Regulatory Analysis for the Proposed Rule: 10 CFR Parts 30, 31, 32, 34, 39, 40, 70 and 150 Modernizing NRC Regulations for Byproduct Material Use

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ABSTRACT

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for the licensing of byproduct material, some source material, and some special nuclear material. The NRC's goal in amending these regulations is to modernize the safe, effective, and efficient use of licensed material. This action will reduce the need for license amendment requests and exemptions from existing regulations while also eliminating unnecessary requirements.

This document presents the regulatory analysis of the proposed rule for the above regulatory issues and changes. To improve the NRC's cost estimates for this regulatory action, the staff conducted (1) an uncertainty analysis to consider the effects of input uncertainty on the cost estimate and (2) a sensitivity analysis for the effect of the discount rate assumption.

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
ANSI	American National Standards Institute
BLS	Bureau of Labor Statistics
CFR	*Code of Federal Regulations*
CPI-U	consumer price index for all urban consumers
DFA	Decommissioning Financial Assurance
DFP	Decommissioning Funding Plan
EO	Executive Order
FR	*Federal Register*
IMPEP	Integrated materials Performance Evaluation Program
NPV	net present value
NRC	Nuclear Regulatory Commission
PERT	program evaluation and review technique
PET	Position Emission Tomography
SNM-LSS	Special Nuclear Material – Low Strategic Significance
USP	United States Pharmacopeia
10 CFR	Title 10 of the *Code of Federal Regulations*

EXECUTIVE SUMMARY

As directed in Executive Order (EO) 14300, Section 5, the NRC reviewed its regulations on the use of byproduct material. The NRC's goal was to identify in its regulations areas that could be modernized while ensuring the continued safe, effective, and efficient use of byproduct material. The NRC has identified changes which will yield significant efficiencies and reduce regulatory burden for licensees, NRC, and Agreement States while still upholding our shared commitment to public safety. These actions will reduce the need for license amendment requests and exemptions from existing regulations.

This regulatory analysis provides an evaluation of the costs and benefits of the proposed rule and implementing guidance relative to the baseline case, the "no-action" alternative.

The NRC staff made the following key findings:

- Rule Analysis: The proposed rule recommended by the staff would result in costs and benefits as shown in Table ES-1.

Table ES-1: Total Annual Costs Savings for Alternative 2

Description	Total (2024 dollars)[a]	
	7% Annualized	3% Annualized
Industry	$1,897,000	$1,992,000
Agreement States	$966,000	$1,004,000
NRC	$125,000	$134,000
Net Cost Savings	**$2,987,000**	**$3,130,000**

[a] Values rounded to the nearest 1,000 dollars.

- Nonquantified Benefits: Based upon the assessment of total costs and benefits, the NRC concludes that the proposed rule, if issued, would increase regulatory clarity for regulators (the NRC and Agreement States) and industry. The proposed rule will result in a more consistent implementation of the NRC's regulatory program. By updating regulations in response to technological change and improved understanding of the industry, public confidence in the safety and security of the use of nuclear materials is reassured. The proposed rule reduces potential delays in licensing important diagnostic and therapeutic products that use radionuclides. The proposed rule provides licensees with more up-to-date and risk-informed approaches based on their site-specific needs, allowing better focus on issues commensurate with their importance to public health and safety.

- Uncertainty Analysis: The regulatory analysis contains a Monte Carlo simulation analysis that shows the mean net cost savings for this proposed rule is $1.48 million with 95 percent confidence that the net benefit is between $1.31 million and $1.66 million using a 7 percent discount rate. The Agreement State labor rate is the factor responsible for the largest variation in averted costs, followed by industry labor rate.

- Decision Rationale: Relative to the no-action baseline, the NRC concludes that the proposed rule will result in cost savings. In addition, the NRC concludes that the rule

provides nonquantified benefits of regulatory clarity, improved consistency in the regulatory program, and public confidence in the safety and security of commercial nuclear material usage. The proposed rule also responds to stakeholder feedback and aligns with EO 14300.

- Implementation: The NRC expects that the final rule will be effective in 2027. The applicable NRC internal procedures will be revised in 2027.

1 INTRODUCTION

This document presents the regulatory analysis of the NRC's proposed rule on modernizing NRC's regulations of byproduct material, some source material, and some special nuclear material. This proposed rule would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 31, 32, 34, and 39 which provide the regulatory framework for licensed material with commercial, industrial, medical, and academic uses. The proposed rule also amends requirements for exempt quantities of licensed material under 10 CFR Part 40 as well as requirements in 10 CFR Part 150 regarding Agreement State licensees.

2 BACKGROUND, STATEMENT OF THE PROBLEM, AND OBJECTIVE

2.1 Background

The NRC has authority to issue both general and specific licenses for the use of byproduct, source, and certain quantities of special nuclear material. The NRC also has authority to exempt material from regulatory control under Sections 53, 63, and 81 of the Atomic Energy Act of 1954, as amended (AEA). A general license is provided by regulation, grants authority to a person for particular activities involving material as described within the general license, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific activities covered by each general license. A specific license is granted on a licensing document and is issued to a named person who has filed an application with the Commission.

Within the National Materials Program, the NRC regulates the use of byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass for a variety of uses pursuant to 10 CFR Parts 19, 20, 30, 31,32, 33, 34, 35, 36, 39, 40, 70 and 150. These materials are used in industrial radiography, moisture-density gauges, medical applications, and well logging. The NRC currently has approximately 2,700 specific licenses for the use and possession of byproduct, source, and certain quantities of special nuclear material. The applicable NRC regulations and specific license conditions establish the requirements for the safe handling, use, and storage of these materials. The NRC inspects facilities to ensure compliance with regulations and takes action when violations occur. The public also uses exempt quantities of byproduct material and source material in consumer products such as smoke detectors, static eliminators, and self-luminous products.

Under Section 274b of the AEA, States can enter into agreements with the NRC that allow States to assume, and the NRC to discontinue, regulatory authority over byproduct, source, and small quantities of special nuclear material. Known as Agreement States, these States can then regulate byproduct, source, and certain quantities of special nuclear materials that are covered in the agreement, using their own legislation, regulations, or other legally binding provisions. The NRC enters into an agreements if the Commission finds the State program adequate to protect public health and safety and compatible with the NRC's regulatory program. The NRC ensures that an Agreement State program remains adequate and compatible through periodic review and assessment under the Integrated Materials Performance Evaluation Program (IMPEP). There are currently 40 Agreement States which regulate approximately 20,000 materials licensees.

2.2 Problem Statement

As directed in EO 14300, Section 5, the NRC reviewed its regulations on the use of byproduct material. The NRC’s goal was to identify in its regulations areas that it could modernize while still ensuring the continued safe, effective, and efficient use of byproduct material. The NRC has identified changes which will yield significant efficiencies and reduce regulatory burden for licensees, NRC, and Agreement States while upholding our shared commitment to public safety. These actions will reduce the need for license amendment requests and exemptions from

existing regulations. Major provisions of this proposed rule include changes in the following areas:

2.2.1 10 CFR Part 30 Reduce Anti-Competitive Barriers in Consortium Definition

The NRC proposes a revision to 10 CFR 30.4, “Definitions” to change the definition for the term “consortium.” The definition would support the regulation of accelerator-produced radioactive materials, including positron emission tomography (PET) radionuclides used in medical imaging. Under the proposed new definition, a consortium would be an association of medical use licensees and a PET radionuclide production facility that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a federal facility, or a medical facility. The proposed rule would remove the requirement to be in the same geographical area and would provide regulatory relief to consortia engaged in the noncommercial production and distribution of PET radionuclides for medical use, including authorization for noncommercial transfers under 10 CFR 30.32(j) without requiring a separate distribution license under 10 CFR 32.72, “Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.”

2.2.2 10 CFR Part 30 Appendix B. Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning

The NRC is revising its regulations to update appendix B to 10 CFR Part 30, “Quantities of Licensed Material Requiring Labeling,” with radionuclides and values from appendix C to 10 CFR Part 20, “Quantities of Licensed Material Requiring Labeling” for values that are equal to or higher than the current default value in appendix B to 10 CFR Part 30. This would add radionuclides not currently listed in appendix B to 10 CFR Part 30, including radionuclides associated with industrial technologies and current and emerging medical uses. In cases where the values in appendix C to 10 CFR Part 20 are lower than the values currently listed in appendix B to 10 CFR Part 30, the NRC proposes maintaining the current values in appendix B to 10 CFR Part 30. This means the values listed in appendix B to 10 CFR Part 30 would align with the majority of values listed in appendix C to 10 CFR Part 20 except for americium-241, cadmium-109, plutonium-239, uranium-233, uranium-234, uranium-235, zirconium-93, the default value for any alpha-emitting radionuclide not listed or mixtures of alpha emitters of unknown composition, and the default value for any radionuclide other than alpha emitting radionuclides not listed or mixtures of beta emitters of unknown composition which would remain at their current values. Each of the values that would remain at their current values are a factor of 10 higher than what is listed in appendix C to 10 CFR Part 20. In addition, the NRC would remove all radionuclides with a half-life of 120 days or less from the appendix since these radionuclides are not considered when developing Decommissioning Financial Assurance (DFA) and amend the title of the table to “Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning,” to more accurately reflect its current use for DFA. The default values would be set to equal the lowest values of the listed radionuclides. NRC experience shows that short-lived radionuclides do not require major decommissioning efforts because

radionuclides with half-lives of 120 days or less naturally decay to negligible levels within a few years. For additional information on NRC's decay-in-storage rulemakings, see the discussions at 10 CFR Part 35.92 in 51 FR 36951 and 67 FR 20299.

The revisions would result in a table with more up-to-date and risk-informed values. These changes, which include the addition of radionuclides associated with emerging medical and industrial technologies that the table currently excludes, could enable more efficient reviews of diagnostic and therapeutic products, thus increasing the availability of new medical and industrial applications to the general public and potentially reducing the number and severity of patient health and safety concerns. Also, implementing this rulemaking would avert some costs to the licensee, NRC, and the Agreement States. Additional details regarding the basis for updating the table values and the approach taken are included in the regulatory basis document supporting the original Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Materials rulemaking (ADAMS Accession No. ML21235A480).

2.2.3 10 CFR Part 31 Creating New Classes of General Licenses and Modernization of Current Classes of General Licenses

The NRC is establishing a new class of general licenses, called standard general licenses. The proposed framework permits general licenses for portable gauges, additional fixed gauges, a subset of diagnostic medical uses, additional analytical instruments, and additional in vitro testing. The standard general licenses are granted by regulation upon submission of a registration, fee, and certification of understanding. Rule language, found in 10 CFR 31.13 – 10 CFR 31.18, is based on standard license conditions and essential standard commitments related to programs necessary for radiological safety and security. Conforming changes were made in other Parts of 10 CFR Parts 30 and 32 to ensure radioactive materials can be distributed to/from the standard general licenses. In addition, requirements would prohibit a single general licensee from aggregation of materials requiring implementation of requirements contained in 10 CFR Part 37, materials requiring a decommissioning plan or financial assurance, and materials requiring an emergency plan. The standard general license pathway would create a second option for licensing such that entities could select between a standard general license or a specific license for certain activities. The specific license pathway for entities wishing to conduct activities in a non-standard manner or outside of the normal conditions would be preserved as to not limit flexibility.

Additionally, the NRC is amending requirements in 10 CFR Part 31 to permit electronic transmission of registrations for 10 CFR 31.5 registerable devices, harmonize holding periods with decommissioning timelines in 10 CFR 30.36, align physical inventory frequencies with equivalent physical inventory limits for specific licenses, and harmonize in vitro test vial limits with labeling limits in 10 CFR Part 20.

2.2.4 10 CFR Part 32 Expanding Distribution Pathways for Microsources

The proposed rule would revise 10 CFR 32.72 to include microsources within its scope, allowing commercial radiopharmacies that are licensed under this provision to prepare and distribute microspheres. This change reflects the similar radiation safety considerations between microsources and radioactive drugs and acknowledges the evolving role of radiopharmacies in

preparing patient-specific doses of microspheres in accordance with USP General Chapter <825>. In addition, the proposed rule would expand those who can use the 10 CFR 32.72 pathway to any applicant who is legally authorized, under applicable Federal or State law, to manufacture, compound, prepare, or distribute radioactive drugs or medical devices to allow flexibility for future pathways allowed by states or the Food and Drug Administration to distribute radioactive drugs and medical devices safely.

The NRC is also proposing to revise 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," to provide provisions specific to microsources, including microspheres. The revised language ensures clarity that licensees can use either 10 CFR 32.72 or 10 CFR 32.74 to distribute microsources. The amendments to 10 CFR 32.74 also clarify that the regulation allows distribution to any licensee authorized to use the source or device under 10 CFR Part 35 and does not limit distribution to specific types of medical use listed under specific subparts to avoid unnecessary limitations.

These changes are intended to reduce regulatory burden and improve clarity for licensees and regulators. These changes will impact radiopharmacy licensees, medical device manufacturing licensees, and medical licensees. By allowing both 10 CFR 32.72 and 10 CFR 32.74 to serve as viable licensing pathways for the distribution of microsources, the NRC is allowing licensees to select the most appropriate regulatory framework based on their business model and operational needs. This flexibility supports compliance with United States Pharmacopeia (USP) <825>, enables timely access to microspheres for patient care, and maintains the NRC's commitment to safety and regulatory efficiency.

2.2.5 10 CFR Part 34 Reduce Anti-Competitive Barriers and Administrative Requirements for Industrial Radiography

The NRC is amending its requirements associated with industrial radiography operations in 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations." These revisions to the rule address anti-competitive barriers due to overly prescriptive performance requirements for industrial radiography equipment, provide clarity regarding ambiguous language in the two-person rule, and reduce or remove administrative and obsolete requirements. These changes are expected to reduce the regulatory burden on licensees and applicants by reducing or eliminating administrative requirements for recordkeeping and notifications. Additionally, revisions to the performance requirements for industrial radiography equipment removes the requirement to meet the requirements in American National Standards Institute (ANSI) N432-1980.

2.2.6 10 CFR Part 32 and Part 40 Consumer Products Containing Small Quantities of Radioactive Material; Modified Reporting and Recordkeeping Requirements

The NRC is proposing updating the regulations in 10 CFR 32.12, 10 CFR 32.16, 10 CFR 32.20, 10 CFR 32.25(c), 10 CFR 32.29(c), 10 CFR 32.32(c) to remove the annual reporting requirements. Currently specific licensees that distribute consumer products to users exempt from licensing requirements must provide a report of all the products transferred under their exempt distribution license, covering the preceding calendar year, on or before January 31 of each year, even if no transfer of products have taken place, at the time of renewal, and when

ceasing distribution. With this proposed change, licensees will be required to maintain the records of transfer per the record retention policy in 10 CFR 30.51 and make the information available to NRC upon request. The elimination of these requirements will reduce the licensee's burden of preparing and providing records and will reduce the burden of the NRC to collect, manage, and store the reports. This change will also be applicable to exempt products under 10 CFR Part 40 and the required reporting under 10 CFR 40.53(c). Records will need to be maintained in accordance with 10 CFR 40.61 and made available to the NRC upon request.

This proposed change will affect specific licensees who maintain a license under 10 CFR 32.11, 10 CFR 32.14, 10 CFR 32.22, 10 CFR 32.26, 10 CFR 32.30, and 10 CFR 40.52 for distribution of consumer products under 10 CFR Parts 30 and 40. Licensees will no longer have to submit an annual report to the NRC. Record retention policy will follow the regulations in 10 CFR 30.51 and 10 CFR 40.61, for byproduct and source material respectively. This will allow the NRC to have access to information when needed, while at the same time reducing the burden of licenses in preparing and submitting the reports. Requesting the information when needed may introduce some burden due to unscheduled data collection, but it will be outweighed by the reduction in burden of annually preparing, submitting, and maintaining the records of the report on an annual basis.

2.2.7 10 CFR Part 39 Streamlining Well Logging Regulations

The NRC is proposing to amend 10 CFR Part 39 to eliminate unnecessary notifications, reduce administrative burden on licensees, and revise regulations that are duplicative or inconsistent to align with the Agency's current practices. The proposed rule is seeking to extend the survey instrument calibration frequency in 10 CFR 39.33 to be consistent with other regulations. The proposed rule would extend this frequency to 12 months to be consistent with other regulations regarding the calibration of survey instruments. It is necessary that well logging licensees use equipment that has been calibrated to ensure accuracy of radiation emitted and associated radiation detection practices, however, this should be consistent with other regulations. This will ensure that radiation safety is maintained while decreasing administrative and financial burden to the licensee.

The proposed rule will also align leak testing requirements in 10 CFR 39.35 to allow for the sealed source leak testing frequency in accordance with the Sealed Source and Device registry. The proposed rule would align the leak testing frequency with other regulations and be consistent with the intervals approved by the Commission or an Agreement State on the Sealed Source and Device Registry. It is necessary that well logging licensees ensure sealed sources are not leaking, however, this should be consistent with the source design specifications of the Sealed Source and Device Registry. This will ensure that radiation safety is maintained, and the leak testing frequency used is specific to the source model.

The proposed rule will reduce administrative burden on applicants and licensees by amending 10 CFR 39.33(c)(1) and 10 CFR 39.35(c)(1), and eliminating the notification requirement in 10 CFR 39.77(c)(1) that requires the licensee to notify the appropriate NRC Regional Office by telephone of the circumstances that resulted in the inability to retrieve the source and obtain NRC approval to implement abandonment procedures. The notification requirement can be eliminated because it is not needed for the licensee to implement operating and emergency procedures for abandonment that have already been approved by the Commission during the

licensing process. Additionally, the NRC takes no action when these notifications are received. This will enable the licensee to conduct oil and gas exploration activities without making unnecessary notifications. The removal of 10 CFR 39.77(c)(1) will eliminate the notification and duplicative approval process for implementing abandonment procedures.

The proposed changes will streamline 10 CFR Part 39 and will affect well logging license holders. By enabling the licensee to conduct oil and gas exploration activities without making unnecessary notifications, the changes will reduce the administrative burden on license holders and provide flexibility.

2.2.8 10 CFR Part 150 Modernizing and Reducing Requirements for Agreement State Licensees in 10 CFR Part 150

The proposed rule would delete 10 CFR 150.14, which requires Agreement State licensees that possess Special Nuclear Material - Low Strategic Significance (SNM-LSS) to meet the physical protection requirements in 10 CFR 73.67. The deletion of 10 CFR 150.14 would affect Agreement State licensees possessing SNM-LSS by removing the nexus to implement the physical protection requirements in 10 CFR 73.67. Agreement State licensees would still need to maintain security over SNM-LSS pursuant to the requirements in 10 CFR Part 20. Under this change, the NRC would no longer have oversight of SNM-LSS in Agreement States and the Agreement States would continue to maintain oversight of the security of this material under their current programs based on security requirements found in 10 CFR Part 20. There would also be a minimal resource savings for the NRC by no longer having regulatory oversight for this requirement. These licensees would still need to meet Agreement State regulations and license conditions to ensure adequate safety and security of the material.

The proposed rule is revising 10 CFR 150.20(b)(1) to reduce the notification time for submitting an initial reciprocity filling from 3 days before engaging in an activity to the day of the activity. This change can be accomplished by not requiring prior NRC approval before engaging in licensed activities. The NRC will still review reciprocity filings but will not be beholden to a strict turnaround period of 3 days. The revision would also delete 10 CFR 150.20(b)(1)(i)-(iii), which currently allows for submittals with less than 3 days for emergent reasons, as it would be superfluous. The proposed revisions to 10 CFR 150.20(b)(1) will allow licensees greater flexibility in scheduling licensed activities that require reciprocity with minimal impact on public health and safety. This change will affect Agreement State licensees performing work in areas of exclusive federal jurisdiction by reducing the administrative burden to file for reciprocity prior to conducting work activities. Specifically, for reciprocity submitted less than 3-days prior to engaging in the initial work activities, Agreement State licensees will no longer be required to provide additional justification regarding the emergent nature of the work.

2.3 Objective

This proposed rule would amend 10 CFR Parts 30, 31, 32, 34, and 39 which provide the regulatory framework for byproduct material with commercial, industrial, medical, and academic uses. The NRC’s goal in amending these regulations is to modernize the safe, effective, and efficient use of byproduct material. This action will reduce the need for license amendment requests and exemptions from existing regulations. The proposed rule also amends

requirements for exempt quantities of source material under 10 CFR Part 40 as well as requirements in 10 CFR Part 150 regarding Agreement State licensees.

Identification and Preliminary Analysis of Alternative Approaches

This section examines the costs and benefits expected to result from the NRC's rule. 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. In some cases, costs and benefits are not monetized because meaningful quantification is not possible.

The NRC analyzed two alternatives to the rule, as described in this section.

2.4 Alternative 1: No-Action Alternative

The no-action alternative is to maintain the status quo. Under the no-action alternative, the NRC would not amend certain provisions of 10 CFR Parts 30, 31, 32, 34, 39, 40, 70 and 150, the NRC regulations for byproduct material, some source material, and some special nuclear material. This alternative serves as the baseline for this analysis.

2.5 Alternative 2— Rulemaking for Modernizing NRC Regulations for Byproduct Material Use

Under this alternative, the NRC would issue a rule in the *Federal Register* that would modernize the safe, effective, and efficient use of byproduct material, some source material, and some special nuclear material. This action will reduce the need for license amendment requests and exemptions from existing regulations.

3 ESTIMATION AND EVALUATION OF COSTS AND BENEFITS

This section examines the costs and benefits expected to result from the proposed rule. 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. In some cases, costs and benefits are not monetized because meaningful quantification is not possible.

3.1 Identification of Affected Attributes

This section identifies the components of the public and private sectors, commonly referred to as attributes, that are expected to be affected by Alternative 2, the rulemaking alternative, identified in Section 2. The NRC staff developed an inventory of the impacted attributes using the list in NUREG/BR-0058, draft Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," issued January 2020 (NRC 2020).

The rule would affect the attributes described below.

(1) Industry Implementation. This attribute accounts for the projected net economic effect to place the alternative into operations. These activities include the submittal of reporting and recordkeeping requirements for applicants and licensees.

(2) Industry Operation. This attribute accounts for the projected net economic effect caused by routine and recurring activities required by the alternative on all affected entities. These activities include the reduction of reporting and recordkeeping requirements for applicants and licensees.

(3) NRC Implementation. This attribute accounts for the projected net economic effect on the NRC to place the alternative into operation. These activities include the costs to complete and issue the final rule and finalize and issue the associated regulatory guides.

(4) NRC Operation. This attribute accounts for the projected net economic effect on the NRC caused by routine and recurring activities required by the alternative after implementation of the final rule. These activities include the reduction in NRC reviews of reports from licensees.

(5) Regulatory Efficiency. This attribute attempts to measure regulatory and compliance improvements resulting from the proposed action (e.g., removing decommissioning barriers to licensing current and emerging medical and industrial technologies that use radionuclides not listed in appendix B to 10 CFR Part 30). This rulemaking will reduce the effort that the industry would make, generating exemption requests and considering alternative means to accomplish the goals of current regulation.

(6) Public Confidence. This attribute accounts for the confidence the public has in the NRC's ability to effectively regulate applicants and licensees, including appropriate responses to statutory requirements.

(7) Other Government (Agreement State) Operation. This attribute accounts for the projected net economic effect on Agreement State entities caused by routine and recurring activities required by the proposed guidance or regulation changes. This includes the development of corresponding regulations. Activities currently performed but would no longer be required if the alternative is implemented are treated as averted costs. For example, Agreement States completing rulemakings to incorporate compatible regulations.

The following attributes are not expected to contribute to the results for Alterative 2:

Attributes that are not expected to be affected under either of the alternatives include public health (routine), occupational health (accident), occupational health (routine), offsite property, onsite property, improvements in knowledge, general public, safeguards and security considerations, and environmental considerations.

3.2 Analytical Method

This section describes the process used to evaluate costs and benefits associated with Alternative 2. The benefits include any desirable changes in affected attributes (e.g., monetary savings). The costs include any undesirable changes in affected attributes (e.g., monetary costs).

Of the seven affected attributes, the analysis quantitively evaluates four attributes—Industry Implementation, Industry Operations, NRC Implementation, and NRC Operations. Quantitative analysis requires a baseline characterization of the affected society, including factors such as the number of affected entities, the nature of the activities currently performed, and the types of systems and procedures that applicants would consider or would no longer implement because of the proposed alternatives. Where possible, the NRC calculated costs for these attributes using distributions to quantify the uncertainty in these estimates. The individual sections for each of the provisions include the detailed cost tables used in this regulatory analysis. The NRC evaluated the remaining attributes qualitatively because the benefits relating to regulatory efficiency are not easily quantifiable or because the data necessary to quantify and monetize the impacts of these attributes are not available.

The NRC documents its assumptions throughout this regulatory analysis. Appendix A to this regulatory analysis summarizes the key assumptions and inputs.

3.2.1 Regulatory Baseline

This regulatory analysis measures the incremental costs of the proposed rule relative to a baseline that reflects anticipated behavior in the event the NRC does not undertake any regulatory action. As part of the regulatory baseline used in this analysis, the staff assumes full licensee compliance with existing NRC regulations. Section 4 of this regulatory analysis presents the estimated incremental costs and benefits of the alternatives compared to this baseline. This regulatory baseline is the no-action alternative (i.e., Alternative 1).

3.2.2 Affected Entities

The proposed rule will reduce the need for license amendment requests and exemptions from existing regulations and address other deregulatory issues deemed relevant by the NRC. The proposed rule covers a wide range of topics, including the following that would result in a reduction in recordkeeping and reporting requirements:

- establishing a low burden class of general licenses
- decommissioning financial assurance
- addressing anti-competitive barriers
- licensing of distribution to exempt persons
- removing or modifying redundant and unnecessary regulations
- reducing the burden for filing amended NRC Form 241s, “Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters,” for work activities conducted in offshore waters.

The staff assumes that the rulemaking alternative would affect multiple entities, including NRC licensees, Agreement States, and Agreement State licensees.

This rulemaking assumes that 10 CFR Part 70 licensees are not impacted because their authorized possession limits already exceed the table values and therefore, they are already required to submit a site-specific financial assurance plan.

Affected Entities

10 CFR Part 30:

For the purposes of this analysis, the NRC estimates that this change would affect 40 NRC licensees and 400 Agreement State licensees.

10 CFR Part 31:

For the purposes of this analysis, the NRC estimates these changes would affect 477 NRC licensees and 716 Agreement State licensees.

10 CFR Part 32:

For the purposes of this analysis, the NRC estimates this change would affect 109 NRC licensees.

10 CFR Part 34:

For the purposes of this analysis, the NRC estimates this changes would affect 67 NRC and 510 Agreement State specific licensees.

10 CFR Part 39:

For the purposes of this analysis, the NRC estimates this change would affect two specific licensees.

10 CFR Part 40:

For the purposes of this analysis, the NRC estimates that there would be 27 NRC licensees affected by this change

10 CFR Part 150:

For the purposes of this analysis, the NRC estimates this change would affect 25 Agreement State-specific licensees annually.

3.2.3 Base Year

All monetized costs are expressed in 2024 dollars and discounted to 2024. The analysis assumes that ongoing costs of operation related to the alternative being analyzed will begin no earlier than 30 days after publication of the final rule unless otherwise stated. The analysis assumes that the final rule will be published in 2027.

The applicants' one-time and periodic and recurring annual operating expenses are estimated. The values for annual operating expenses are modeled as a constant expense for each year of the analysis horizon. The NRC performed a discounted cash flow calculation to discount these annual expenses to the 2024 base year.

3.2.4 Discount Rates

In accordance with NUREG/BR-0058, net present value (NPV) calculations are used to determine how much society will need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using NPVs, costs and benefits are valued at a common reference year for comparison, regardless of when the cost or benefit is incurred in time. The related measure of discounted value, used in this report unless otherwise indicated, is the annualized value. This annualized value is the constant value for each year of the period of analysis that is equivalent to the NPV calculated at the same discount rate as the NPV. The choice of a discount rate and its associated conceptual basis is a topic of ongoing discussion within the Federal Government. Consistent with NRC guidance, present-worth calculations in this analysis use 3 percent and 7 percent real discount rates.

3.2.5 Labor Rates

For the purposes of this regulatory analysis, the NRC applied incremental cost principles to develop labor rates that include only labor and material costs that are directly related to the implementation, operation, and maintenance of the rule requirements. This approach is consistent with the guidance in NUREG/CR-3568, "A Handbook for Value-Impact Assessment," issued December 1983 (NRC 1983), and general cost-benefit methodology. The NRC incremental labor rate is $158 per hour for fiscal year 2025.[1]

[1] The NRC labor rates presented herein differ from those developed under the NRC's license fee recovery program (10 CFR Part 170, "Fees for facilities, materials, import and export licenses, and other regulatory services under the

The staff used data from the 2024 Bureau of Labor Statistics (BLS) Occupational Employment and Wages data (www.bls.gov), which provides labor categories and the mean hourly wage rate by job type, and used the inflator discussed above to inflate these labor rate data to 2024 dollars. The labor rates used in the analysis reflect total hourly compensation, including wages and nonwage benefits using a burden factor of 2.4. The NRC used the BLS data tables to select appropriate hourly labor rates for performing the anticipated tasks necessary during and following implementation of the proposed alternative. In establishing this labor rate, wages paid to the individuals performing the work plus the associated fringe benefit component of labor cost (i.e., insurance premiums, pension, and legally required benefits) are considered incremental expenses and are included.

Table summarizes the data on which the labor rates are based.

Table 1: Labor Rates

Position Title (in this analysis)	Standard Occupational Classification (SOC Code)	Hourly wage in 2024 dollars			
		Weighting	25%	Median	75%
Industry					
NRC Licensees Labor Rate	Financial Managers (11-3031)	25%	$139.46	$189.58	$250.08
	Environmental Engineers (17-2081)	25%	$92.45	$120.98	$154.58
	Occupational Health and Safety Specialists and Technicians (19-5010)	25%	$67.56	$90.24	$117.43
	Lawyers (23-1011)	25%	$115.22	$184.15	$263.38
Industry blended mean wage			$103.67	$146.24	$196.37
Agreement States					
Agreement State Licensing Staff	Financial Managers (11-3031)	25%	$109.94	$136.78	$165.77
	Environmental Engineers (17-2081)	25%	$92.40	$112.51	$137.09
	Occupational Health and Safety Specialists and Technicians (19-5010)	25%	$69.60	$86.88	$106.87
	Lawyers (23-1011)	25%	$102.70	$128.40	$161.30
Agreement States blended mean wage			$93.66	$116.14	$142.76

3.2.6 Sign Conventions

The sign conventions used in this analysis are that all favorable consequences for Alternative 2 are positive and all adverse consequences are negative. Negative values are shown using parentheses (e.g., negative $500 is displayed as ($500)). This convention is the long-standing

Atomic Energy Act of 1954, as amended"). NRC labor rates for fee recovery purposes are appropriately designed for full-cost recovery of the services rendered and as such include nonincremental costs (e.g., overhead, administrative, and logistical support costs).

practice of the NRC and is used throughout this report except when an exception is noted for alignment with external conventions.

3.2.7 Analysis Horizon

The NRC used an analysis horizon extending from issuing the proposed rule for public comment in 2026 through 2041 for most items (15 years). The Agreement States can take up to 3 years to implement the rule (e.g., 2027 through 2030). The time horizon after the rule is active is from 2027 through 2042 (15 years). The 15-year period is the standard licensing period for material licensees.

3.3 Data

This analysis discusses the data and assumptions used in analyzing the quantifiable impacts associated with the alternative. To collect data for this analysis, the NRC used input from subject-matter experts, knowledge gained from past rulemakings, and information obtained during public meetings and from correspondence. The NRC considered the potential differences between the new requirements and the current requirements and incorporated the incremental changes into this regulatory analysis. The data is summarized in Table .

Table 2: Data

Activity	Mean estimate	Distribution	Low Estimate	Best Estimate	High Estimate
General					
Base Year	2024				
Year Rule is Active	2027				
Length of Horizon Analysis (years)	15				
Discount Rate	7%				
Supplemental Discount Rate	3%				
NRC Staff labor rate	$158				
Labor Rate Multiplier	2.40				
Agreement State Labor Rate	$116.83	Program Evaluation and Review Technique (PERT)	$93.66	$116.14	$142.76
Industry Labor Rate	$147.50	PERT	$103.67	$146.24	$196.37
Part 30 PET					
Agreement State Licenses avoided per year	1.20	PERT	0.80	1.20	1.60
NRC Licenses avoided per year	0.30	PERT	0.20	0.30	0.40
PET license renewal labor					
Licensee	140	PERT	105	140	175

Agreement States	3	PERT	2	3	4
NRC	5	PERT	4	5	6
Part 30 DFA Cost Savings					
AS Administered Decommissioning Funding Plans (DFPs) with Lowered Threshold	400	PERT	300	400	500
NRC Administered DFPs with Lowered Threshold	40	PERT	30	40	50
Change in Threshold	$112,000				
Financing Cost of DFP	5.00%	PERT	4.50%	5.00%	5.50%
Inflation Rate Projection	2.00%	PERT	1.50%	2.00%	2.50%
Part 30 Reporting/Records					
Agreement State Licensees					
Certifications	150	PERT	113	150	188
Funding Plan	250	PERT	188	250	313
Exemptions	15	PERT	11	15	19
NRC Licensees					
Certifications	15	PERT	11	15	19
Funding Plan	25	PERT	19	25	31
Exemptions	2	PERT	2	2	3
Response Burden Hours					
Certifications	44	PERT	33	44	55
Funding Plan	60	PERT	45	60	75
Exemptions	10	PERT	8	10	13
Record Keeping	1	PERT	0.8	1.0	1.3
Part 31 Reporting					
Agreement State No. of Respondents					
31.5(c)(15)	274	PERT	206	274	343
31.13(b)(2)	716	PERT	537	716	895
31.13(f)(1)	14	PERT	11	14	18
31.13(f)(2)(i)	4	PERT	3	4	5
31.13(f)(5)	18	PERT	14	18	23
31.13(g)	4	PERT	3	4	5
31.13(h)	40	PERT	30	40	50
31.11	53	PERT	40	53	66
31.14(c)(9)(iv)(B)	2	PERT	2	2	3
31.15(c)(8)(iv)(B)	2	PERT	2	2	3
31.17(c)(5)(iv)(B)	1	PERT	1	1	1
31.13(a)(1)	716	PERT	537	716	895
NRC No. of Respondents					
31.5(c)(14)	36	PERT	27	36	45
31.13(b)(2) [NRC 1003]	477	PERT	358	477	596
31.13(f)(1)	10	PERT	8	10	13

31.13(f)(3)	2	PERT	2	2	3
31.13(f)(5)	12	PERT	9	12	15
31.13(g)	2	PERT	2	2	3
31.13(h)	26	PERT	20	26	33
31.11	7	PERT	5	7	9
31.14(c)(9)(iv)(B)	1	PERT	1	1	1
31.15(c)(8)(iv)(B)	1	PERT	1	1	1
31.17(c)(5)(iv)(B)	1	PERT	1	1	1
31.13(a)(1)	274	PERT	206	274	343
Response Burden Hours					
31.5(c)(15) and 31.5(c)(14)	0.05	PERT	0.04	0.05	0.06
31.13(b)(2)	3.80	PERT	2.85	3.80	4.75
31.13(f)(1)	0.50	PERT	0.38	0.50	0.63
31.13(f)(2)(i) and 31.13(f)(3)	40.00	PERT	30.00	40.00	50.00
31.13(f)(5)	5.00	PERT	3.75	5.00	6.25
31.13(g)	1.00	PERT	0.75	1.00	1.25
31.13(h)	0.50	PERT	0.38	0.50	0.63
31.11	0.17	PERT	0.13	0.17	0.21
31.14(c)(9)(iv)(B)	1.00	PERT	0.75	1.00	1.25
31.15(c)(8)(iv)(B)	1.00	PERT	0.75	1.00	1.25
31.17(c)(5)(iv)(B)	1.00	PERT	0.75	1.00	1.25
31.13(a)(1)	3.30	PERT	2.48	3.30	4.13
Part 31 Record Keeping					
Agreement State No. of Recordkeepers					
31.14(c)(2)(ii)	66	PERT	50	66	83
31.15(c)	181	PERT	136	181	226
31.16(c)	105	PERT	79	105	131
31.17(c)	107	PERT	80	107	134
31.18(c)	10	PERT	8	10	13
NRC No. of Recordkeepers					
31.14(c)	88	PERT	66	88	110
31.15(c)	242	PERT	182	242	303
31.16(c)	141	PERT	106	141	176
31.17(c)	142	PERT	107	142	178
31.18(c)	13	PERT	10	13	16
Recordkeeping Burden Hours					
31.14(c)(2)(ii)	1.45	PERT	1.09	1.45	1.81
31.15(c)	1.30	PERT	0.98	1.30	1.63
31.16(c)	1.80	PERT	1.35	1.80	2.25
31.17(c)	0.45	PERT	0.34	0.45	0.56
31.18(c)	1.90	PERT	1.43	1.90	2.38
Part 32					
No. of Respondents					

32.12	5	PERT	4	5	6
32.16	50	PERT	38	50	63
32.2	19	PERT	14	19	24
32.25	16	PERT	12	16	20
32.29	10	PERT	8	10	13
32.32	9	PERT	7	9	11
Licensee Response Burden Hours Saved					
32.12	0.30	PERT	0.23	0.30	0.38
32.16	0.30	PERT	0.23	0.30	0.38
32.2	0.30	PERT	0.23	0.30	0.38
32.25	0.30	PERT	0.23	0.30	0.38
32.29	0.30	PERT	0.23	0.30	0.38
32.32	0.50	PERT	0.38	0.50	0.63
NRC Response Labor Hours Saved					
32.12	0.50	PERT	0.38	0.50	0.63
32.16	0.50	PERT	0.38	0.50	0.63
32.2	0.50	PERT	0.38	0.50	0.63
32.25	0.50	PERT	0.38	0.50	0.63
32.29	0.50	PERT	0.38	0.50	0.63
32.32	0.50	PERT	0.38	0.50	0.63
Part 34					
Agreement State No. of Actions					
34.101(c)	28	PERT	21	28	35
34.89(b)	482	PERT	362	482	603
NRC No. of Actions					
34.101(c)	1	PERT	1	1	1
34.89(b)	66	PERT	50	66	83
Labor Hours Saved per Action					
34.101(c)	0.50	PERT	0.38	0.50	0.63
34.89(b)	0.50	PERT	0.38	0.50	0.63
Part 39					
Agreement State No. of Actions					
39.77	6	PERT	5	6	8
NRC No. of Actions					
39.77	2	PERT	2	2	3
Labor Hours Saved per Action					
39.77	0.50	PERT	0.38	0.50	0.63
Part 40					
NRC No. of Actions					
40.53(c)	28	PERT	21	28	35
Labor Hours Saved per Action					

40.53(c)	0.50	PERT	0.38	0.50	0.63
Part 70					
New DFA Mechanisms	40	PERT	30	40	50
Reduction in DFA Exemption Requests per year	2.0	PERT	1.5	2.0	2.5
Labor Hours per New DFA Mechanism	40	PERT	30	40	50
Labor Hours per DFA Exemption Request	30	PERT	23	30	38
Part 150					
No. of Amendments Eliminated					
150.2	540	PERT	405	540	675
Labor Hours Saved per Action					
150.2	0.25	PERT	0.19	0.25	0.31

4 RESULTS

This section presents the incremental quantitative and qualitative benefits and costs by attribute for Alternatives 2 relative to the regulatory baseline (Alternative 1). Incremental benefits and costs are calculated values and impacts that are above the baseline condition. The baseline condition for this rulemaking action includes the benefits and costs to comply with the current requirements. As described in the previous sections, costs and benefits are quantified where possible and are shown to be either positive or negative, depending on whether the alternative has a favorable or adverse effect relative to the regulatory baseline (Alternative 1). Those attributes that are not easily represented in monetary values are discussed in qualitative terms. This "ex ante cost-benefit analysis"[2] provides helpful information that the NRC can use to decide whether to select an alternative. The potential benefits and costs of the alternatives are analyzed for (1) licensees, (2) Agreement States, and (3) the NRC. The analyses in this section are based on the NRC's assessment and input from stakeholders.

4.1 NRC Implementation

The NRC's development and publication of the final rule would result in incremental costs to the agency. These include the costs of reviewing and addressing public comments on the proposed rule and developing the final rule. The staff estimates the NRC would require approximately 1,745 hours to develop the final rule across the 2 years (2025 and 2026), with estimated costs of ($466,000) NPV at the 7 percent discount rate and ($528,000) at the 3 percent discount rate. These rulemaking costs are not included in total cost savings, because they will be sunk costs if the proposed rule becomes the basis for a final rule.

The NRC will incur minor costs compared to the regulatory baseline for verifying the initial reviews by licensees are accurate. The staff did not quantify these costs due to the expectation that the costs are minor relative to the net benefits and difficult to quantify.

4.2 NRC Operation

This attribute accounts for the projected net economic effect of routine and recurring activities required by the proposed alternative for the NRC.

- The NRC would no longer receive for review a select amount of reports and notifications that it previously received, as a result of this rule.

- The NRC will no longer have to review applications and amendments for specific licensees that transition to standard general license and entities that take advantage of the new definition of consortium.
- The NRC will have to review registrations for standard general licensees.

[2] An "ex ante cost-benefit analysis" is prepared before the implementation of a policy, program, or alternative and can assist in deciding whether to allocate resources to that alternative.

- The NRC will have a reduction in sample size for inspection program based on alignment of routine safety tasks.
- The NRC will have an additional inspection element for training and experience of individuals working under standard general license.
- The NRC will no longer have to inspect or provide oversight of Agreement State licensees who possess special nuclear material of low strategic significance.

The NRC will incur costs from reviewing new and revised DFPs or other financial assurance funding mechanisms for decommissioning that licensees will submit because of this rulemaking. NRC staff estimates it will review 40 DFA mechanisms when the rule goes into effect due to the updates made to the Appendix B table.

These activities result in estimated annualized costs of ($20,000) annualized at the 7 percent discount rate and ($18,000) at the 3 percent discount rate. The NRC will also have averted costs due to a reduction in the number of exemption requests for DFPs or financial assurance funding, estimated at $7,200 (7 percent) and $8,400 (3 percent). Based on the number of exemptions the NRC has previously granted, staff estimates the rulemaking would eliminate 32 exemption requests (2 per year during the analysis period).

Including all changes described in Table 2, staff estimates NRC's total net cost savings of $125,000 annualized at 7 percent and $133,000 annualized at 3 percent.

4.3 Industry Operations

Industry will face reduced costs under the provisions of the proposed rule:

- Submission of certain reports/notifications no longer required.
- Submission of applications and amendments for specific licensees that transition to standard general license and entities that take advantage of the new definition of consortium no longer required.
- Industry will submit registrations for standard general licensees.
- Annual fees and costs associated with routine safety tasks could be reduced.

Licensees are currently required to provide an up-to-date DFA or DFP every 3 years and at the time of license renewal. The proposed rulemaking would not change this requirement. Licensees will need to review the changes made to the radionuclide-specific values in the updated appendix B table and determine if these changes impact their current DFA or DFP. In addition, some licensees may choose to submit a new DFP because of these changes.

As a result, some licensees will incur costs from having to update their DFPs and DFAs to the amount of ($1,388,000) annualized at the 7 percent discount rate. However, licensees will avert costs due to not having to revise decommissioning financial assurance mechanism values of approximately $252,000 (7 percent) and $272,000 (3 percent). Licensees will also experience averted costs due to the proposed rule reducing the number of revisions of DFPs or financial assurance funding of approximately $154,000 at 7-percent. Some licensees will not be impacted by the changes to the values in the updated appendix B table and therefore will not require any changes to their DFA or DFP.

Including all changes described in Table 2, the total net cost savings to industry are estimated to be $2,987,000 annualized at 7-percent and $3,129,000 annualized at 3-percent.

4.4 Agreement State Operation

This attribute accounts for the projected net economic effect of routine and recurring Agreement State activities if the proposed rule is issued. Once corresponding rulemakings have been completed and incorporated in their regulations, Agreement States will incur costs from reviewing licensees' new or revised DFAs or financial assurance funding. These activities are estimated to result in costs to Agreement States of approximately ($596,000) annualized at the 7 percent discount rate and ($667,000) at the 3 percent discount rate. The proposed rule would avert the need for Agreement States to review exemption requests from licensees for their DFPs, resulting in averted costs of approximately $618,000 (7 percent) and $816,000 (3 percent). Therefore, the total net averted costs to Agreement States are approximately $22,000 (7 percent) and $149,000 (3 percent).

The Agreement States will incur minor costs compared to the regulatory baseline to verify that the initial reviews by Agreement State licensees are accurate. The staff did not quantify these costs due to the expectation that the costs are minor relative to the net benefits and difficult to quantify.

Including all changes described in Table 2, the total net cost savings to Agreement States are estimated to be $966,000 annualized at 7-percent and $1.00 million annualized at 3-percent.

4.5 Agreement State Implementation

This attribute accounts for the costs of implementing the changes allowed by the proposed rule. Because the effect of the rule is deregulatory, the more stringent requirements currently required by Agreement States are consistent with the mandate to adequately administer safety regulations. However, Agreement States are likely to expend resources to amend state regulations and guidance documents to be consistent with the proposed rule. The staff did not quantify these costs due to the expectation that the costs are minor relative to the net benefits and difficult to quantify.

4.6 Regulatory Efficiency

The proposed rule enhances regulatory efficiency by streamlining and clarifying requirements for the use of byproduct material, reducing unnecessary regulatory burden while maintaining the NRC's commitment to public health and safety. By consolidating outdated provisions, eliminating duplicative requirements, and aligning regulatory language with current practices and technologies, the rule improves the clarity and usability of the regulations for both licensees and regulators. The NRC expects these changes to reduce administrative costs, minimize the need for some guidance documents, and facilitate more consistent implementation across NRC and Agreement State programs. Overall, the modernization effort supports a more agile and responsive regulatory framework, better suited to evolving medical and industrial uses of byproduct material.

4.7 Uncertainty and Sensitivity Analyses

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

4.7.1 Uncertainty Analysis Assumptions

The NRC provides the following analysis of the variables with the greatest uncertainty on estimates of values. As noted above, the NRC performed this analysis with a Monte Carlo simulation analysis using the @Risk software program. Monte Carlo simulations involve introducing uncertainty into the analysis by replacing the point estimates of the variables used for the point estimates of 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 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 (1) the minimum, most likely, and maximum values of a PERT distribution,[3] (2) the minimum and maximum values of a uniform distribution, and (3) 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.

Table 2 (see page 17) identifies the data elements, the distribution and summary statistic, and the mean value of the distribution used in the uncertainty analysis.

4.7.2 *Uncertainty Analysis Results*

The NRC performed the Monte Carlo simulation by repeatedly recalculating the results 10,000 times. For each iteration, the values identified in Table 2 were chosen randomly from the probability distributions that define the input variables. The values of the output variables were recorded for each iteration, and these values were used to define the resultant probability distribution.

For the analysis shown in each figure below, the NRC ran 10,000 simulations in which it changed the key variables to assess the resulting effect on costs and benefits.**Error! Reference source not found.Error! Reference source not found.Error! Reference source not**

[3] 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. Technically, it is a special case of a scaled beta (or beta general) distribution. The PERT distribution is generally considered superior to the triangular distribution when the parameters result in a skewed distribution because the smooth shape of the curve places less emphasis in the direction of skew. Similar to the triangular distribution, the PERT distribution is bounded on both sides and, therefore, may not be adequate for some modeling purposes if the capture of tail or extreme events is desired.

found.Error! Reference source not found. Figure 1, Figure 2, Figure 3, and Figure 4 display the histograms of the incremental costs and benefits from the regulatory baseline (Alternative 2 compared to Alternative 1) for each affected entity and the total net benefit of the rule. The analysis shows that the rulemaking results in net cost savings for Industry, the Agreement States, the NRC and in total with greater than 95 percent confidence.

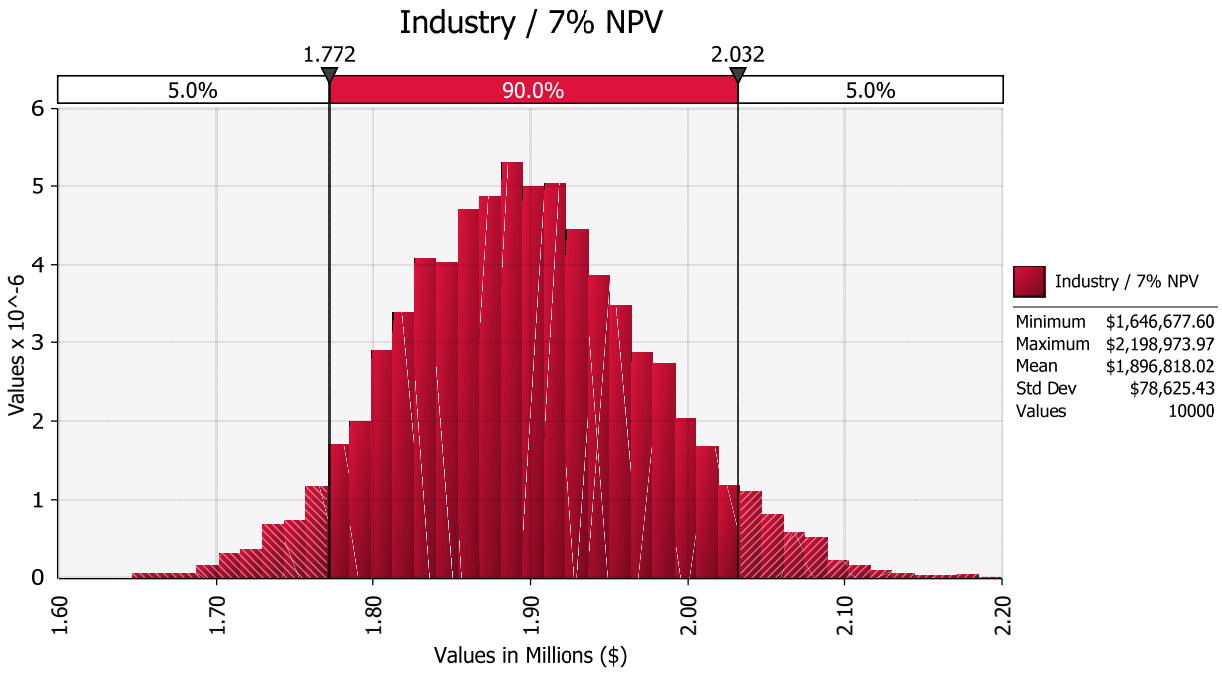

Figure 1. Total Net Cost Savings for Industry (7 Percent Annualized)—Alternative 2

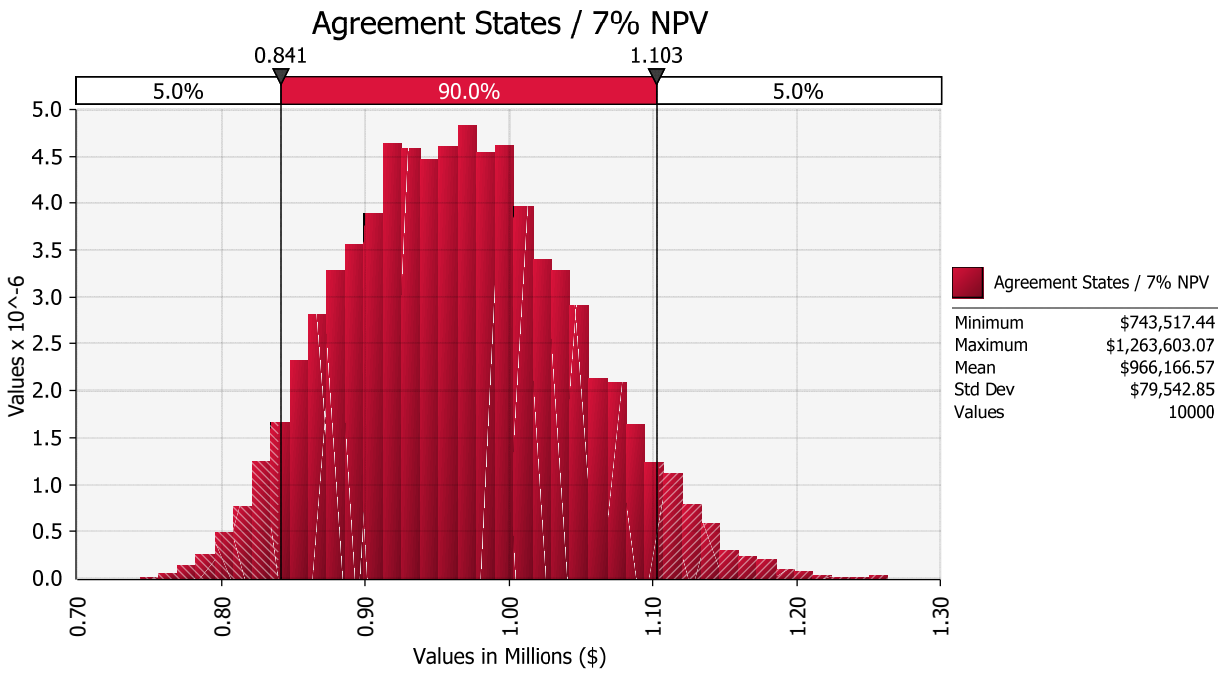

Figure 2. Total Net Cost Savings for Agreement States (7 Percent Annualized)—Alternative 2

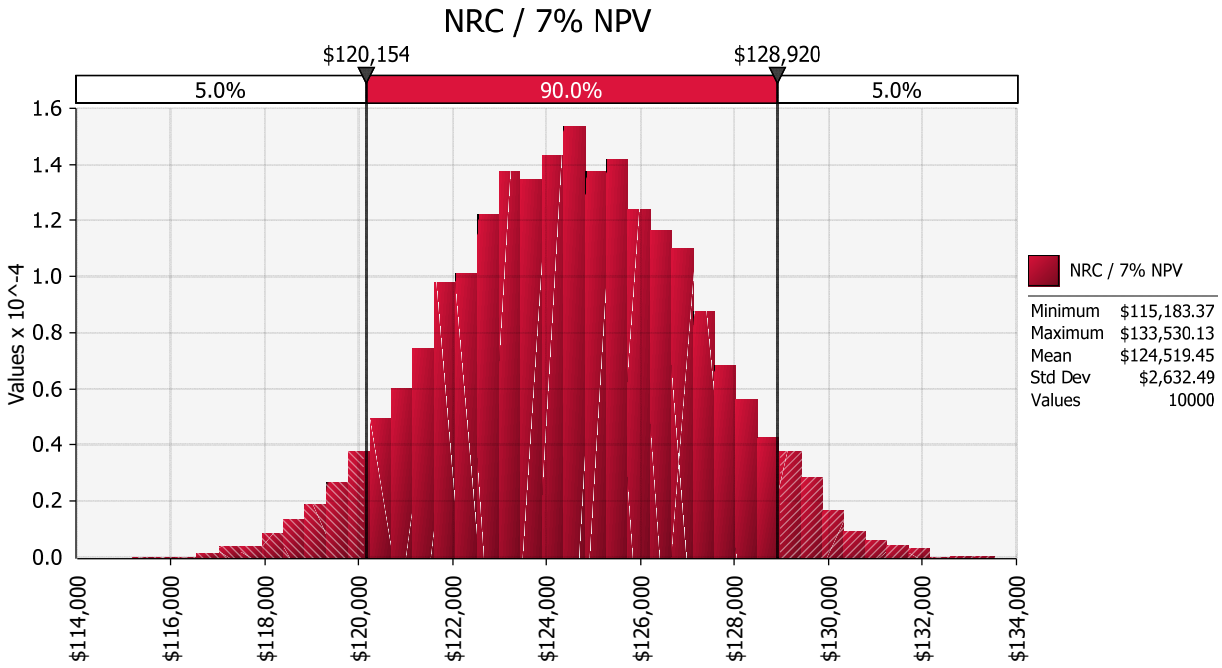

Figure 3. Total Net Cost Savings for NRC (7-percent annualized)—Alternative 2

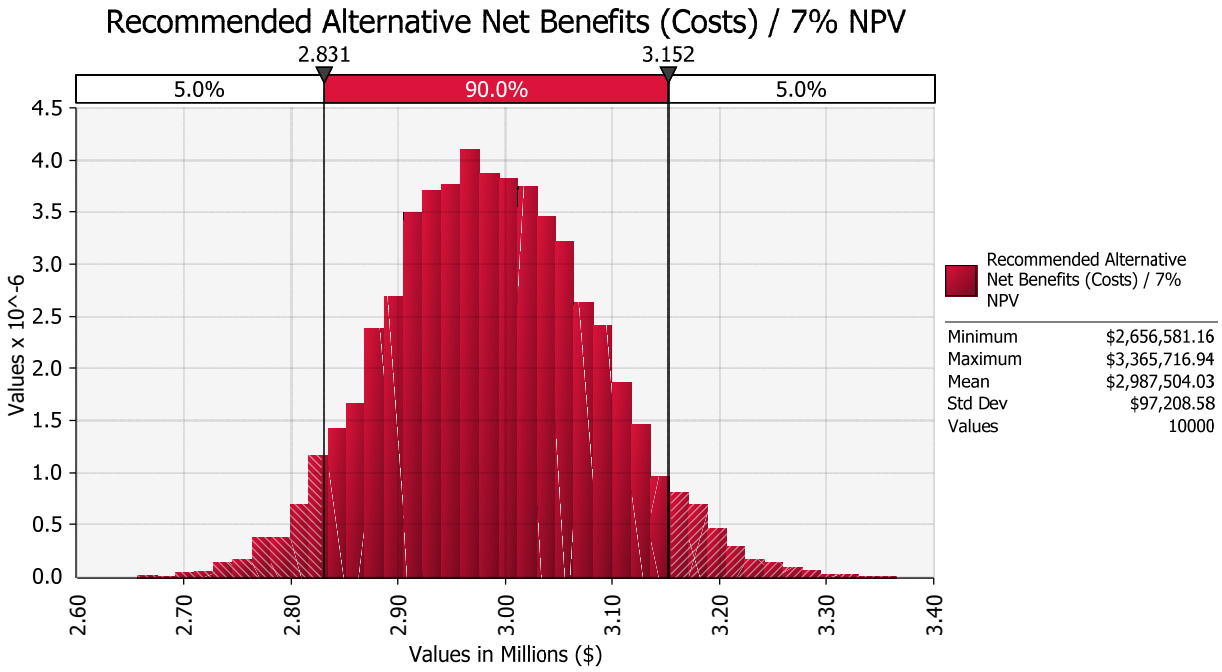

Figure 4. Total Net Cost Savings (7 Percent Annualized)—Alternative 2

Table 3: Descriptive Statistics for Uncertainty Results (7 Percent Annualized)

Uncertainty Result	Total Cost Savings (2024 Million Dollars)				
	Min	Mean	Max	5%	95%
Industry	$1.65	$1.90	$2.20	$1.77	$2.03
Agreement States	$0.74	$0.97	$1.26	$0.84	$1.10
NRC	$0.12	$0.12	$0.13	$0.12	$0.13
Total	$2.66	$2.99	$3.37	$2.83	$3.15

Table 3 displays the key statistical results, including descriptive statistics on the uncertainty analysis and the 90 percent confidence interval in which the net benefits would fall between the 5 percent and 95 percent values.

Figure 5 is a tornado diagram that ranks the variables based on their contribution to the uncertainty in cost. The largest contributor to uncertainty is uncertainty about the Agreement State labor rate followed by Industry labor rate. The remaining variables showing smaller effects on the uncertainty in the total cost savings include the number of licensees performing different actions, the labor hours per action and the costs of financing DFA each year.

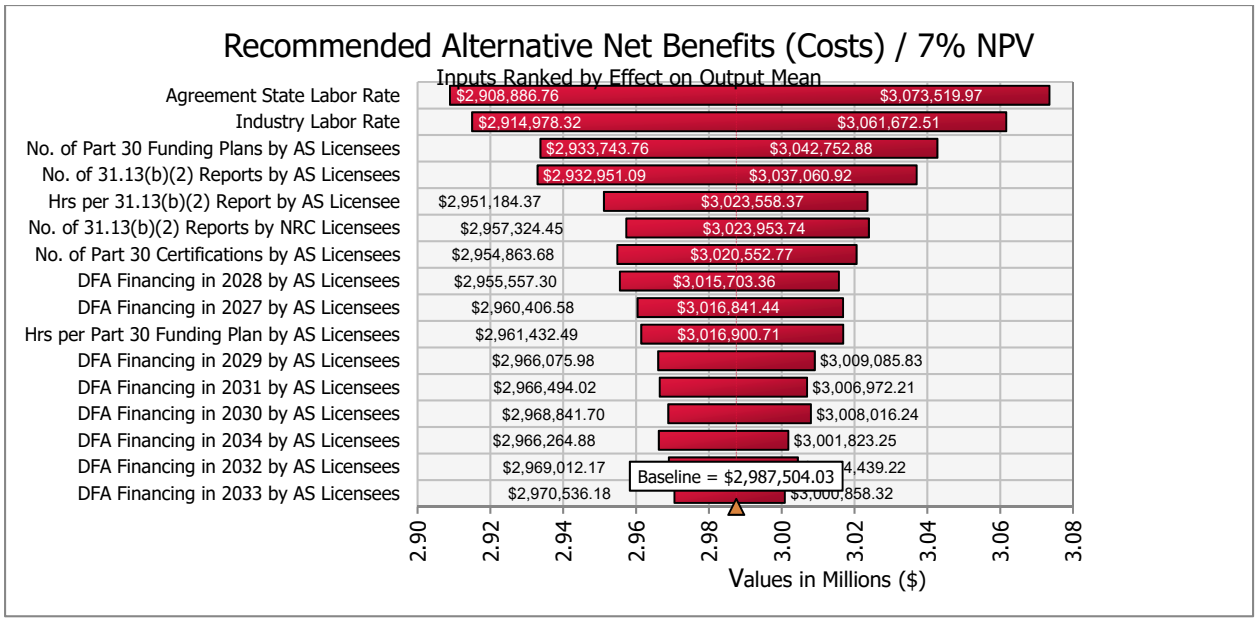

Figure 5. Tornado Diagram—Total Cost Savings—7-Percent Annualized

4.7.3 Summary of Uncertainty Analysis

The simulation analysis shows that the estimated mean cost savings for this rule is $2.99 million with 90 percent confidence that the net benefit is between $2.83 million and $3.15 million using a 7 percent discount rate. The NRC's quantitative estimates show that the rule alternative provides is cost savings to Industry, the Agreement States, and the NRC.

4.7.4 Sensitivity Analysis

The NRC conducted a sensitivity analysis using a discount rate of 3 percent. The sensitivity analysis shows that the estimated mean benefit (i.e., positive averted costs or savings) for this rule is $3.13 million with 90 percent confidence that the net benefit is between $2.97 million and $3.26 million at the 3 percent discount rate. Therefore, the sensitivity analysis demonstrates that the alternative is cost beneficial at a range of discount rates.

4.8 Disaggregation

To comply with the guidance in NUREG/BR-0058, Section 4.3.2, "Criteria for the Treatment of Individual Requirements," the NRC performed a screening review to determine whether any individual requirement would be unnecessary to achieve the objectives of the rulemaking. The staff did not identify any unnecessary or unrelated provisions; therefore, it did not perform, a disaggregation for this regulatory analysis.

4.9 SUMMARY OF THE RESULTS

4.9.1 Quantified Net Benefits

This regulatory analysis identifies both quantifiable and nonquantifiable costs and benefits that would result from Alternative 2 (rulemaking). Although quantifiable costs and benefits appear to be more tangible, decisionmakers should not discount costs and benefits that cannot be quantified. Such benefits or costs can be as important as or even more important than benefits or costs that can be quantified and monetized.

Table summarizes the estimated quantified benefits and costs for the alternatives, compared to the regulatory baseline (Alternative 1). The quantitative analysis used best estimate values.

Table 4: Quantified Annual Net Costs*

Description	Total (2024 dollars)	
	7% Annualized	3% Annualized
Industry	($1,897,000)	($1,992,000)
Agreement States	($966,000)	($1,004,000)
NRC	($125,000)	($134,000)
Net Cost Savings	**($2,987,000)**	**($3,130,000)**

* For external reporting purposes the sign convention in this table differs from the rest of this report. Costs and benefits in this table are judged as separate categories. Benefits are treated the same as in the report, but costs (increased spending by an entity) are reported as positive. Thus, the quantified net cost values reported in this table, being cost savings, are negative values denoted by parentheses.

4.9.2 Nonquantified Benefits

In addition to the quantified costs, the NRC considered benefits that could not be monetized but would still affect the public, industry, and regulators.

Alternative 2 increases regulatory clarity for industry, the NRC, and Agreement States and will result in a more consistent implementation of the NRC's regulatory program. By updating regulations in response to technological change and improved understanding of the industry, public confidence in the safety and security of the use of nuclear materials is reassured.

Alternative 2 reduces licensing obstacles that could discourage the development of new medical and industrial applications, which may reduce delays and improve patient health and safety.

Alternative 2 also provides licensees with more up-to-date and risk-informed approaches based on their individual, site-specific needs. A risk-informed approach to regulatory decisionmaking represents a philosophy whereby risk insights are considered, together with other factors, to establish requirements that better focus licensee and regulatory attention on issues commensurate with their importance to public health and safety.

4.10 Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended at 5 U.S.C. 601 et seq., requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

The NRC has established standards for determining which of its licensees qualify as small entities pursuant to 10 CFR 2.810, “NRC size standards.” These standards are based on the Small Business Administration’s most common receipt-based size standards and provide for business concerns that are manufacturing entities, with the use of a criteria of less than 500 employees.

The Small Business Regulatory Enforcement Fairness Act requires that the NRC prepare a written compliance guide to assist small entities in complying with each rule for which the NRC prepares a regulatory flexibility analysis.

The net effect of this proposed rule is deregulatory, so to the extent that small businesses operate under the proposed rule, they will experience cost savings relative to the no-action alternative.

5 DECISION RATIONALE

The assessment of total costs and benefits discussed previously leads the NRC to the conclusion that the proposed rule, if implemented, would result in quantifiable net cost savings for industry, the NRC, and Agreement States. In addition, the NRC concludes that the rule provides nonquantified benefits of regulatory clarity and improved consistency in the regulatory program. The proposed rule also responds to stakeholder feedback and aligns with EO 14300.

Table 5 summarizes these benefits.

Table 5: Summary of Totals

Quantified Benefits (Costs)	Nonquantified Benefits (Costs)
Alternative 1: No Action $0	None
Alternative 2: **Industry: (all provisions)** $1,897,000/year using a 7% discount rate $1,992,000/year using a 3% discount rate **Agreement States: (all provisions)** $996,000/year using a 7% discount rate $1,004,000/year using a 3% discount rate **NRC: (all provisions)** $125,000/year using a 7% discount rate $134,000 /year using a 3% discount rate **Net Benefit (Cost): (all provisions)** $2,987,000/year using a 7% discount rate $3,130,000/year using a 3% discount rate	**Benefits:** • Increase regulatory clarity for the NRC, Agreement States, and industry. • More consistent implementation of the NRC's regulatory program. • Reduces potential delays in licensing important diagnostic and therapeutic products that use radionuclides. • Provides licensees with more up-to-date and risk-informed approaches based on their site-specific needs, allowing better focus on issues commensurate with their importance to public health and safety.

6 IMPLEMENTATION SCHEDULE

The NRC assumed for this analysis that the effective date of this final rule would be in 2027.

Example: This final rule will become effective 30 days after publication in the *Federal Register*.

7 REFERENCES

Bureau of Labor Statistics BLS, “SOC Code: Standard Occupational Classification Code,” U.S. Department of Labor, January 2021. Available at http://www.bls.gov/soc/home.htm; last accessed on June 2, 2022.

BLS, “Archived Consumer Price Index Supplement Files: May 2022 Historical CPI-U, Historical Consumer Price Index for All Urban Consumers (CPI-U): U.S. City Average, All Items,” U.S. Department of Labor, June 2022. Available at https://www.bls.gov/cpi/tables/; last accessed on July 12, 2022.

U.S. Nuclear Regulatory Commission (NRC), “A Handbook for Value-Impact Assessment,” NUREG/CR-3568, December 1983 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML062830096).

NRC, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” NUREG/BR-0058, draft Revision 5, January 2020 (ADAMS Accession No. ML19261A277).