due to the clarified process. The uncertainty in this variable would result in a range of net benefits from \$1.0 million to \$1.8 million with a 90 percent confidence level.

The remaining variables result in smaller differences between \$100,000 and \$350,000.

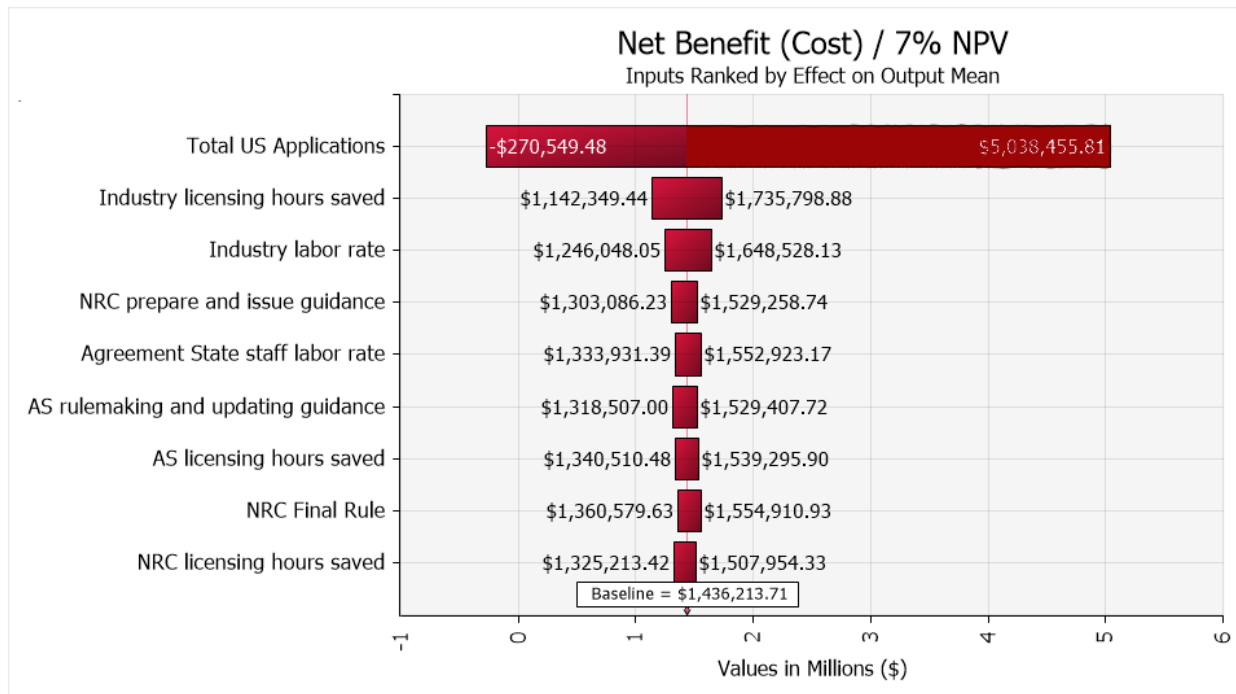


Figure 6 Key Variables for Which Uncertainty Drives the Largest Impact on Costs (7-percent Net Present Value)

6.0 OTHER IMPACTS AND REGULATORY CONSIDERATIONS

Other impacts and issues related to using rulemaking to ensure that fusion machine operations with radiological materials do not pose unreasonable risks to public health and safety, the common defense and security, or the environment include complying with the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) and conducting a peer review of the regulatory analysis.

6.1 Regulatory Flexibility Act

The Regulatory Flexibility Act, enacted in September 1980, requires agencies to consider the impact of their regulatory proposals on small entities, analyze alternatives that minimize small entity impacts, and make their analyses available for public comment. The structure of the industries that would form to use the emerging fusions machine technologies is uncertain. The most significant potential sector that could use fusion machines is the electric power sector. Among electric utilities that might operate a fusion machine, 90 percent have revenues between \$7.8 million and \$1.2 billion (EIA, 2022). Thus, for 95 percent of electric utilities, the cost impact of the proposed rule would be a benefit of less than 0.6 percent. Note that larger utilities would be more likely to have an economy of scale that could benefit from fusion machines in their power supply mix. An electric utility that might be classified as a small entity would be less likely to be able to afford to invest in fusion technology. Therefore, the NRC estimates that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities.

6.2 Peer Review of Information Contained in this Regulatory Analysis

The Office of Management and Budget bulletin “Final Information Quality Bulletin for Peer Review” requires each Federal agency to subject “influential scientific information” to peer review before dissemination. The bulletin defines “influential scientific information” as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”⁷ NRC’s Information Quality Guidelines and Management Directive (MD) 3.17 specify additional factors NRC may consider when making such determinations.⁸ This regulatory analysis does not rely on any new “influential scientific information” that would require peer review.

7.0 CONCLUSION AND DECISION RATIONALE

The NRC has extensive experience with ensuring the safe and secure use of radiological materials that are anticipated to be part of fusion machine technology as fuel, activated products, and waste. Existing regulations require licenses for the use, generation, and disposal of byproduct material. The proposed rule would provide fusion-machine specific requirements and clarify how existing requirements apply to licensing and overseeing fusion machines that generate radiological material under the 10 CFR Part 30 byproduct material framework. Neither Alternative 2 nor 3 would significantly change the regulatory requirements already in place for fusion machine applicants, but these alternatives would lead to significant savings in the time required for the application process due to improved clarity. Alternatives 2

⁷ <https://www.federalregister.gov/documents/2005/01/14/05-769/final-information-quality-bulletin-for-peer-review>

⁸ <https://www.govinfo.gov/content/pkg/FR-2002-10-01/pdf/02-24944.pdf> and <https://www.nrc.gov/docs/ML1610/ML16105A321.pdf>

and 3 would require guidance development and/or rulemaking efforts by Agreement States to ensure their regulations and guidance are compatible with NRC regulations and guidance. The Agreement States would also benefit from the clarity of Alternatives 2 and 3, which would avert the effort needed to independently develop approaches under existing regulations that apply to fusion machines, saving the effort needed when Agreement States prepare for anticipated fusion machines within their respective jurisdictions.

Relative to the no action alternative (Alternative 1), the proposed rulemaking (Alternative 2) results in quantifiable net benefits of approximately \$1.38 million at a 7 percent discount rate or \$3.25 million at a 3 percent discount rate. For the guidance-only alternative (Alternative 3), the quantifiable net benefits are estimated to be \$2.03 million at a 7 percent discount rate or \$4.22 million at a 3 percent discount rate. Significant benefits that cannot be quantified reliably also accrue from both alternatives. The NRC has concluded that both Alternative 2 and Alternative 3 of the proposed rule are cost beneficial. Although the net benefit monetized for Alternative 2 is less than the net benefit monetized for Alternative 3, additional nonmonetized benefits are expected for Alternative 2. The guidance associated with Alternative 2 can more directly cite the revised regulations explicitly associated with fusion machines, while the guidance developed for Alternative 3 would not have the benefit of revised regulations and would rely on more case-by-case regulatory tools such as customized license conditions and exemptions. Nonmonetized savings accrue to Alternative 2 due to avoiding the need to develop, justify, and review custom license conditions and exemptions for individual fusion machine applications.

In summary, while both Alternatives 2 and 3 would ensure consistency in byproduct material licensing reviews associated with fusion machines, provide an efficient licensing process, and clarify ongoing regulatory requirements for the full life of a fusion machine through decommissioning, Alternative 2 is the recommended alternative due to qualitative considerations described above.

8.0 IMPLEMENTATION

The NRC assumes that the final rule would become effective 30 days after its publication in the *Federal Register* in 2026.

9.0 REFERENCES

10 CFR Part 30. *Code of Federal Regulations*, Title 10, *Energy*, Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material.”

ACRS Letter—Draft SECY White Paper on Licensing and Regulating Fusion Energy Systems October 5-7, 2022, Full Committee, October 21, 2022, Agencywide Documents Access and Management System Accession No. ML22290A177.

EIA, U.S. Energy Information Administration, Preliminary Monthly Electric Generator Inventory (based on Form EIA-860M as a supplement to Form EIA-860), https://www.eia.gov/electricity/data/eia860m/archive/xls/december_generator2023.xlsx, December 24, 2023.

“Final Information Quality Bulletin for Peer Review.” Office of Management and Budget, Washington, D.C., December 16, 2004.

National Environmental Policy Act of 1969, as amended. 42 U.S.C. 4321 et seq.

Regulatory Flexibility Act. 5 U.S.C. 601 et seq., Public Law 96-354, 94 Stat. 1164.

“Staff Requirements—SECY-23-0001—Options for Licensing and Regulating Fusion Energy Systems.” SRM-SECY-23-0001, U.S. Nuclear Regulatory Commission, April 13, 2023, Agencywide Documents Access and Management System Accession No. ML23103A449.

“Staff Requirements—SECY-20-0032—Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors.’” SRM-SECY-20-0032, U.S. Nuclear Regulatory Commission, October 2, 2020, Agencywide Documents Access and Management System Accession No. ML20276A293.

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Appendix A Cost-Benefit Calculations

Table A-1 Projection of Fusion Machine Installations and Agreement State or NRC Regulation of the Machines

Year	Fusion Machines				Agreement State Regulation of Fusion Machines	
	Cumulative Total	Added	Agreement State Regulated	NRC Regulated	Total	Added
2026	0	0	0	0	0	0
2027	1	1	1	0	1	1
2028	2	1	1	0	2	1
2029	3	1	1	0	3	1
2030	4	1	1	0	4	1
2031	5	1	1	0	5	1
2032	5	0	0	0	5	0
2033	5	0	0	0	5	0
2034	7	2	2	0	6	1
2035	9	2	1	1	7	1
2036	17	8	8	0	13	6
2037	22	5	5	0	17	4
2038	29	7	6	1	18	1
2039	41	12	11	1	19	1
2040	53	12	12	0	22	3
2041	66	13	12	1	24	2
2042	82	16	14	2	24	0
2043	101	19	18	1	26	2
2044	124	23	21	2	28	2
2045	147	23	22	1	28	0

Table A-2 Alternative 1 Benefit and Costs by Year During Period of Analysis

Year	Agreement States		NRC		Industry
	Costs		Costs	Benefits	Benefits
	Implementation	Operations	Implementation	Operations	Operations
2025			(\$359,103)		
2026					
2027	(\$50,393)	\$4,540			\$48,452
2028	(\$50,393)	\$4,540			\$48,452
2029	(\$50,393)	\$4,540			\$48,452
2030	(\$50,393)	\$4,540			\$48,452
2031	(\$50,393)	\$4,540			\$48,452
2032					
2033					
2034					\$96,905
2035	(\$50,393)	\$4,540		\$12,261	\$96,905
2036	(\$302,358)	\$36,319			\$387,619
2037	(\$201,572)	\$22,700			\$242,262
2038	(\$50,393)	\$27,239		\$12,261	\$339,167
2039	(\$50,393)	\$49,939		\$12,261	\$581,429
2040	(\$151,179)	\$54,479			\$581,429
2041	(\$100,786)	\$54,479		\$12,261	\$629,882
2042		\$63,559		\$24,523	\$775,239
2043	(\$100,786)	\$81,718		\$12,261	\$920,596
2044	(\$100,786)	\$95,338		\$24,523	\$1,114,406
2045		\$99,878		\$12,261	\$1,114,406

Appendix B Analysis Input Variables

Table B-1 Analysis Input Variables

Activity	Mean estimate	Distribution*	Low Estimate	Best Estimate	High Estimate	Source or Basis of Estimate
General						
Base Year	2023			2023		Price level Available
Year Rule is Active	2026		2026			Staff assumption.
Analysis Horizon	2045		2045			Staff assumption
Discount Rate	7%		7%			NUREG/BR-0058
Supplemental Discount Rate	3%		3%			NUREG/BR-0058
NRC Staff labor rate	\$152		\$152			Calculated value based on NRC actuals
NRC FTE Hours	1510		1510			
Agreement State staff labor rate	\$56	PERT	\$40.75	\$56.84	\$69.58	NRC estimate based on BLS OEWS data
Industry labor rate	\$100	PERT	\$85.29	\$100.57	\$113.07	NRC estimate based on BLS OEWS data
NRC Implementation						
<i>Rulemaking</i>						
Prepare final rule and supporting documents	1,979 hours	PERT	1,472	1,963	2,552	NRC estimate based on prior rules.
Prepare and issue guidance	383 hours	PERT	285	380	494	NRC estimate based on prior rules.
Prepare draft guidance without rule	766 hours	PERT	570	760	988	NRC estimate based on prior rules.
NRC Operation						
<i>Licensing</i>						
Hours saved for each licensing due to clarified regulations	81 hours	PERT	60	80	104	NRC estimate
Industry Operation						
<i>Licensing</i>						
Hours save for each licensing due to clarified regulations	484 hours	PERT	360	480	624	NRC estimate
Agreement State Implementation						
<i>Rulemaking</i>						
Updating guidance only	173 hours	PERT	129	172	223	NRC estimate based on previous rulemaking.
Rulemaking and updating guidance	895 hours	PERT	666	888	1,154	NRC estimate based on previous rulemaking.

Agreement State Operation						
Hours saved for each licensing due to clarified regulations	81 hours	PERT	60	80	104	NRC estimate
Fusion Machines by State at end of Analysis Period**						
Alabama	5.10		0	0	27	Staff Model Assumptions
Alaska	1.51		0	0	8	Staff Model Assumptions
Arizona	7.74		0	0	41	Staff Model Assumptions
Arkansas	6.04		0	0	32	Staff Model Assumptions
California	13.21		1	3	70	Staff Model Assumptions
Colorado	3.78		1	3	20	Staff Model Assumptions
Connecticut	0.38		0	0	2	Staff Model Assumptions
Delaware	0.38		0	0	2	Staff Model Assumptions
District of Columbia	0.00		0	0	0	Staff Model Assumptions
Florida	28.51		0	0	151	Staff Model Assumptions
Georgia	5.66		0	0	30	Staff Model Assumptions
Hawaii	0.38		0	0	2	Staff Model Assumptions
Idaho	0.38		0	0	2	Staff Model Assumptions
Illinois	0.57		0	0	3	Staff Model Assumptions
Indiana	2.08		0	0	11	Staff Model Assumptions
Iowa	1.70		0	0	9	Staff Model Assumptions
Kansas	0.38		0	0	2	Staff Model Assumptions
Kentucky	1.32		0	0	7	Staff Model Assumptions
Louisiana	6.42		0	0	34	Staff Model Assumptions
Maine	0.38		0	0	2	Staff Model Assumptions
Maryland	0.57		0	0	3	Staff Model Assumptions
Massachusetts	1.00		1	3	5	Staff Model Assumptions
Michigan	5.10		0	0	27	Staff Model Assumptions
Minnesota	2.27		0	0	12	Staff Model Assumptions
Mississippi	10.95		0	0	58	Staff Model Assumptions
Missouri	1.32		0	0	7	Staff Model Assumptions
Montana	0.38		0	0	2	Staff Model Assumptions
Nebraska	1.13		0	0	6	Staff Model Assumptions
Nevada	7.55		0	0	40	Staff Model Assumptions
New Hampshire	0.38		0	0	2	Staff Model Assumptions
New Jersey	0.57		0	3	3	Staff Model Assumptions

New Mexico	1.32		0	0	7	Staff Model Assumptions
New York	0.94		0	3	5	Staff Model Assumptions
North Carolina	5.66		0	0	30	Staff Model Assumptions
North Dakota	0.38		0	0	2	Staff Model Assumptions
Ohio	1.13		0	0	6	Staff Model Assumptions
Oklahoma	6.04		0	0	32	Staff Model Assumptions
Oregon	2.83		0	0	15	Staff Model Assumptions
Pennsylvania	0.38		0	0	2	Staff Model Assumptions
Rhode Island	0.38		0	0	2	Staff Model Assumptions
South Carolina	3.21		0	0	17	Staff Model Assumptions
South Dakota	0.38		0	0	2	Staff Model Assumptions
Tennessee	1.89		0	0	10	Staff Model Assumptions
Texas	8.87		0	5	47	Staff Model Assumptions
Utah	2.08		0	0	11	Staff Model Assumptions
Vermont	0.38		0	0	2	Staff Model Assumptions
Virginia	4.91		0	0	26	Staff Model Assumptions
Washington	3.21		1	5	17	Staff Model Assumptions
West Virginia	0.38		0	0	2	Staff Model Assumptions
Wisconsin	3.40		1	3	18	Staff Model Assumptions
Wyoming	0.57		0	0	3	Staff Model Assumptions
Puerto Rico	0.38		0	0	2	Staff Model Assumptions
U.S. Pacific Territories	0.57		0	0	3	Staff Model Assumptions
U.S. Virgin Islands	0.19		0	0	1	Staff Model Assumptions
Total U.S. Applications	166.50	PERT	5	28	882	Staff Model Assumptions

*PERT distributions were used to describe stochastic variables, with the distributions defined by the low, best, and high estimates provided in the table. These PERT parameters are also referred to as minimum, most likely (or mode), and maximum values.

**A PERT distribution was assumed for the cumulative total fusion machines licensed in the United States. A PERT distribution is defined by a low, best, and high estimate, which were summed from the low, best, and high estimates. The low estimate for each State is based on the anticipated near-term number of expected fusion machines. The best estimate is biased toward the low estimate because of the risk of failure of a newly emerging technology. The high estimate is the total number of electrical utility sector CCGT plants operating in the State currently with 2 assumed in States without CCGT plants and Puerto Rico. Additionally for the high estimate, 3 was assumed in New Jersey because of fusion machine activity in the State, 3 for U.S. Pacific Territories because of the unconnected locations, and 1 for the U.S. Virgin Islands because of the small population. The growth was distributed among States proportionate to the Total US PERT distribution using the high estimate for each State.